CEPI

Annual Progress Report

Covering the period from:
1 January to 31 December 2019

2019 Annual Progress Report

Coalition for Epidemic Preparedness Innovations (CEPI)

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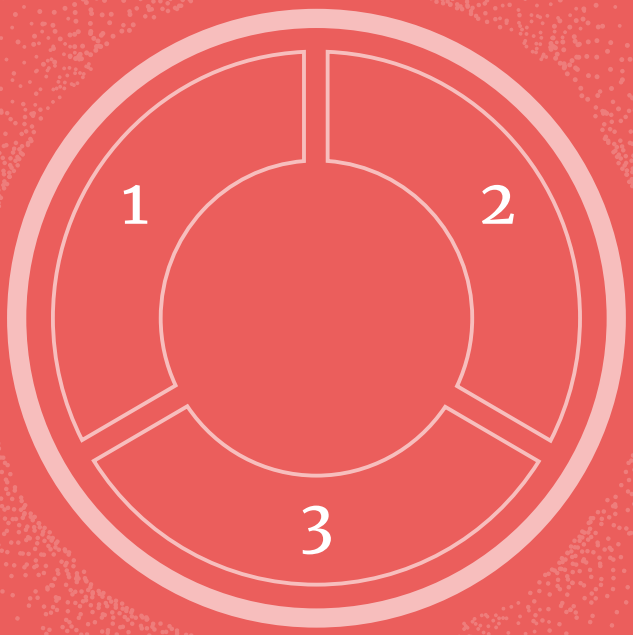
CEPI'S VISION

A world in which epidemics are no longer a threat to humanity

CEPI's mission - **to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks** - is supported by three strategic objectives:



Preparedness

Advance access to safe and effective vaccines against emerging infectious diseases

Response

Accelerate the research, development and use of vaccines during outbreaks

Sustainability

Create durable and equitable solutions for outbreak response capacity

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List of abbreviations

AVAREF	The African Vaccine Regulatory Forum
CEPI	Coalition for Epidemic Preparedness Innovations
CfP	CEPI Calls for Proposals
CfP 1	Call for Proposals for vaccine candidates against Lassa, Nipah and MERS
CfP2	Call for Proposals for platform technologies against an unknown pathogen
CfP2r	Rolling Call for Proposals for platform technologies
CfP3	Call for Proposals for vaccine candidates against CHIK and RVF
CHIKV	Chikungunya virus
CMO	Contract manufacturing organisation
COVID-19	Coronavirus Disease 2019 (SARS-CoV2)
DNA	Deoxyribonucleic Acid
EDCTP	European & Developing Countries Clinical Trials Partnership
EIC	(CEPI) Executive Investment Committee
EID	Emerging Infectious Diseases
EMA	European Medicines Agency
FIND	The Foundation For Innovative New Diagnostics
GAVI	GAVI, the Vaccine Alliance
IFFIm	GAVI International Finance Facility for Immunisation
IND	Investigational New Drug
IVI	International Vaccine Institute
JCG	(CEPI) Joint Coordination Group
LMICS	Low- and Middle-Income Countries
MERS	Middle East Respiratory Syndrome
NIAID	US National Institute of Allergy and Infectious Diseases
NIBSC	(UK) National Institute of Biological Standards and Control
P1	Phase 1 clinical trials
P2	Phase 2 clinical trials
PreC	Preclinical Trials
PSMB	(CEPI) Portfolio Management Review Board
R&D	Research and Development
RNA	Ribonucleic Acid
RVF	Rift Valley Fever
SAC	(CEPI) Scientific Advisory Committee
SAGE	(WHO) Strategic Advisory Group in Experts on Immunization
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SDGs	UN Sustainable Development Goals
UNICEF	United Nations International Children's Emergency Fund
VR&D	(CEPI) Vaccine Research and Development
WG	Working Group
WHO	UN World Health Organisation

INTRODUCTION

The urgency of advancing candidates within CEPI's portfolio has never been greater. At the time of writing this introduction, we are faced with a global outbreak of a novel coronavirus, SARS-CoV-2 (the virus responsible for COVID-19). To help address this unveiling catastrophe, we have been taking a forward leaning stance, in preparation to pivot the portfolio – and the organisation – toward investing in vaccine development against COVID-19 as part of the global response to an emerging health humanitarian and economic crisis of global proportions. We are looking to balance innovative platform technologies – including some that were already in our portfolio – with more traditional approaches to radically accelerate the development and manufacture of vaccines to rapidly respond to COVID-19, and continue our preparations for future outbreaks of unknown pathogens.

For this reason, this progress report is more concise than the first iteration and focuses primarily on measuring our progress according to indicators in the results framework. Feel free to make contact for more information on any of the areas of work touched upon in this report.

CEPI has come a long way, very fast. To our initial portfolio of vaccine candidates against three priority pathogens, we have added Rift Valley Fever (RVF) and Chikungunya (CHIKV) and are now advancing 19 vaccine candidates against five priority pathogens, in addition to three rapid response platforms. We are part of a consortium that is responding to the outbreak of Ebola in the Democratic Republic of Congo through a trial of a second vaccine with a total of 4331 vaccinated by 31 December 2019.

CEPI is fully committed to strengthening strong institutional commitments and alliances. We know that succeeding with our mission will depend on operating seamlessly within an ecosystem that can support and sustain the development of vaccines and other countermeasures against known and emerging infectious disease threats. In a conscious effort to foster the development of such an ecosystem, we work closely with the World Health Organization (WHO) and other multilateral partners through our Joint Coordination Group, with more than 130 organizations through our partnerships, with our funders, with governments and partners in countries at risk of the diseases we are fighting and with vaccine development partners.

Crucial to succeeding with CEPI's mission is equitable access and engagement with affected countries. This year has seen notable highlights including the launch of a Lassa epidemiology study with five African countries, the welcome addition of the Federal Democratic Republic of Ethiopia into the Coalition, collaboration with the Indian government through the dedicated partnership "Ind-CEPI" on the development of our Chikungunya vaccine candidate, and through the support to convene global experts on Lassa in Nigeria and on Nipah in Singapore. We have also established an Equitable Access Committee providing oversight of and counsel to the Secretariat.

We have come a long way, but 2020 will be a watershed moment, not only for CEPI but for the world.

Sincerely,

Dr. Richard Hatchett, CEO of CEPI

Key highlights from 2019

1. Concrete progress on vaccine candidates

By the end of 2019 CEPI had a total of 19 vaccine candidates against five priority pathogens and three rapid response platforms in its portfolio.

2019 was the first full year of actively advancing candidates (as opposed to building the portfolio). As such, a key priority was to support the advancement and success of vaccine candidates through careful technical and financial management. Through these efforts, CEPI's portfolio is on track to deliver the goal of establishing stockpiles of investigational vaccines within 5 years of programme initiation.

Several important milestones of progress were reached in 2019:

- Two Lassa vaccine candidates entered phase 1 trials. These are the first Lassa vaccines ever tested in humans.
- Commencement of a phase 1 clinical trial of one candidate against Middle Eastern Respiratory Syndrome (MERS).
- Commencement of a clinical trial of a second Ebola vaccine during the Ebola outbreak in the Democratic Republic of Congo.

In addition, the start of 2020 saw rapid preparations to launch a Call for Proposals (CfP) to develop vaccines candidates against COVID-19.

2. Expansion of the portfolio

CEPI has built out its portfolio at a rapid but prudent investment rate, committing up to $456 million to fund vaccines, technology platforms and enabling science programmes. These investments were made possible by the substantial initial commitments from existing Investors including the Governments of Japan, Germany, Norway, Canada and the Bill and Melinda Gates Foundation and the Wellcome Trust, as well as new commitments made in 2019 from the European Commission and the Governments of the United Kingdom and Australia.

2019 also saw great strides in extending the number of diseases that CEPI will be able to respond to.

Highlights include:

- Launching a rolling call on platform technologies, allowing CEPI to respond quickly to innovative investment opportunities against "Disease X".
- Launching a call for proposals on Rift Valley Fever (RVF) and Chikungunya (CHIKV), expanding the coverage of pathogens prioritised by the World Health Organization.
- Investments in enabling science that support the advancement of our vaccine candidates, including the launch of a large-scale Lassa epidemiological study and programmes for biological standards and assays.

3. Strengthened partnerships with affected countries

Engagement of affected countries is critical to delivering CEPI's mission and to enabling access to vaccine candidates to populations at risk. Highlights from 2019 include:

- Ethiopia pledging to invest in CEPI and becoming the first African country to join the Coalition.
- Collaborative launch of an epidemiology study in Benin, Guinea, Liberia, Nigeria and Sierra Leone in anticipation of the progression of CEPI's Lassa vaccine candidates.
- Operationalising the partnership with the Government of India (IndCEPI) resulting in co-funding vaccine development against the Chikungunya virus.
- Convening of global experts on the Lassa virus in Nigeria, and on the Nipah virus in Singapore.

1. CEPI'S MISSION AND THEORY OF CHANGE

In 2019 CEPI produced an updated Business plan for the period 2019 – 2022. The purpose of the update was to clarify long-term priorities and to provide a roadmap for delivering CEPI's mission **to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks**. In line with this mission, CEPI's work is guided by three strategic objectives namely, preparedness, response and sustainability.

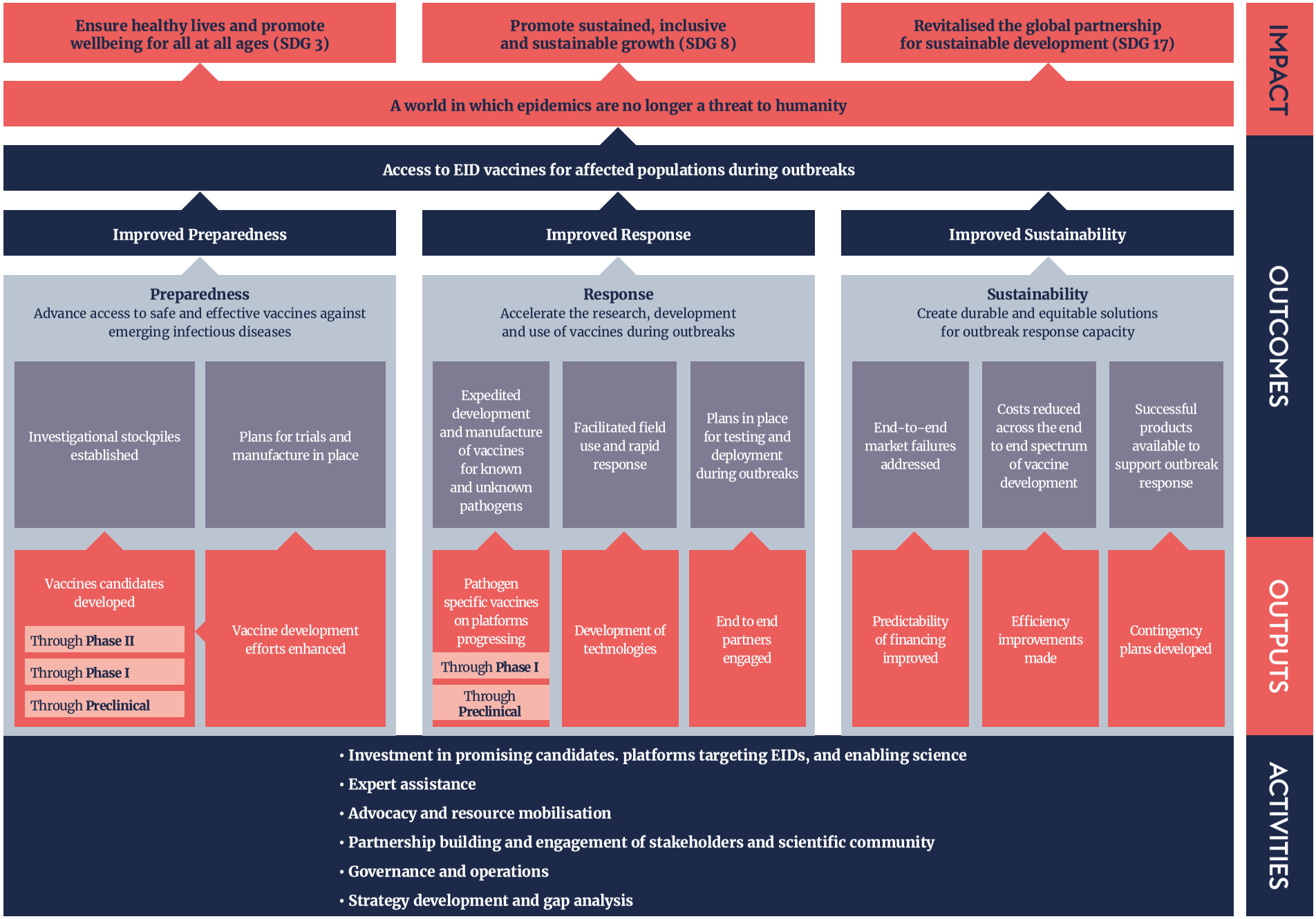
This report highlights CEPI's progress towards the strategic objectives for the period from 1 January to 31 December 2019. Section 2 describes key activities carried out and progress against targets as set out in the results framework. A Status box is provided for each indicator depicting an assessment of whether the 2019 targets have been reached.[1] Section 3 provides a summary of financial status and section 4 outlines CEPI's approach to risk management.

Figure 1 below describes the Theory of Change to support CEPI's mission and how CEPI's activities contribute to higher level objectives such as the UN Sustainable Development Goals through activities, outputs and outcomes[2].

[1] A full copy of the results framework is available to Investors from the Secretariat

[2] See CEPI's Programme Document for a more detailed explanation.

Figure I: CEPI's Theory of Change



2. PROGRESS AGAINST THE STRATEGIC OBJECTIVES

2.1 Strategic objective 1: Preparedness

Advance access to safe and effective vaccines against emerging infectious diseases

CEPI's ability to select and advance vaccine candidates against our priority pathogens is a key test of our achievement against our mission. However, vaccine development against EIDs is a lengthy and challenging process for many reasons, including the difficulty of demonstrating vaccine effectiveness, the unpredictability of epidemics, the substantial complexity of conducting clinical trials during an outbreak, and the substantial costs associated with development efforts. Advancement of vaccines, particularly for epidemic diseases, also requires active involvement from industry, academics and public health experts. This section highlights the efforts CEPI has undertaken in 2019 to support advance access to safe and effective vaccines against emerging infectious diseases. Under this pillar CEPI's activities are focused on:

- Investing in promising candidates targeting emerging infectious diseases to drive development of vaccines where markets incentives are insufficient
- Facilitating the establishment and maintenance of the investigational stockpiles and developing robust plans to allow for trials and eventual deployment of vaccines during outbreaks.
- Provide expert assistance and funding enabling science and technologies to enhance vaccine development efforts.

2.1.2 Invests in promising candidates targeting emerging infectious diseases to drive development of vaccines where markets incentives are insufficient

2.1.2.1 Advancing a portfolio of candidates against emerging infectious diseases

In 2019, CEPI continued to grow its portfolio, by adding two new pathogens to CEPI's priority pathogens: Rift Valley Fever (RVF) and Chikungunya (CHIKV) (See Box 1 for information about the diseases). The decision to prioritise these pathogens was generated from the WHO R&D Blueprint and guidance from CEPI's Scientific Advisory Committee (SAC), taking into consideration the feasibility of vaccine development and the potential public health impact of vaccines developed against these diseases[3]. To support the advancement of vaccine candidates against these new priority diseases further towards licensure, CEPI launched a Call for Proposals (CfP3) in January 2019 to attract vaccine developers with promising R&D results.

[3] The European Commission is providing substantial co-funding for the RVF and CHIKV vaccine candidates

Box 1: In 2019, CEPI announced the launch of a $48 million fund to advance vaccine candidates against Chikungunya and Rift Valley fever:

First identified in Tanzania in 1952, the Chikungunya virus has since spread across the world. Chikungunya has caused over 3.4 million cases in over 43 countries since its re-emergence in 2004. An alphavirus transmitted by female Aedes mosquitoes Chikungunya causes fever, severe joint pain, muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can last for weeks to years. The socioeconomic cost of the virus is estimated to be USD 185 billion in the Americas alone. Millions of people have been affected by the disease and today over a billion people live in areas where Chikungunya is endemic. Despite the large outbreaks and significant consequences there is currently no specific antiviral drug treatment for Chikungunya nor are any vaccines currently approved for human use.

Rift Valley Fever was first identified in 1931 on a farm in the Rift Valley of Kenya. Today, it is found across Africa and in parts of the Arabian Peninsula. The virus is a member of the Phlebovirus genus and is transmitted by mosquitoes and blood feeding flies that usually affects livestock animals but can also affect people. Outbreaks have been reported across Africa and in Saudi Arabia and Yemen since 2000, resulting in over 4800 cases and over 900 deaths. Those most at risk of infection are some of the world's most vulnerable people. Endemic across Africa, outbreaks usually occur in pastoral communities. These rural communities have reduced access to public health services and their livelihoods are often intertwined with their livestock, which also happens to be the main reservoir for the virus. The virus is on the WHO's R&D Blueprint.

By the end of 2019, CEPI had signed agreements with four vaccine candidates against RVF and CHIKV and had finalised one new partnership for a Nipah candidate under CfP1. These four new partnerships brought the total number of candidates against CEPI's priority diseases to 19.

The figure below demonstrates that CEPI has established a diverse portfolio of early stage vaccine candidates (with the exception of CHIK which had a more established base). CEPI's candidates have made great progress, reaching significant milestones at an accelerated speed. Much of this progress is due to the technical support and management that CEPI has provided to vaccine developers. Expert assessments[4] of technical and partnership risks in CEPI projects indicate that the current Lassa, MERS and Nipah portfolio are expected to deliver at least one successful stockpile for both Lassa and for MERS, as well as a stockpile outcome for Nipah. This assessment assumes a high-risk portfolio of good scientific and technical performance but variable partnership and financial risks (that are handled appropriately). Overall, the core programme is on track and, accounting for attrition, should deliver a mid-stage clinical pipeline with stockpiles for each of Lassa and MERS available from end of 2022 at the earliest, broadly in line with CEPI's original planning.

[4] CEPI undertook its first Annual Portfolio Review (APR) meeting in Washington on 5-6 November 2019. The purpose of CEPI's first APR was to engage key coalition partners in a strategic and scientific assessment of CEPI's R&D portfolio in order to review progress made to date and to help develop future priorities for R&D investment. The review brought together over 75 individuals, including 57 individuals representing CEPI's Board, Investors Council, Joint Coordination Group (JCG), Scientific Advisory Committee and other Coalition Partners; in addition to 20 CEPI Secretariat staff.

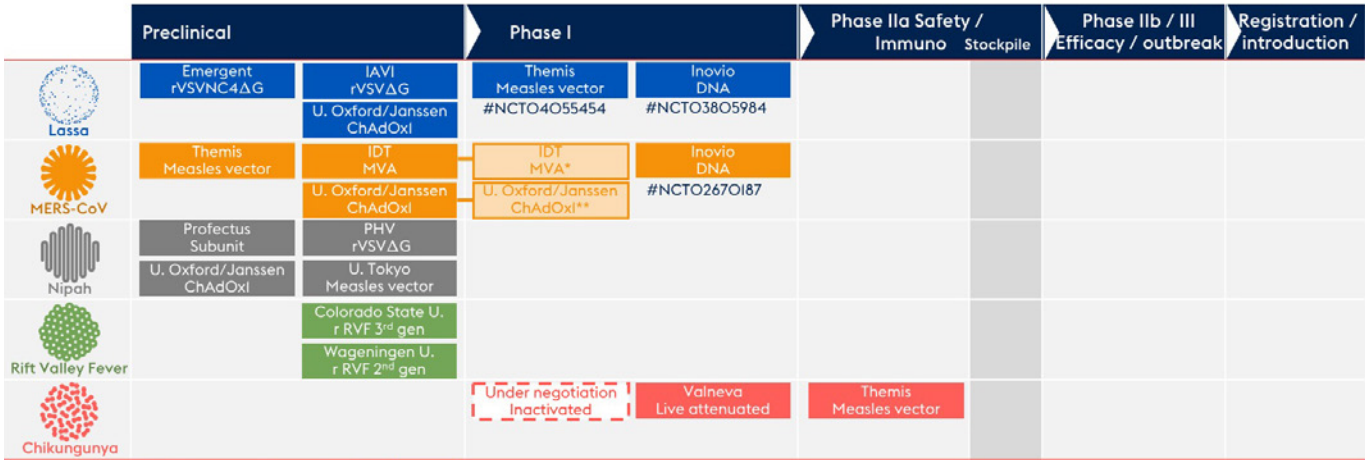


Figure 2: CEPI's vaccine candidate and platform portfolio as at end of 2019

Indicator 8	Disease	Phase	Baseline	Target 2019	Actual 2019	Target 2020	Target 2021	Target 2022	Status
Number of vaccine candidates – for each priority disease – advanced for each priority disease	Lassa	PreC	0	3	3	4	4		*On track*
		P1	0	2	2	3	3		
		P2	0	0	0	0	2	3	
	Nipah	PreC	1	3	4	4	4		*On track*
		P1	0	0	0	3	3		
		P2	0	0	0	0	1	3	
	MERS	PreC	4	2	3	3	4		*On track*
		P1	0	1	1	2	3		
		P2	0	0	0	1	1	3	
	CHIKV	PreC	3	-	-	1			*On track*
		P1	2	-	-				
		P2	0	-	-			1	
		P3	0	-	-	1			
		Lisc.	0	-	-		1		
	RVF	PreC	0	2	-	2			*On track*
		P1	2	-	-		2		
		P2	0	-	-				

Comment on progress for 2019

CEPI has exceeded targets in the year 2019. Two Lassa vaccine candidates have passed stage gates and are entering phase 1 trials, becoming the first Lassa vaccines ever tested in humans, in addition to exceeding our targets. One vaccine candidate for MERS is commencing a phase 1 clinical trial of one MERS candidate. Although 2019 targets have been achieved for all diseases, the overall status for each disease can change rapidly based on the high-risk nature of vaccine research and development. Portfolio fill and flow is being closely monitored, and CEPI is in a position to take action to address any issues arising from unanticipated portfolio attrition.

NB: The two new priority pathogens have been added to this indicator

2.1.2.2 Continued work on Ebola

A trigger for CEPI's establishment was to support the work towards finishing the job on Ebola with the overall goal of attaining licensure for two or more Ebola vaccines. 2019 was a particularly challenging year with a deterioration of the outbreak in the Democratic Republic of Congo (DRC). To date, there have been over 3400 cases of Ebola and nearly 2250 deaths in DRC, making this the second worst Ebola outbreak in history.

In line with the mounting severity of the situation, CEPI confirmed its place as part of a global consortium supporting the DRC Government to introduce a second investigational Ebola vaccine, as part of ongoing efforts to contain the outbreak in the eastern part of the country through a large-scale clinical trial. The introduction of second vaccine from Janssen was recommended by the WHO Strategic Advisory Group of Experts on Immunization (SAGE). The trial has enrolled over 10,000 participants, with over 4331 participants having received dose 1 as of 31 December 2019. CEPI is also supporting a trial of the Janssen vaccine in healthcare and frontline workers in Uganda, as well as two trials in the IMI EBOVAC3 consortium[5] in DRC, Sierra Leone and Guinea in healthcare workers and infants, respectively.

2.2.1 Facilitates the establishment and maintenance of investigational stockpiles and develops robust plans to allow for trials and eventual deployment of vaccines during outbreaks

2.2.1.2 Partnering with at risk countries in planning for clinical trials

Epidemiology studies are valuable because they plug knowledge gaps that would otherwise make evaluation of vaccine effectiveness challenging. They provide a baseline for measuring vaccine effectiveness and can facilitate the design and inform the location of vaccine trials. In addition, such studies offer a very good opportunity to strengthen capacity in at risk countries by building on national surveillance and ongoing research and providing a framework for laboratory testing and diagnostics and good clinical practice for future vaccine trials. In preparation for Lassa vaccine candidates being ready for clinical development in 2019, CEPI has made significant progress toward a large-scale epidemiology study in five West African countries[6]. Achievements include:

- Defining and implementing an inclusive study governance framework
- Developing key local partnerships and identifying needs for external technical support
- Building launching technical working groups
- Completing due diligence and protocol development

This process was an excellent opportunity to implement CEPI's commitment to strengthen capacity and embed ownership by affected countries in its activities. At the end of 2019, four out of five partnerships had been signed. The final partnership is anticipated to be signed in early 2020.

An investigational vaccine can only help curb an outbreak if the vaccine can be accessed— either through clinical trials or emergency use provisions. Planning ahead to understand the size of stockpiles needed to support an adequate level of preparedness is therefore very important. In 2019, CEPI and the European & Developing Countries Clinical Trials Partnership (EDCTP) operationalised their partnership through the launch of a jointly funded call for proposal[7] to support the preparation and conduct of phase IIb and III clinical trials with the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of novel Lassa virus vaccine candidates. The call was launched in November 2019 for a period of 6 months. An anticipated outcome of this investment is enhanced capabilities in affected countries to plan and conduct clinical trials.

[5] The EBOVAC3 project aims to assess, through clinical trials in children and adults in Africa, the safety and effectiveness of an Ebola vaccine regimen.

[6] The study is designed to estimate age and sex specific incidence of disease and infection five Lassa affected countries (Nigeria, Benin, Liberia, Sierra Leone and Guinea)

[7] A €10 million CEPI investment is matched by a €30 million EDCTP investment.

2.2.1.3 Provisions fit for purpose to support equitable access

Equitable access is a key component of our work—from discovery to licensure—and is particularly important as it relates to deployment during outbreaks. Implementation of equitable access starts with an extensive due diligence process to selected projects that have the potential to be delivered at the right scale and price where needed. These elements are in turn a key component of our partnering agreements and are monitored and reinforced at each key stage in development.

The CEPI Board is fully informed as to the approaches being taken in our partnering agreements to advance equitable access. Further, CEPI formed an Equitable Access Committee of the Board in late 2019 with the purpose of overseeing implementation of the Equitable Access Policy and proactively enhancing CEPI's approach to equitable access in line with the advancement of CEPI's portfolio and evolving best practice. CEPI provides summaries to the general public as to how CEPI enables equitable access through its partnership agreements. It is intended that COVID-19 CEPI agreements will be drafted to enable the unique global access challenges arising in a global pandemic.

Indicator 5	Baseline	2019	Target 2020	Target 2021	Target 2022	Status
Number of vaccine candidates in investigational stockpile for outbreak situations and ready for efficacy studies and emergency use	0	0	0	0	4 candidates (total) for at least 2 priority diseases (Lassa, RVF, MERS, and/ or Nipah)	*Action may be required*
	Actual	0				

Comment

Although 2019 targets have been achieved for all diseases, the assigned orange status is based upon CEPI's latest attrition forecast. We remain confident, but recognise that some candidates may not be ready until 2023. Due to the reasons listed under indicator 8, action may be required to reach the targets for 2022. There are steps that can be taken in the early stages to improve existing plans to accelerate preparedness. For example, the Secretariat will raise the issue of stockpiling in stage gate reviews early on to ensure that stockpiling remains a key priority throughout the development process.

Indicator 6	Baseline	2019	Target 2020	Target 2021	Status
Percent of vaccine Partnership Agreements that have manufacturing plans in place to enable vaccine production in response to an outbreak.	N/A	100%*	100%*	100%*	*On track*
	Actual	100%			

Comment

All development partners have committed to have manufacturing plans in place when they reach phase II clinical trials or beyond. However, the Secretariat will continuously review manufacturing plans and recommend changes to these based on assessments in stage gate reviews.

**Subject to completion of phase 1 and transitioning to p2.*

Indicator 7	Baseline	2019	Target 2020	Target 2021	Status
Percent of vaccine development partners agreeing to terms that are fully consistent with CEPIs Equitable Access Policy	N/A	100%*	100%*	100%*	*On track*
	Actual	100%			

Comment

CEPI has established an Equitable Access Committee under the Board and has committed to provide summaries to the Board as to how CEPI enables equitable access by means of its partnership agreements. Summaries of the Equitable Access Committee are available via the website.

2.3. Provides expert assistance and funds enabling science and technologies to enhance vaccine development efforts

2.3.1 Accelerating vaccine development through enabling science

CEPI funds a range of cross-cutting activities to facilitate and accelerate vaccine candidate development and to improve the environment for regulatory approval and use. Activities include development of common biological standards, animal models and assays; epidemiology studies; diagnostics; regulatory working groups. This is a cost-effective approach in a pre-competitive space whereby individual manufacturers should no longer be required to conduct their own, separate studies.

Standardisation of biological materials needed for vaccine development can help reduce timelines and ease comparison across multiple vaccine developers. In 2019, CEPI supported such efforts through the distribution of standard antigens to vaccine developers as well as sourcing and distributing serum material – a key component for determining the relevant lineage of the virus. CEPI committed to providing common biological standards to the different vaccine developers for evaluation of vaccine responses (in particular during Phase II clinical trials). As part of this work, CEPI initiated several projects and established partnerships with the National Institute of Biological Standards and Control (NIBSC), Tulane University, Bernard Nocht Institute for Tropical Medicine (BNITM), International Vaccine Institute (IVI) and International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).

Key achievements in 2019 include:

- Launching of Lassa, Nipah and MERS Task Forces with regulatory experts, disease specialist and vaccine developers
- In June 2019 a Task Force workshop was held in Oslo for Lassa fever, Nipah and MERS-CoV; with a meeting report published
- Co-organisation of the Nipah@20 conference in Singapore in December
- Launching a Lassa diagnostic program evaluating and supporting better diagnostic capacity in affected countries.
- Supporting serum collection in affected countries and developing biologic standards and assays to harmonise immune response measurements across vaccine candidates in CEPI's portfolio.
- Developing and harmonising animal models to support quality and integrity of data for regulatory authorities.

Indicator 9	Baseline	2019	Target 2020	Target 2021	Target 2022	Status
Number of available Biological Standards and validated assays (including Standard Operating Procedures) for evaluation of vaccine candidates against CEPI's priority pathogens	0	0	Necessary biological standard for evaluation of immune response against Lassa; Nipah, MERS Ag-Stds for MERS & Nipah		At least one validated assay available for Rift, Lassa, Nipah and MERS; Necessary biological standard for evaluation of immune response against Rift	*On track*
	Actual	3 biological standards for Lassa				

Comment

CEPI has exceed the target this year and has already made available 3 antigen-standards for Lassa. Four agreements to support the development of biological standards against priority pathogens were signed in 2019. If the current advancement continues, CEPI anticipates to achieve the targets ahead of 2022.

Indicator 10	Baseline	Target 2019	Target 2020-22	Status
Percent of vaccine candidates in clinical development (e.g. being tested in humans), with relevant engagement from national authorities—including regulators—in at-risk countries.	N/A	100%*	100% for each disease at every stage	*On track*
	Actual	N/A		

Comment

While no projects had progressed to require formal engagement with regulators for clinical trials, one project had a pre-IND (Investigational New Drug) meeting with the National Regulatory Agency in the country where they plan on conducting a trial, subject to passing relevant stage gate review.

2.2 Strategic objective 2: Response

Accelerate the research, development and use of vaccines during outbreaks

Disease X is prioritised for early-cross cutting research, based on the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease. Response to an unknown pathogen requires the necessary tools to expedite vaccine development, and innovative technologies can make uptake and delivery of the vaccine more effective. To support this, CEPI:

1. Invests in platforms to speed the development and manufacture of vaccines
2. Supports the development of technologies to facilitate field use and rapid response
3. Engages end-to end partners to plan for the testing and deployment of vaccines during outbreaks

Our progress under Response is relayed in the following sections.

2.2.1. Invests in platforms to speed the development and manufacture of vaccines

Vaccine platform technologies refers to a system that uses the same basic vaccine components as a backbone, which can be adapted or built upon for use against different pathogens. This adaptation significantly improves speed of vaccine development against multiple pathogens. Such a diverse portfolio should enable rapid vaccine R&D response to new or unexpectedly emerging pathogen outbreaks.

In 2019 CEPI's 'Disease X' portfolio comprised of three rapid response platforms. This relatively small set of rapid response technologies has potentially broad application potential. Each platform is being tested through phase 1 for three diseases. As can be seen from the table below, in addition to developing the platform as such, these platforms thus have the potential for additional vaccines being produced against:

- 2 against Influenza;
- 2 against Rabies;
- 1 against MERS;
- 1 against Marburg;
- 1 against Lassa;
- 1 against Respiratory Syncytial Virus; and
- 1 against yellow fever.

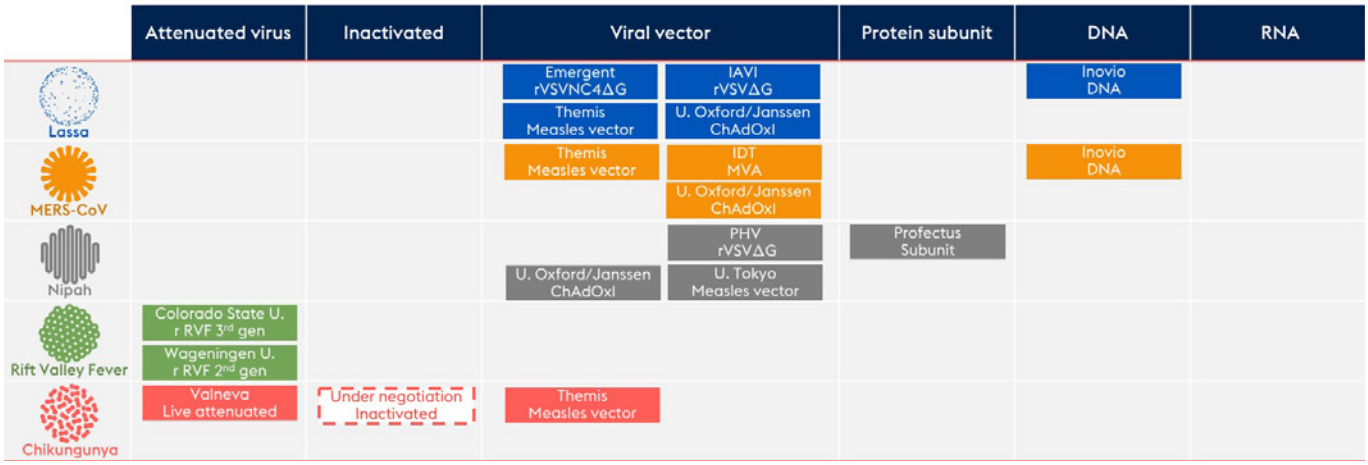


Figure 3: CEPI investments in platform technologies

The current Disease X portfolio is projected to deliver new evidence on safety and rapid vaccine R&D response potential of the platforms' filoviruses by mid-2022. To support this projection, and activate the long term budget allocation of $120million, CEPI intends to enlarge the portfolio through a rolling call for proposals.[8]

The emergence of a novel coronavirus in December 2019 – COVID-19 - has offered a real time opportunity to pivot CEPI's rapid response platforms toward rapid development and manufacture of a proven vaccine approach that can be used against COVID-19.

Indicator 11	Baseline	2019	Target 2020	Target 2021	Target 2022	Status
Number of vaccine platform technologies that can be rapidly adapted to develop vaccines against unknown pathogens for use in humans	0	0	0	0	2 or greater, including at least one novel (innovative) platform (i.e., that has no prototyped licensed vaccine)	*Action may be required*
	Actual	0				

Comment

This indicator is not expected to show any progress until 2022 when CfP2 vaccines move through phase I studies. Because only 3 projects have been contracted to date and given expected attrition, a rolling call for CFP2 commenced in 2019. At the time of writing, the CfP2 (r) had been been paused in order to leverage existing platform technologies toward COVID-19. In early in 2020, two of these platforms had pivoted toward COVID-19.

Indicator 14	Baseline	2019	Target 2020	Target 2021	Target 2022	Status
Number CfP2 vaccine candidates progressing through preclinical and P1	0	0	0	0	8 products through preclinical and 6 products progressed through Phase I	*Action may be required*
	Actual	0				

Comment

Only three of the six selected projects made it through contract negotiations, a rolling call for proposals was launched to replenish the portfolio, so mitigating actions are already ongoing forward. At the time of writing, this rolling call was paused due to an organisational pivot toward immediate response to COVID-19. In early in 2020, two of these platforms had pivoted toward COVID-19.

[8] As per March 2019 Board meeting, this was launched in autumn 2019.
However due to the emergence of COVID-19 the CfP 2 rolling call has been put on hold early 2020

2.2.2. Supports the development of technologies to facilitate field use and rapid response

Indicator 15	Baseline	2019	Target 2020-22	Status
Annual analysis of available technologies and the gaps that currently exist	N/A	Annual update	Annual update	*Additional action required*

Comment

Now that a portfolio has been established, CEPI is in a better position to assess what types of technologies would be most helpful to address challenges faced. The creation of a tech watch facility was delayed in 2019. CEPI is monitoring the outcomes of the GAVI mapping and prioritisation of such technologies. The anticipated introduction of a content management system is anticipated to inform a thorough analysis in 2020 and beyond.

2.2.3. Engages end-to end partners to plan for the testing and deployment of vaccines during outbreaks

CEPI continuously scans for new ways of improving development and delivery of vaccines. An important part of this work is to proactively look for new opportunities and building into CEPI's processes the ability to adapt when new solutions present themselves. Some technologies for vaccine delivery (e.g. patch technologies) have been raised at Board level but are currently considered outside of CEPI's core priorities.

CEPI has been performing landscape analysis of relevant fields to understand the level of vaccine preclinical and clinical development. To date these are performed through manual searches for different databases and also as written requests for information. The material compiled has given an understanding of at what level the eligibility criteria of the developers should be to enter the call and also what would be the relevant endpoint of the call.

Landscape analysis has also been used to reach out to developers to invite them for call for proposals. The aim for 2020 is to establish a centralised database for several departments of CEPI to populate, but also use actively in their daily work reaching out to interesting developers and for potential research mobilisations.

2.2.3.1 Facilitating alignment and coordination

While CEPI works with a broad set of partners, the key platform for coordination is the Joint Coordination Group (JCG). An institutional roundtable comprised of organisations that have a vested interest in seeing CEPI's vaccines succeed, the JCG met 3 times in 2019 to discuss and troubleshoot the development, licensure and delivery of CEPI's vaccine candidates including face to face meetings in Nigeria (for CEPI's Lassa candidates) and in Singapore (Nipah vaccine candidates).

Critical issues that drive the work of the JCG include:

- The need for regulatory alignment and cooperation across endemic countries early in the vaccine development process for establishing clinical trial protocols and an eventual path to licensure for investigational vaccines.
- Engaging the right community leaders and country authorities in each country in advance for a successful in-country clinical trial. Identifying and developing local relationships, with key authorities and community leaders is necessary, noting that each country will need a tailored approach.
- The lessons that can be learned from the experience with manufacturers of the second Ebola vaccine during the West Africa outbreak, including alignment of clinical trial data across multiple trials; the need for a standardisation of vaccine labels; and understanding the import/export rules of each country shipping and receiving the vaccines.

Summaries of JCG meetings can be found here while activity undertaken by JCG working groups is outlined in Table 1 below.

Name	Comment	2019 update
Regulatory	The purpose is to focus on the regulatory hurdles our vaccine candidates might face, and to problem solve for them in such a way that might help our vaccines and any other vaccines that are similarly situated.	Regulatory outreach in Europe to raise the profile of CEPI and its portfolio of vaccine candidates . The first Regulatory Roundtable was held during the Nipah 2020 conference in Singapore, with this group anticipated to serve as the foundation of a Regulatory Response Network in the region.
Sustainable manufacturing	This group has been tasked with developing a proposal for a Sustainable Manufacturing solution for the CEPI pathogens taking into account manufacturing/quality, people and infrastructure.	The group has been leading work on workstreams detailed in Section 2.3.2.2. Preparatory work on a planned call for in 2020 to align CEPI's core programme has pivoted to align global manufacturing capacity with COVID19 partner needs for a robust manufacturing response once vaccines are proven in the clinic.
Biological standards	Co-Chaired by the WHO to stimulate consensus on essential assays, strive for harmonisation and increase transparency. Work is channelled through disease specific task forces to share advice on bio-standard specifications, assays and data. Groups established for Lassa, Nipah and MERS. RVF, CHIKV and COVID-19 groups are planned.	This group has been instrumental in driving progress highlighted in Section 2.3.1., including collection and distribution of antigens, sourcing material biological material to test different lineages

Table 1: CEPI JCG Working Groups

Indicator 12	Baseline	Target 2019	Target 2020-22	Status
Percent of vaccine development partners with necessary agreements in place for vaccines to be deployed and tested during an outbreak	N/A	100%*	100%	*On track*

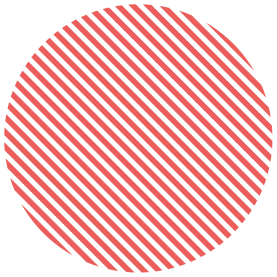
Comment

All vaccine development partners had necessary agreements in place, thereby giving an indication of CEPI's ability and commitment to respond quickly. More information on the approach taken by CEPI can be found here.

Indicator 13	Baseline	Target 2019	Target 2020-22	Status
Percent of vaccine development partners with plans in place for equitable access fully consistent with CEPI's Equitable Access Policy.	N/A	100%*	100% of projects which have passed stage gate review for progression from Phase I to Phase II trials	*On track*

Comment

Access plans will be put in place when projects enter Phase II trials. In 2019, no projects progressed to phase II trials. Going forward each stage gate review will have a requirement to review the status of compliance towards access obligations, with an aim to make it an integrated part of how our partners do business.



2.3 Strategic objective 3: Sustainability

Create durable and equitable solutions for outbreak response capacity

While preparedness and response are key priorities for an organisation working on emerging infectious diseases, sustainability is a key component within all priorities and investments will ultimately ensure that the products we help develop stand the test of time. CEPI has developed an organisational structure to ensure that investments made are robust to tackle the unpredictable nature of epidemics, and that they can help drive systemic changes in vaccine R&D for EIDs through innovation and alignment with priorities of other organisations. To ensure that CEPI's approach is sustainable, CEPI

1. Improves the predictability of financing to address end-to end market failures
2. Drives efficiencies to reduce costs across the end to end spectrum of vaccine development
3. Develops contingency plans to reduce risk so that successful products are available to support outbreak response.

Our progress under Sustainability is summarised under these three areas is described below.

2.3.1. Improves the predictability of financing to address end-to end market failures

2.3.1.1 Strengthened resource mobilisation efforts

Since its launch, CEPI has secured unearmarked funding commitments totalling $778m[9] to its common pool from Australia, Belgium, Canada, the Bill and Melinda Gates Foundation, European Commission, Germany, Japan, Norway, the United Kingdom, and Wellcome Trust. In 2019, CEPI adopted a new resource mobilization strategy which includes defined categories for resource mobilization targets and the development of country engagement strategies for all active CEPI targets.

A highlight was the execution of a frontloading mechanism through the unique architecture (Gavi's International Financing Facility for Immunisation (IFFIm[10]), which enabled the Government of Norway, a longstanding partner of CEPI, IFFIm and Gavi to transfer an already committed multi-year contribution to CEPI of NOK 600 million (approximately US$ 66 million). IFFIm then issued bonds in Norwegian krone against that contribution, thus frontloading the funds for CEPI's immediate use. The transaction highlights the benefits that collaborative and innovative partnerships can bring to quickly access funding to speed up the development of vaccines.

In 2020, CEPI will actively work to broaden its investment base. A number of new prospects have voiced an interest in joining the Coalition. In addition, CEPI will develop the approach to funding the next business plan, from 2022 onwards. More information on the financial commitments by investors to CEPI can be found in **Section 3**.

[9] Exact amount depending on exchange rates

[10] IFFIm was initiated in 2006 to rapidly accelerate the availability and predictability of funds for immunisation. IFFIm uses government pledges to support the issuance of Vaccine Bonds sold to institutional and individual investors.

2.3.2.1 Alignment of funding and scope with other organisations

CEPI is continuing the work through the Joint Coordination Group (JCG) with key partners such as WHO, Gavi, UNICEF, IFRC and MSF to clarify roles and responsibilities in preparedness and response activities. The part of CEPIs mission that is to enable equitable access depends on downstream partners in the global community taking responsibility in a coordinated fashion, in which CEPI plays a facilitator role. This includes late-stage development, licensure, sustainable manufacturing, delivery, administration and post-licensure pharmacovigilance and monitoring. CEPI is continuously working bilaterally with partners along the end-to-end development and delivery spectrum to achieve this purpose. In addition, CEPI has dedicated tripartite meetings with WHO and Gavi to strategically plan for preparedness activities and clarify roles and responsibilities.

Indicator 16	Baseline	2019	Target 2020	Target 2021	Target 2022	Status
Agreements with downstream financing partners in place for each of CEPI's priority diseases	0	0	0	0	5 agreements in place (1 for each of Rift, CHIKV, Lassa, Nipah and MERS)	*Action required*
	Actual	0				

Comment

CEPI continues to prioritise its broader Coalition engagement in line with the progress of the portfolio and has initiated a dialogue with Gavi on the principles around how to achieve this. CEPI is not due to achieve a target on this indicator in this reporting period.

Indicator 17	Baseline	2019	Target 2020	Target 2021	Target 2022	Target 2023	Status
$1bn raised as multi-year contributions to CEPI	$630m	$1b	$1bn	0	0	0	*Substantial action required*
	Actual	$778					

Comment

Current funds raised total around $USD 778, (exact amount depending on exchange rates). Several prospects are projected to become commitments in early 2020. However CEPI's response to COVID-19 has altered existing resource mobilisation efforts.

2.3.2 Drives efficiencies to reduce costs across the end to end spectrum of vaccine development

CEPI was established as a financing mechanism for vaccine development for emerging infectious diseases, tasked to try and do things differently as well as actively seeking out solutions that could make a lasting impact. There are two areas that CEPI has worked on specifically in this regard in 2019; managing our portfolio (including expediting CfP process) and sustainable manufacturing.

2.3.2.1 Managing the portfolio

The portfolio has grown significantly in 2019, and in view of its scale and complexity, CEPI has implemented core capabilities in R&D project management, risk management and portfolio management to actively monitor and manage the investments made in these R&D projects. Portfolio management capabilities that were established in 2019 include:

- A common portfolio management cycle – disciplined project identification, selection, management and evaluation processes, informed at each stage by rigorous review procedures and subject-matter expertise.
- Effective portfolio governance – with a newly established Portfolio Strategy and Management Board (PSMB) consisting of senior members of the CEPI leadership team and internal technical and subject matter experts) meeting on a bi-weekly basis to ensure effective oversight and routine decision-making around R&D investments.
- Standardised project and portfolio management practices – core processes to drive harmonisation and comparability across the portfolio, including:
  a) continuously updated external R&D pipeline screening for new opportunity identification;
  b) modelling of the potential impact of attrition across the portfolio to ensure that the portfolio of vaccines is appropriately sized and structured to meet strategic objectives[11].
- Clear and consistent management of project and portfolio information – standard reporting introduced to provide CEPI stakeholders with timely and relevant information for effective review and decision-making.

Figure 4: CEPI's Portfolio Management

[11] Estimates of probability of success have been used to model the potential impact of attrition across the R&D portfolio, both in terms of: a) the size 11of the portfolio needed to deliver the target objectives for each pathogen; and b) the impact on the overall investment requirements, accounting for project failure.

The concerted efforts to develop a R&D Portfolio Management system for advancing CEPI's portfolio has also strengthened CEPI's ability to identify opportunities and expedite processes to make new investments through the launch of calls for proposals, thereby driving efficiencies. Having undergone three full calls for proposals since commencement and one rolling call, CEPI has significantly reduced the time taken to launch, review, assess and activate R&D investments as described below:

- The first call for proposals (CFP) process covering Lassa Nipah and MERS took more than two years in total, the CFP2 process proceeded in around 18 months, while the CFP3 process for CHIKV and RVF took less than a year.
- A rolling call for platform technologies (CFP2R) was launched in 2019, to allow partners with innovative platform technologies to partner with CEPI in a more flexible way.
- The preparation for the CfP2R started early summer 2019 and the SAC providing advice and recommendations in developing the scope and criteria of the call. The rolling call was launched 15 October 2019 and was planned to be open until 14 October 2020 with set dates for periodic reviews of received proposals. At the time of writing, due to the COVID-19 outbreak, the decision was taken to put CfP2 R on hold.
- In CFP3 (covering CHKV and RVF), efficiencies were made in the partnership assessment processes with the technical, financial, and legal due diligence processes undertaken in parallel. With streamlined procedures initiated in CFP3, CEPI was able to move from launch to the first signed partnership in three months.
- Alongside this CEPI, established TechTalks during autumn of 2019, as a 60 minute informal meeting with presentation of technology and discussion and potential shaping of applications or expressions of interest for the active announcements by CEPI. Currently TechTalks are widely used for recruitment and shaping towards the CfP2R. TechTalks are also planned for the COVID-19 call for proposals anticipated in early 2020.

In addition, CEPI held its first Annual Portfolio Review during 5-6 November 2019, engaging over 110 coalition partners in a portfolio assessment, reviewing progress made to date and informing future priorities for R&D investment.

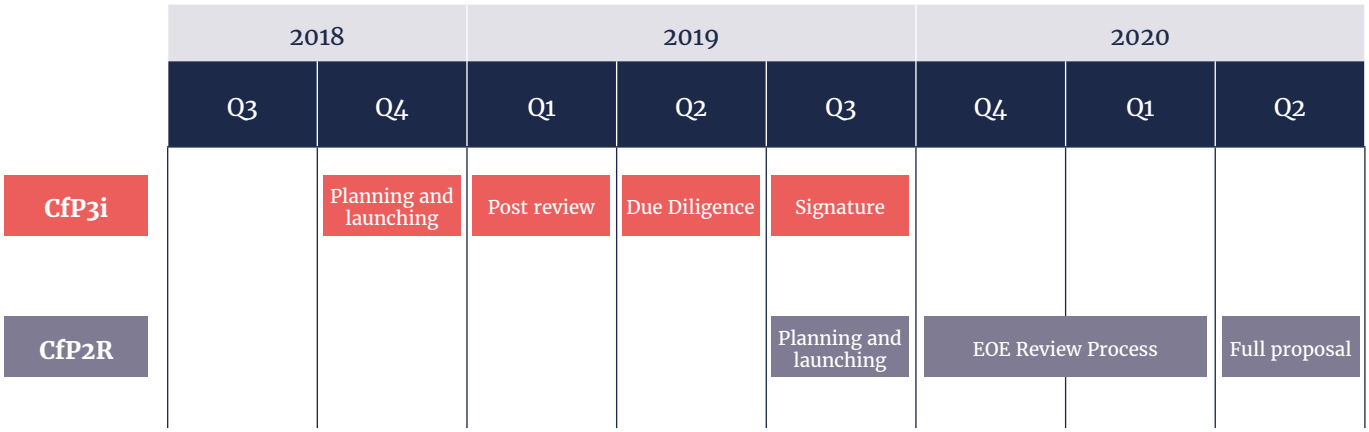


Figure 5: Timeline for conducting Calls for Proposals

CEPI has also driven advancements on diseases specific areas to identify and solve challenges unique to some of our priority diseases. We have hosted multiple workshops and conferences to this end; see Box 2 for an overview of the CEPI hosted Nipah conference.

Box 2: Nipah@20 conference: facilitating engagement between stakeholders

The Nipah@20 conference was co-hosted by the Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organization (WHO), the U.S. National Institute of Allergy and Infectious Diseases (NIH/NIAID) and the Duke-NUS Medical School (Duke-NUS). The Conference marked the 20th anniversary of the discovery of Nipah virus and brought together 200 experts and global health stakeholders to review past outbreaks and discuss the need for and latest developments in diagnostics, vaccines and therapeutics. Since its first identification in Malaysia and Singapore in 1999, the understanding of Nipah and its pandemic potential has advanced substantially.

The Conference provided a forum to review the history and key scientific findings over the last 20 years, and to understand the current challenges in developing Nipah diagnostics, therapeutics and vaccines. To foster international collaboration in the context of epidemic preparedness, Nipah@20 brought together 218 scientists and public health professionals working in 21 different countries around the globe. Importantly, all henipavirus-affected countries (Australia, Bangladesh, India, Malaysia, the Philippines and Singapore) were represented in the event. CEPI also facilitated a meeting between regulatory authorities to discuss potential regulatory pathways for a Nipah-vaccine.

2.3.2.2 Sustainable manufacturing and clinical trials

Since epidemics are unpredictable, ensuring adequate manufacturing capacity that can be scaled up in the event of a crisis has been a costly endeavour. CEPI's efforts in this area are driven by a dedicated working group on sustainable manufacturing (see Section 2.2.3), whose focus on finding innovative solutions to bring down costs across developers. Achievements in this area are highlighted below:

- **Epidemiological modelling to determine manufacturing needs:** The epidemiology for Lassa, MERS, and Nipah was modelled to understand the size of clinical reserves needed to respond to the most likely outbreaks. With the addition of the CHKV and RVF to the portfolio, modelling for these diseases was completed as well. Recognizing that there may be additional demand for CHIKV products to support routine use, travellers, and private markets the group added a market research element to fully understand demand. The epidemiology output and market research output will be reviewed in 2020 to confirm the target demand and supply chain requirements.
- **Identification of manufacturers that can quickly pivot towards new threats:** A key part of the effort in 2019 was to build a 270-company database of biological manufacturers world-wide. CEPI also contacted 70 of the best-known companies and asked for willingness and capacity to work with CEPI on creating the capacity needed to manage outbreaks and stockpiles. Out of this call, CEPI has identified 14 "tier 1" suppliers that have the competency and capacity to support the CEPI sustainable manufacturing needs for 2022 – 2026. This horizon-scanning exercise is anticipated to be of particular use in the long-term response to the COVID-19 outbreak.
- **Adapting manufacturing solutions to future needs of CEPI's portfolio:** CEPI has engaged with current partners to gain support for establishing standard work and contracts to advance all programs in a consistent and efficient manner. These standards will simplify the management of network of manufacturing partners and support rapid adaptation to any technology in our portfolio - including during an outbreak.

Indicator 18	Baseline	Target 2019	Actual 2019	Target 2019-22	Status
Percent of priority actions taken to achieve efficiencies	0	50%	0	50%	*Action required*

Comment

The intended scoping exercise to identify and prioritize actions did not take place as originally planned in 2019. Priority actions for next reporting period will be identified by end of Q2 2020.

2.3.3 Develops contingency plans to reduce risk so that successful products are available to support outbreak response

Availability of the products we help fund is key to CEPI success. CEPI is therefore committed to establishing contingency plans that provide alternative routes when the primary solution fails. For manufacturing, this means ensuring that vaccines will be available to enable phase 3 testing in the event of an emergency. To support such a safety net, CEPI has established three different manufacturing routes:

1) The development partner itself as the first of option
2) An external partner identified by the development partner (and agreed upon by) if it cannot manufacture the required doses itself or
3) If the development partner is not willing to manufacture the required doses, CEPI has additional options to enable us to proceed with other partners.

TOC # 3.3.1, indicator # 19	Baseline	Target 2019	Actual 2019	Target 2019-22	Status
Percent of vaccine Partnership Agreements in place that contain contingency plans for manufacturing	0	100%	100%	100%	*On Track*

Comment

All partnership agreements in place contains contingency plans. As part of the work of the Sustainable Manufacturing working group, recommendations may come forward related to the requirements and operationalisation of these contingency plans.

3. FINANCE

2019 was a year of continued growth for CEPI, both in terms of resources and the investment portfolio. The Finance & Operation team has continued to implement and secure a diligent internal control environment and the procurement of goods and services in a way that ensures value for money.

3.1. Cash flow overview

5 year plan

CEPI's cash flow overview consists of contributions from Investors, R&D investment projects, Secretariat costs (split between three activities), Financial costs and Cash flow adjustments and tax. Together these provide the cash balance per year and accumulated over time.

5 Year Plan MUSD	2017 Actual	2018 Actual	2019 Actual	2020 Forecast	2021 Plan	2022 Plan	2023 Plan	Total
Contributions*	82,7	112,7	211,0	145,2	215,8	189,1	114,7	**1071,2**
R&D projects	-	34,7	103,8	223,6	243,7	189,1	104,0	**898,7**
R&D project support	5,5	8,7	13,7	19,7	20,7	21,4	22,2	**112,0**
Resource Mobilisation cost	0,7	1,1	1,0	1,8	2,0	2,1	2,2	**10,9**
Admin cost	1,9	8,0	9,0	11,1	11,6	12,0	12,4	**66,0**
Financial cost	0,2	-3,5	-5,6	-1,5	-1,0	-1,0	-1,0	**-13,4**
Cash flow adj & tax	-5,5	3,6	-1,1	-	-	-	-	**-3,0**
Cash Balance	**79,9**	**60,1**	**90,1**	**-109,5**	**-61,1**	**-34,5**	**-25,0**	**0,0**
Accumulated Cash Balance	**79,9**	**140,0**	**230,1**	**120,6**	**59,5**	**25,0**	**0,0**	**0,0**
Accumulated Cash Balance net of operating reserve of MUSD 25	**54,9**	**115,0**	**205,1**	**95,6**	**34,5**	**0,0**	**0,0**	

Table 2: CEPI's financial overview[12]

* Contributions for 2022 and 2023 includes required RM of MUSD 293,9 to cover existing commitments. CEPI hopes to raise at least this amount if not more through RM and for CEPI 2.0

Contributions

As per beginning of 2020, investors have committed contributions of MUSD 778,4 to CEPI. **Table 3** shows how much different investors have committed over time. It also highlights contributions intended for specific projects/pathogens. See **Section 2.3.1.1** for more detail on resource mobilisation.

[12] March Board version. No major changes between 2020 budget and forecast. Contributions has decreased by MUSD 11 (delta of frontload of payments into 2019 and new contributions). R&D investment projects are down by MUSD 3 (several minor adjustments). No changes to Secretariat and Financial costs.

Contributions from Investors MUSD	Category	2017 Actual	2018 Actual	2019 Actual	2020 Forecast	2021 Plan	2022 Plan	2023 Plan	Total
Norway (MNOK 1600)	Common Pool	11,9	17,1	81,7	26,7	40,0	-	-	**177,4**
Wellcome (MUSD 100,4)	Common Pool	1,7	20,0	0,1	0,0	78,5	-	-	**100,4**
BMGF (MUSD 100)	Common Pool	22,0	20,0	20,0	20,0	18,0	-	-	**100,0**
Germany (MEUR 90)	Common Pool	18,7	16,3	39,3	5,6	22,4	-	-	**102,3**
Japan (MUSD 125)	Common Pool	25,0	25,0	25,0	25,0	25,0	-	-	**125,0**
Australia (MAUD 6,5)	Common Pool	-	1,4	0,7	1,2	1,2	-	-	**4,5**
Belgium (MEUR 0,5)	Common Pool	-	0,6	-	-	-	-	-	**0,6**
Canada (MCAD 14)	Common Pool	2,8	0,3	7,5	-	-	-	-	**10,7**
UK (GBP 30)	Common Pool	-	12,6	13,0	12,7	-	-	-	**38,3**
South Korea (MUSD 9)	Common Pool	-	-	-	3,0	3,0	3,0	-	**9,0**
Ethiopia (MUSD 0,3)	Common Pool	-	-	-	0,3	-	-	-	**0,3**
EC (MEUR 80)	Chik & RVF	-	-	18,4	40,9	25,2	5,0	-	**89,5**
EC (MEUR 6)	Ebola DRC	-	-	3,7	2,0	-	1,0	-	**6,7**
Wellcome/DFID (MUSD 8,7)	Ebola DRC	-	-	-	7,8	-	0,9	-	**8,7**
Vulcan (MUSD 5)	Ebola DRC	-	-	2,5	-	2,5	-	-	**5,0**
TOTAL		**82,2**	**113,3**	**211,9**	**145,2**	**215,8**	**9,9**	-	**778,4**

Table 3: Overview of financial commitments to CEPI

CEPI receives contributions from both public and private foundations/investors. Public investors represent the largest investor group. Most of the contributions are included in a common pool of funds, though when outbreaks occur, it is apparent that some funds received will come with specific requirements on spend. Funding from the European Commission is targeted at specific pathogens and includes a clause that CEPI shall top up funding at a certain percentage.

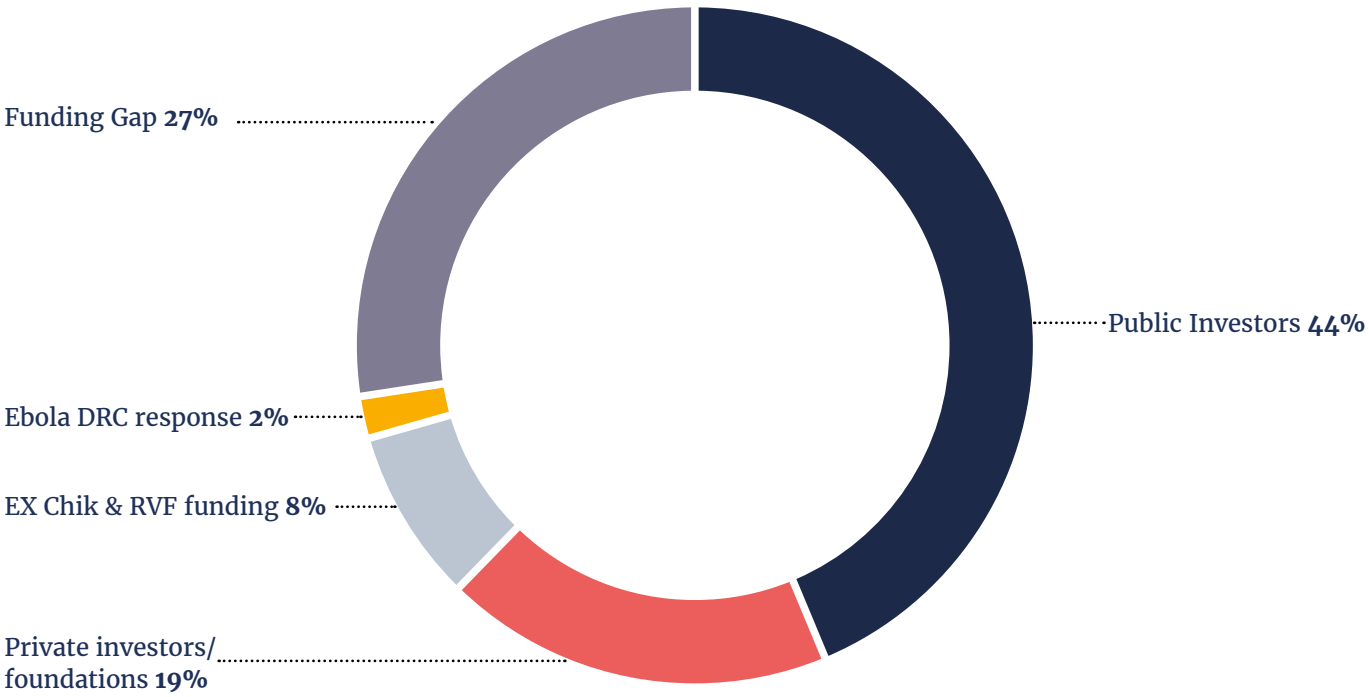


Figure 6: Total contribution pr. Investor category, percentage split 2017-2023

CEPI's contributions in 2019 added up to MUSD 211,0 (incl. currency adjustments), MUSD 11,5 lower than budgeted. The variance relates to timing of payments, currency and frontloading effects, offset by new contributions from UK, Australia and Vulcan[13].

[13] Vulcan Inc. is a privately held company to establish and oversee the business activities and philanthropic endeavours founded by the Microsoft co-founder Paul Allen and his sister Jody Allen

3.2 R&D project investments

CEPI's portfolio of investments is grouped into Priority pathogens, Platform technology, Enabling Science and Rapid response. For the full 5-year plan, the R&D project investment costs amount to MUSD 898,7 and includes both contractual committed funds, uncommitted funds of ongoing projects and placeholders for future planned investments. Committed funds currently amount to MUSD 330,8.

R&D project investment costs MUSD	2018 Actual	2019 Actual	2020 Forecast	2021 Plan	2022 Plan	2023 Plan	Total
Priority pathogens	34,2	74,4	141,5	157,2	114,2	79,6	**601,2**
Platform technology	-	13,5	38,3	36,9	30,5	24,3	**143,6**
Enabling Science	0,5	6,3	33,2	43,5	44,2	-	**127,7**
Rapid response	-	9,6	10,7	6,0	0,1	-	**26,3**
Total R&D projects	**34,7**	**103,8**	**223,6**	**243,7**	**189,1**	**104,0**	**898,7**

Table 4: CEPI's R&D project investment costs

Investments in Priority pathogens comprise the largest investments and include projects directed towards pathogens mentioned in the WHO blueprint for priority diseases. CEPI's portfolio covers Lassa, MERS, Nipah (CfP1[14]), Chikungunya and Rift Valley Fever (CfP3), EDCTP/Lassa (European and Developing Countries Clinical Trials Partnership) and Ebola.

Platform technologies covers investments in Nucleic acids and Recombinant proteins (CfP2 and CfP2R).

Enabling science projects support vaccine development and the portfolio through projects related to Assays & standards, Animal models, Epidemiology, Immunology, Clinical development, Capacity strengthening and Regulatory work. Sustainable Manufacturing and Preparatory late stage projects are also included under Enabling Science.

Rapid response includes projects related to CEPI's response to unforeseen outbreaks. The investments in the current plan relates to the DRC Ebola outbreak and CEPI's involvement in conducting clinical trials for a new vaccine.

Table 5 shows CEPI's R&D project categories, comparing 2019 actuals with budget. The speed of investment has not been as high as planned, due to delay of project initiation, ongoing project delays, and one project not materialising.

R&D project investment costs MUSD	2019 Actual	2019 Budget	2019 Variance
Priority pathogens	74,4	97,7	-23,3
Platform technology	13,5	37,3	-23,7
Enabling Science	6,3	21,9	-15,6
Rapid response	9,6	0,0	9,6
TOTAL	**103,8**	**156,9**	**-53,1**

Table 5: R&D project investment costs 2019

[14] Call for Proposal (CfP). # refers to sequence of calls. R indicates a running call.

3.3 Secretariat costs

Secretariat costs (OPEX) are shown by activity in CEPI's cash flow overview and refers to whether an expense is channelled towards R&D project support, Resource Mobilisation[15] or Administration[16]. This provides insight into whether operating expenses are directed towards adding value to the portfolio of investments through project support, or to managing the organisation or raising funds, the last two typically labelled overhead costs.

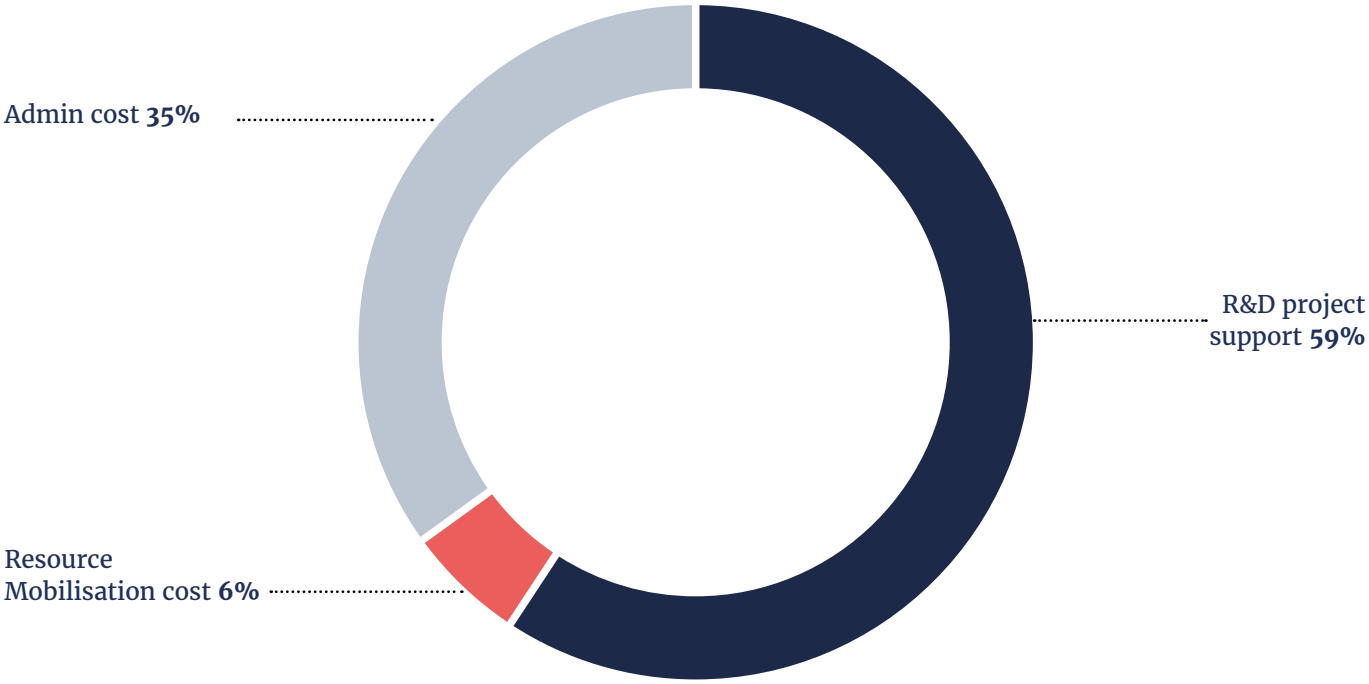


Figure 7: Secretariat costs, average percentage split 2017-2023

Secretariat costs (OPEX) can also be viewed by type, referring to the kind of expense that is budgeted/ incurred depending on the nature of the expense, irrespective of activity. Both ways of viewing the operating expenses provide the same total.

Activity
R&D project support
Resource mobilisation (overhead costs)
Administration (overhead costs)

=

Type
Employment
Consultancy
Travel
Infrastructure
Service providers/Other

Figure 8: Secretariat costs by activity vs type

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

[16] Administration costs also includes shared costs like IT, Office facilities, Finance & Operations and HR.

CEPI´s secretariat costs for 2019 reflect that CEPI is still in a build-up phase. The total secretariat costs in 2019 amounted to MUSD 23,8, up from MUSD 17,9 in 2018, but lower than the approved 2019 budget of MUSD 24,9. CEPI's secretariat costs will continue to increase in 2020 as the portfolio continues to grow and the high workload indicates a shortage in staff. The percentage increase from 2018 to 2019 has been 33%, while the increase from 2019 to 2020 is expected to be 37%. In absolute figures, the largest increase by far is in R&D project support. From 2021 onwards the costs are expected to flatten out, only adjusted for inflation.

Secretariat costs MUSD	2019 Actual	2019 Budget	2019 Variance
R&D Project support	13,7	13,6	0,1
Resource Mobilisation	1,0	1,5	-0,5
Administration	9,0	9,8	-0,8
TOTAL	**23,8**	**24,9**	**-1,2**

Table 6: Secretariat costs by activity 2019

As the below figures indicate, hiring was below plan for 2019, leading to increased consultancy spend.

Secretariat costs MUSD	2019 Actual	2019 Budget	2019 Variance
Employment	8,0	10,5	-2,5
Consultancy	10,4	8,8	1,6
Travel	2,9	3,1	-0,2
Infrastructure	1,1	1,0	0,0
Service Providers/Other	1,3	1,5	-0,2
TOTAL	**23,8**	**24,9**	**-1,2**

Table 7: Secretariat costs by type 2019

3.4 Total expenditure

CEPI's main activity is vaccine development through investments in R&D projects. R&D project costs are split between investments and the secretariat costs related to supporting the project portfolio (R&D project support).

Figure 8 below gives a figurative depiction of the expenses in the 5-year plan, where secretariat expenses are depicted by activity. It shows that R&D project investment costs by far represent the largest expense category, and even more so when including the R&D project support that add value to the projects. Figure 8 also shows that secretariat costs decline as a share of total expenses over time, as investment costs increase while operational expenses remain stable from 2020 onwards.

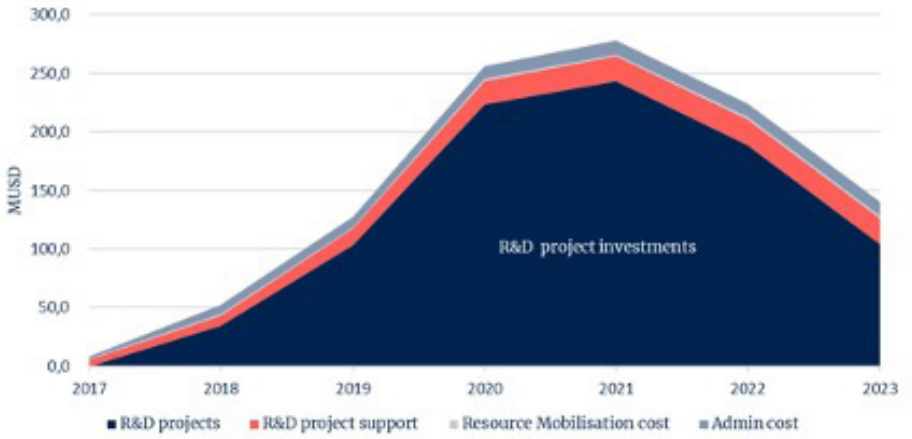


Figure 9: Secretariat & R&D project investment costs over time

In 2019, 93% of CEPI's total expenses were R&D project costs. The below percentage allocation of costs also represents the average for years 2017 to 2023.

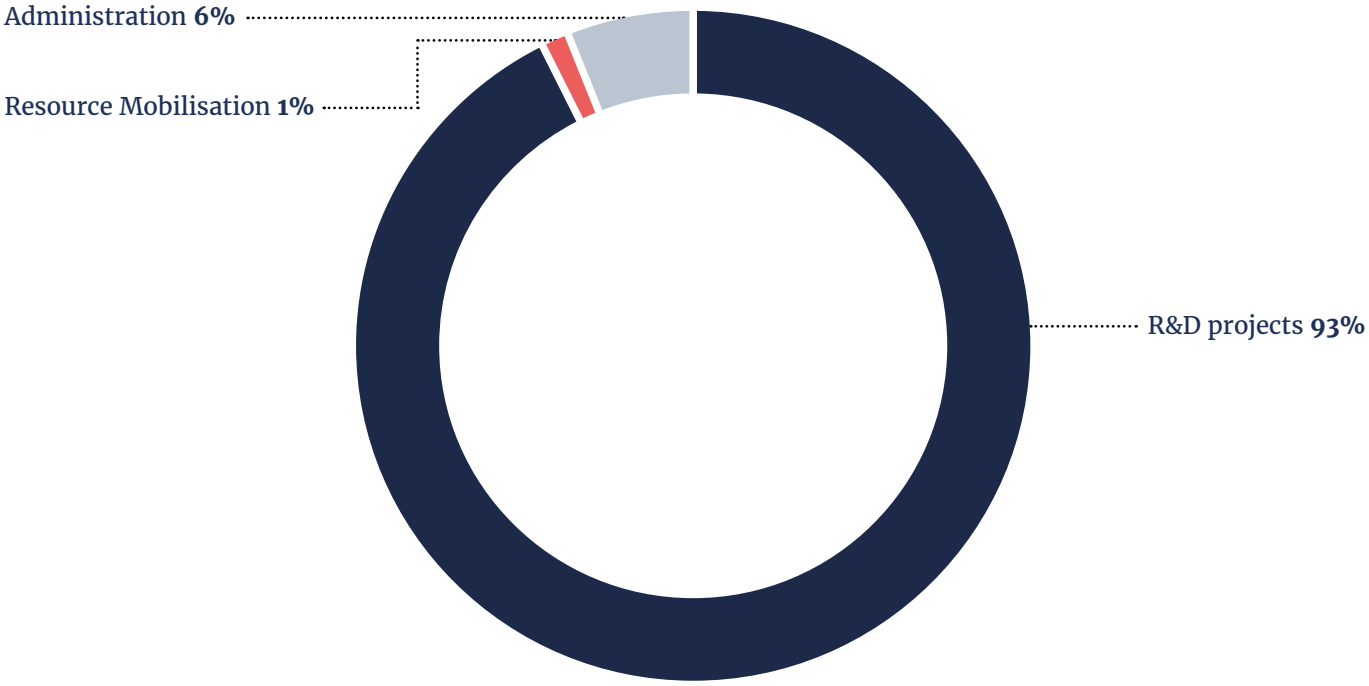


Figure 10: Expenditure by activity 2019

3.5 Procurement

CEPI places great emphasis on creating value for money in all areas of its business, including when procuring goods and services.

CEPI's procurement policy outlines how CEPI commits to conduct procurement based on the principle of value for money, balancing the needs of CEPI with the quality and cost of the product or service. Another key principle is that procurements should be carried out to maximise competition to the greatest extent practical and that all decision-making and actions related to procurement shall be impartial, unbiased and free from conflict of interest. The policy and procedures reflect international best standards and EU directives, and was drafted in close consultation with our Investors, ensuring that our approach was in line with legal requirements.

The procedure includes general rules and principles, eligibility criteria for tenderers, specification of tender procedure types and duration of contracts. It also defines thresholds that trigger different procurement processes (Direct procurement/simple tender/full tender), in which the steps and scrutiny undergone reflects the value and type of procurement.

Type of procurement process
Direct Procurement (value below KNOK 100)
Simple Tender (value between KNOK 100 - 500)
Full tender (value above KNOK 500)

Table 8: Overview of procurement thresholds

CEPI updated its procurement procedures in 2019 in order to simplify the process, reduce administrative burden and enable the organisation to move with greater speed and agility, while ensuring that the procurement process is still proportional to expected value of procurement and in compliance with rules and regulations.

Additional compliance staff were hired in 2019, including an Operations and Procurement Manager and a Contract Controller with dedicated responsibility for implementing and improving the procedures, as well as overseeing that procurements are made according to its guidance. We have also focused on raising awareness on the procurement process across the organization and establishing good routines. To this end, a SharePoint site summarising and explaining the procurement procedures, with detailed steps and templates, was created for internal employee use. In 2019 approximately 35 procurements took place in accordance with CEPI's Procurement Procedure. CEPI is currently in the process of planning a new information management system, where automation of key processes is within the scope. Procurement and contract management are two of these such key processes.

4. RISK MANAGEMENT

CEPI's risk management framework is designed to manage, rather than eliminate, the risk of failing to achieve the coalition's strategic objectives. The framework provides reasonable, but not absolute, assurance for CEPI to reach its goals, through processes and activities embedded in the Secretariat and the governing bodies of the coalition. These are set out in the risk governing structures, through operationalisation of risk, development of internal controls and measures for mitigating key risks.

While several of these structures and processes are already in place, in 2019 CEPI continued to strengthen and formalise its risk management approach based on this framework. This section addresses activities undertaken and developments throughout the year:

- In 2019 the risk register was updated with a more granular risk scoring methodology: both the impact of a risk and the probability of occurrence are scored on a 1-5 scale – with a maximum score of 25. The concept of measuring the level of control for the risk and mitigating actions has also been introduced. When considering both the Gross Risk level and the level of efficiency for the controls, the result can be expressed as the Net Risk. The assumed way of managing the net risk is outlined in a Net Risk chart.
- Implementation of the Risk Management Policy through a Procedure started late 2018. In 2019, risk management was further integrated as part of CEPI's working processes at all levels of the organization. Employees and consultants are trained in the risk management methodology and procedure. Risk registers are maintained on organisational, departmental and project level and each risk item has a dedicated owner. The risk register also includes a "Top CEPI risks overview" – as selected by the Leadership Team based on the feedback from each team. Key risks were regularly reviewed by the Board Audit and Risk Committee throughout the year.
- Managing risks has become a more integral part of CEPI's annual planning and monitoring activities. Regular updates on organisational and departmental priorities are shared with the Leadership team, and discussions include a focus on risk. Furthermore, the Leadership team performs deeper dives into organisational and departmental plans on a quarterly basis, course-correcting if needed, reviewing budget allocations, human resources and the organisational risk register.
- The ability of CEPI's awardees/ partners to manage risk directly influences CEPI's risk exposure. Project specific risks are declared by the potential awardees in the application and revised in the Integrated Product Development Plan (IPDP). Further risks are identified through technical, legal and financial due diligence. The risks are monitored by both CEPI's project management team and the Joint Monitoring and Advisory Group (JMAG) established for each project, and risks and mitigating measures will be part of each milestone review. Throughout project implementation, the (JMAG) reviews risks and escalates changes and increased risks to the Vaccine R&D Team via the SAC.
- As well as managing project risk, CEPI has developed a comprehensive framework to manage the overall R&D portfolio risk. The core principle is that the impact of attrition on CEPI's portfolio should be modelled based on the specific risk profiles of individual projects. This is intended to provide the most relevant – and therefore most realistic – view of the risk and impact of project failure on the overall CEPI portfolio, thereby overcoming some of the limitations associated with use of standard external industry benchmarks alone. The is proactively considered through the Portfolio Strategy Management Board

- The Internal Audit function reports to the Leadership Team for operational purposes and to the Board Audit and Risk Committee for its oversight role. Internal audit plays a role in assisting the Leadership Team and Audit and Risk Committee in the performance and discharge of their functions and duties. In 2019 the Internal Audit Function focused on the first set of partners contracted for the first vaccine development projects (CfP1), being the partners with projects of the longest duration and at a more mature stage, than more recent partnerships. The audits identified relevant findings, none of which were considered to have material impact. Recommended improvements have been addressed and the awardees have initiated improvement activities, and CEPI monitors progress until being closed.
- The travel pattern of CEPI staff continues to evolve as business activities includes project work in areas or at locations of higher risk. As this results in potentially exposing employees, contractors and consultants to critical situations, CEPI's insurance program was restructured to better fit with the change in risks related to the current operation and travel pattern. In addition, a more comprehensive travel procedure and approval system was implemented, focusing on pre-travel preparations to better plan the travels and reduce potential risks. A supplier of travel risk support was also contracted to support the organisation through all steps of a travel, including emergency support in case of medical or safety/security events.
- CEPI contracted KPMG to perform a benchmark of current state against internationally accepted security frameworks. The benchmark provided guidance to CEPI's cyber security program in order continue to evolve to meet the demands of the cyber security threat landscape.
- The CEPI Board reviewed the organisational risks in their annual risk review in 2019, in particular the top risks as indicated in the below risk table[17].

Risk	Impact	Probability of occurrence	Risk Score	Level of control
Understanding in Secretariat leading to too high workload, reduced quality, delays and not delivering on CEPI's mission	4	4	16	3
CEPI not developing safe and effective vaccines five years after launch	5	5	25	3
Insufficient collaboration with central partners (e.g., WHO, GAVI) leading to lack of coordination of resources related to outbreaks	5	4	20	2
Leakage of sensitive information	4	4	16	3
CEPI not achieving its 1 bn funding target	5	4	20	2
Abuse of power, misuse of public funds	5	3	15	3

Table 9: CEPI's top risks

[17] The full risk register is available to Investors on request

APPENDIX I: ORGANISATIONAL UPDATE

To accommodate the growing portfolio, a number of changes were made to the structure of the organisation, in particular:

Establishment of the Portfolio Strategy and Management Board:

The Portfolio Strategy and Management Board was established and consists of senior members of the CEPI leadership team and internal technical and subject matter experts. The PSMB is an intra-Secretariat, cross-departmental decision-making group. Primarily, the PSMB functions as a board which:

- oversees the progress, challenges, and interdependencies across the portfolio, in addition to conducting an annual strategic portfolio review with CEPI's stakeholders
- drives decision-making for CEPI's portfolio of vaccine candidate and platform projects, primarily with regards to value, cost, time, risk, and diversity.

Unifying vaccine science and vaccine development in a new department: Vaccine Research and Development: In December 2019, it was decided to merge the Vaccine Science (VS) and Vaccine Development (VD) departments in order to strengthen the ability to work effectively across disciplines and groups. The Secretariat used a consultative process to maximize the value added from employees and consultants and to ensure that employees in the VS/VD departments, were properly engaged in the process. The process resulted in a merger of the two teams into one R&D department, and an organization of the R&D resources in a simple organizational structure promoting coordination and collaboration

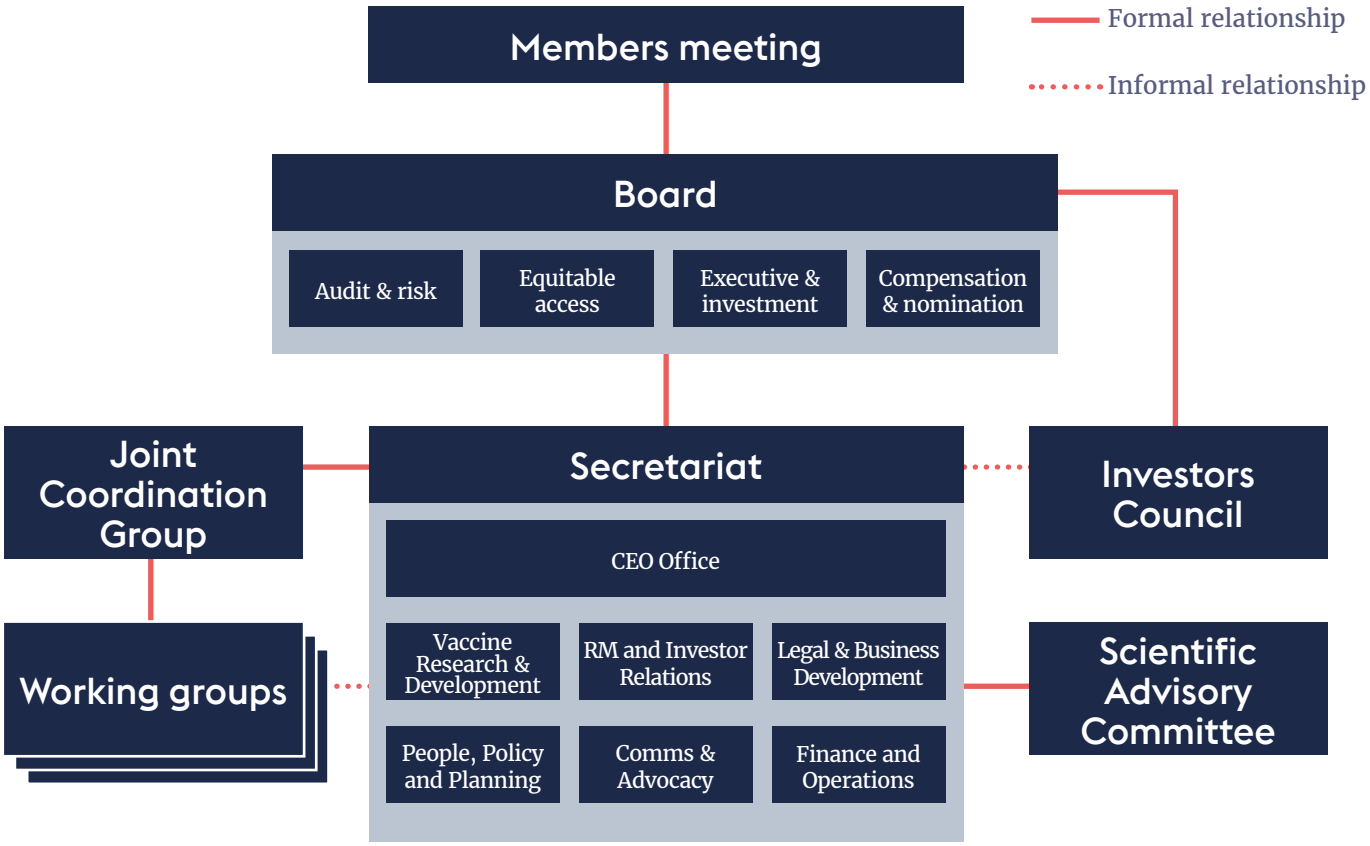


Figure II: Updated governance structure

APPENDIX 2: FINANCE

Contributions 2019

Contributions from Investors MUSD	Category	2019 Actual	2019 Budget	2019 Variance
Norway	Common Pool	81,7	93,8	-12,0
Wellcome	Common Pool	0,1	38,7	-38,5
BMGF	Common Pool	20,0	20,0	-
Germany	Common Pool	39,3	11,2	28,1
Japan	Common Pool	25,0	25,0	-
Australia	Common Pool	0,7	-	0,7
Belgium	Common Pool	-	-	-
Canada	Common Pool	7,5	0,4	7,1
UK	Common Pool	13,0	-	13,0
EC	Chik & RVF	18,4	33,5	-15,1
EC	Ebola	3,7	-	3,7
Vulcan	Ebola	2,5	-	2,5
Currency adjustment		-0,9	-0,6	-0,3
TOTAL CONTRIBUTIONS		**211,0**	**221,9**	**-10,9**

CEPI has also received in-kind contributions in 2019. This includes pro-bono services provided by Norwegian Institute of Public Health (NIPH) for office space at an estimated value of MUSD 0,6.

In addition to its cash contribution, Wellcome has also provided office space, meeting rooms and other services which have not been possible to quantify.

R&D project investments 2019 – details

Priority pathogens MUSD	2019 Actual	2019 Budget	2019 Variance
MERS	9,6	15,5	-5,9
Lassa	23,0	37,9	-15,0
Nipah	13,1	17,1	-4,0
Rift Valley Fever	5,3	8,5	-3,2
Chikungunya	21,7	8,5	13,2
Ebola	1,8	10,1	-8,3
TOTAL	**74,4**	**97,6**	**-23,2**

Platform technology MUSD	2019 Actual	2019 Budget	2019 Variance
Recombinant viruses	-	16,6	-16,6
Recombinant proteins	2,2	4,5	-2,4
Nucleic acids	11,4	16,1	-4,8
TOTAL	**13,5**	**37,3**	**-23,7**

Enabling Science MUSD	2019 Actual	2019 Budget	2019 Variance
MERS	0,4	4,3	-3,9
Lassa	4,1	7,8	-3,8
Nipah	0,2	4,5	-4,3
Cross Cutting	1,5	5,2	-3,6
TOTAL	**6,3**	**21,9**	**-15,6**

Rapid Response MUSD	2019 Actual	2019 Budget	2019 Variance
Ebola DRC response	9,6	-	9,6
TOTAL	**9,6**	**-**	**9,6**

R&D project investments 2019 – details

Pathogen/Platform technology MUSD	2019 Actual	2019 Budget	2019 Variance
MERS	11,8	10,0	21,8
Lassa	20,2	27,0	47,3
Nipah	2,2	13,3	15,5
Rift Valley Fever		5,3	5,3
Chikungunya		21,7	21,7
Ebola		11,4	11,4
Cross cutting		1,5	1,5
Recombinant proteins		2,2	2,2
Nucleic acids		11,4	11,4
TOTAL	**34,2**	**103,8**	**137,9**

Secretariat costs by type 2019 – detailed overview

Secretariat costs	2019 Actual	2019 Budget	2019 Variance
Salary and Social	**8 038**	**10 507**	**-2469**
CEO	707	729	-23
Senior Management & BoD remuneration	2 042	1 994	48
Advocacy, Communication & Resource mobilsation	1 306	1 169	137
Scientists	2 590	4 084	-1495
Finance, Operations, Admin Support & HR	924	1 837	-913
Legal Contract & Business Development	469	693	-224
Consultants/Consultancy/Secondees	**10 437**	**8 822**	**1 615**
R&D	3 915	2 967	948
Due Diligence	1 494	1 407	57
Rapid Response	0	0	0
Resource Mobilisation	151	597	-446
Strategy/Governance	981	477	504
Portfolio Management	456	420	36
Communication	279	184	95
Legal & Contract Management	2 350	1 850	500
Finance and Operations	626	799	-173
HR	215	120	95
Travel	**2 874**	**3 063**	**-189**
Travel	2 577	2 798	-221
Board meetings	98	70	28
Committees (SAC & JCG)	198	195	3
Infrastructure	**1 095**	**1 049**	**46**
Hardware	**182**	**84**	**98**
Software	**148**	**90**	**59**
IT Operation costs and maintenance fees	**322**	**391**	**-69**
IT consultancy	**27**	**0**	**27**
Telephony	**80**	**164**	**-84**
Office costs	**335**	**320**	**15**
Service providers/Other	**1 314**	**1 477**	**-163**
Accounting fees	202	234	-33
Audit (External and internal)	290	300	-10
Media & Communication	272	284	-12
Recruitment	333	377	-44
Meetings	173	238	-65
Staff social	44	44	0
TOTAL	**23757**	**24919**	**-1162**

APPENDIX 3: HUMAN RESOURCES

As a secretariat, CEPI has focused recruitment, values and culture, diversity and inclusion and people performance management. Achievements in the area of human resource management include:

- A concerted recruitment effort resulting in a number of new hires. Many of the recruitments were handled in-house, external recruitment agencies were also used for selected roles.

- The development of CEPI's Reward and Recognition concept with the goal to attract, retain and develop new and existing employees.

- CEPI's core values were articulated and defined by Secretariat staff during an interactive session at the 2018 all-employee retreat. The 'TRAIT' values (Teamwork-Respect-Achievement-Integrity-Transparency) are highlighted and celebrated by senior leadership and form the basis for CEPI organizational culture. In 2019, the work on culture and values continued.

- Work on Diversity and Inclusion was high up on the agenda in 2019 and was discussed in all employee meetings chaired by the CEO. The topic was also discussed at a Board meeting where the Secretariat provided an update of the composition of the Secretariat, gender pay gaps and the overall efforts in the area of diversity and inclusion.

- While a Performance Management and Salary Review System were developed in 2018, it was only partially implemented. In 2019, the system was further strengthened and implemented. Employees were trained and line managers received specific training based on the key agreed leadership mechanisms for supporting the performance management system:

  - to agree with staff on expectations

  - to provide and receive regular feedback, both formal and informal, on progress and development

  - to support and challenge the development journey of each employee

Composition of Secretariat
CEPI global HR policy and recruitment procedures highlights CEPI's commitment to promoting diversity and foster inclusion. When recruiting, CEPI carefully details skills, experience, qualifications and attributes essential for the role to make sure job profile and advertisements do not discriminate against candidates, either directly or indirectly. Deliberate and continuous efforts have been made and has contributed to develop the Secretariat into an international group of employees represented by 19 different nationalities.

Composition of the CEPI Secretariat:

- 59 permanent and fixed-term employees

- Gender balance: 49% female

- Gender balance in CEPI Leadership Team (LT): 43% female

- The 59 Secretariat employees are from 19 different countries; 17% of the employees are from Low- and Middle-Income Countries (LMICs)

- Of the employees in scientific roles, 28% are from LMICs.

APPENDIX 4:CEPI BOARD SUMMARY

Board effectiveness review: on the advice of the Board, the Secretariat conducted a Board effectiveness review to reflect on 18-24 months of the current governance structure, and provide recommendations on any needed adjustments or course correction. McKinsey was contracted as an independent consultant to conduct this review. Recommendations were presented to the Board in December. The Secretariat has been working on implementing the recommendations.

Equitable Access Committee: an Equitable Access Committee was established in September to provide strategic guidance to the Board and CEO on the implementation of CEPI's Equitable Access Policy. A list of members of the committee can be found here.

Administrative items:

- Nadine Gbossa, Representative Nigeria, International Fund for Agricultural Development, joined as a new voting member in March 2019
- Patricia J. García, former Minister of Health Peru, Dean of the School of Public Health, UPCH, and former Chief of Peruvian NIH, joined CEPI's Board as a voting member in June 2019
- Norway's term as a Sovereign Investor representative on the Board expired. The Investors Council voted for the UK to take over this seat from March 2019.

Members of CEPI Board as of December 2019		
Organisation/Affiliation	Name	Position
Independent Members		
	Jane Halton	(Board Chair)
Africa, Centres for Disease Control and Prevention	John Nkengasong	Director
Translational Health Science & Technology Institute	Cherry Kang	(Board Vice-Chair) Executive Director
London School of Hygiene and Tropical Medicine	Peter Piot	Director
School of Public Health, Cayetano Heredia University, Lima-Peru	Patricia J. Garcia	Professor
Medicines for Malaria Venture	David Reddy	Chief Executive Officer
Nigeria, International Fund for Agricultural Development	Nadine Gbossa	Representative
Vaccine Business Unit, Takeda	Rajeev Venkayya	President
Investor Representatives		
Wellcome Trust	Jeremy Farrar	Director
Division Health Research, Federal Ministry of Education and Research, Germany	Joachim Klein	Deputy Head
National Institute of Infectious Diseases, Japan	Ichiro Kurane	Director-General
UK Department for International Development	Charlotte Watts	Chief Scientific Advisor
Non-voting Members		
Coalition for Epidemic Preparedness Innovations	Richard Hatchett	Chief Executive Officer
Wits Reproductive Health and HIV Institute	Helen Rees	(Chair SAC) Executive Director
American Association for the Advancement of Science	Peggy Hamburg	(Chair JCG) Chair of the Board
World Health Organization	Soumya Swaminathan	(WHO representative) Chief Scientist
Health, Nutrition and Population World Bank	Muhammad Ali Pate	(World Bank representative) Global Director

APPENDIX 5: MEMBERS OF THE SCIENTIFIC ADVISORY COMMITTEE (SAC)

Members of CEPI Scientific Advisory Committee (SAC) as of December 2019	
Organisation/Affiliation	Name
University of Texas Medical Branch	Alan D. Barrett
Institute of Human Virology	Alash'le Abimiku
Global Virus Network	Christian Bréchot
African Center of Excellence for Genomics of Infectious Diseases	Christian Happi
United States Army Medical Research Institute of Infectious Diseases (USAMRID)	Connie Schmaljohn
Consultant	Daniel Brasseur
Ghana Food and Drug Authority	Delese Mimi Darko
Chinese Center for Disease Control and Prevention	Dong Xiaoping
Wits Reproductive Health and HIV Institute (Chair of CEPI SAC)	Helen Rees
US Center for Disease Control and Prevention	Inger Damon
James Robinson Biologics Consulting	James Robinson
London School of Hygiene & Tropical Medicine	John Edmunds
University of Maryland	Kathleeen Neuzil
Department of Global Health Policy, University of Tokyo	Kenji Shibuya
Independent Consultant	Michel De Wilde
University of Maryland	Myron Levine
US National Institutes of Health	Paula Bryant
Bill & Melinda Gates Medical Research Institute	Penny Heaton
London School of Hygiene & Tropical Medicine	Peter Smith
US Food and Drug Administration	Phil Krause
Independent Consultant (also for BMGF)	Ralf Clemens
VaxConsult	Stanley Plotkin
African Academy of Sciences	Tom Kariuki
Advisor of state in extraordinary service, France	Yves Lévy

Members of CEPI Scientific Advisory Committee (SAC) as of December 2019	
Non-voting Members	Name
Takeda	Ali Alloueche
Sanofi	Jean Lang
J&J	Johan van Hoof
Wellcome Trust	Josie Golding
Pfizer	Kathrin Jansen
World Health Organization	Vaseeharan Sathiyamoorthy

APPENDIX 6: MEMBERS OF THE JOINT COORDINATION GROUP (JCG)

Members of CEPI Joint Coordination Group (JCG) as of December 2019	
Organisation/Affiliation	Name
Advisor	Mark Feinberg
Chair	Peggy Hamburg
European Medicines Agency	Marco Cavaleri
US Food and Drug Administration	Marion Gruber
Gavi, The Vaccine Alliance	Aurelia Nguyen
International Federation of Red Cross and Red Crescent Societies	Emanuele Capobianco
Médecins Sans Frontières	Else Torreele
National Institute for Biological Standards and Control	Mark Page
United Nations Children's Fund	Robin Nandy
Wellcome Trust	Charlie Weller
World Health Organization	Ana Maria Restrepo
World Health Organization	Vaseeharan Sathiyamoorthy
World Health Organization/AVAREF	Dicky Akanmori
Working Group (Assays)	Emer Cooke
Working Group (Regulatory)	Daniel Brasseur
Working Group (Regulatory)	Murray Lumpkin

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