



Photo credit: Shutterstock

CEPI Progress Report

Period: Jan-Dec 2018

CEPI ANNUAL PROGRESS REPORT

Reporting Period	January 2018 – December 2018
Date report submitted	31 March 2019

Main contact details:

Name:	Frederik Kristensen, Deputy CEO
Address:	P.O. BOX 123, Torshov, 0412 Oslo, Norway
Email:	Frederik.kristensen@cepi.net
Website:	cepi.net

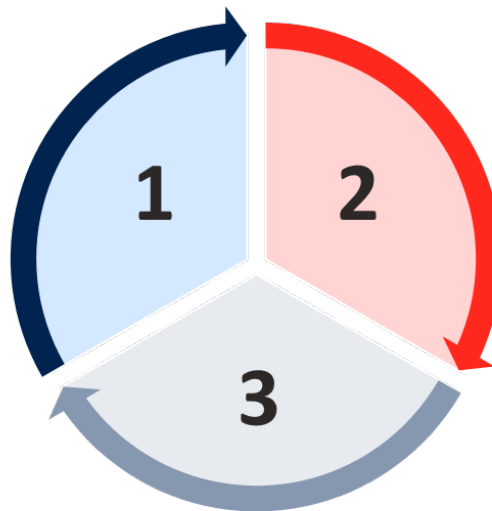
CEPI's Vision

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

Box 1: Key highlights from 2018**1. CEPI's vaccine portfolio established**

We committed to investing up to \$242M to six new partnerships to advance the development of vaccine candidates against our three priority pathogens, Lassa, MERS and Nipah and almost \$20 million to develop vaccine platform technologies to rapidly develop vaccines against Disease X. At the end of 2018 we had 17 candidates in our portfolio, with more expected by 2019 following the recent launch of our third call for proposals (CFP3) to develop vaccines against Chikungunya and Rift Valley Fever viruses.

2. New funding mobilised

After the substantial commitments made to CEPI following our launch in 2017, 2018 has seen increased interest from investors. Canada and Australia have renewed their commitments and UK has come on as a new investor. The European Commission has also committed to co-fund CEPI calls for proposals, enabling us to expand the number of priority pathogens through CFP3. Together, CEPI commitments now total \$750 million. Additionally, co-funding commitments from EDCTP and in-kind support from NIAID/NIH has further enabled us to make a lasting impact.

3. Permanent governance arrangements established

In 2017, the decision was made to develop a revised governance model for CEPI. This structure was established throughout 2018, with a permanent Board in place, a permanent Joint Coordination Group constituted and a strengthened Scientific Advisory Committee. The Secretariat has also been reinforced to fully operate in a diligent manner and enabled to closely follow and support a demanding portfolio across three geographic locations.

Contents

1. Introduction	8
2. CEPI Mission and Strategic Objectives	10
3: Preparedness.....	12
3.1. Invests in promising candidates targeting emerging infectious diseases to drive development of vaccines where markets incentives are insufficient	13
3.1.1 Establishing a portfolio of candidates through CFP1.....	13
3.1.2 Expanding our list of priority diseases through the launch of CFP3	13
3.1.3 Continued work on Ebola	13
3.2. Facilitates the establishment and maintenance of investigational stockpiles and develops robust plans to allow for trials and eventual deployment of vaccines during outbreaks.....	14
3.2.1 Partnering with at-risk countries in planning for trials.....	14
3.2.2 Provisions fit for purpose to support equitable access	14
3.3. Provides expert assistance and funds enabling science and technologies to enhance vaccine development efforts	15
3.3.1 Supporting the advancement of our portfolio	15
3.3.2 Accelerating vaccine development through enabling science	16
4: Response	18
4.1. Invests in platforms to speed the development and manufacture of vaccines	19
4.2. Supports the development of technologies to facilitate field use and rapid response.....	20
4.3. Engages end-to end partners to plan for the testing and deployment of vaccines during outbreaks.....	20
4.3.1 Facilitating alignment and coordination	20
4.3.2 The Joint Coordination Group.....	20
5. Sustainability	24
5.1. Improves the predictability of financing to address end-to end market failures.....	25
5.1.1 Strengthened resource mobilisation efforts	25
5.1.2 Alignment of funding and scope with other organisations	25
5.2 Drives efficiencies to reduce costs across the end to end spectrum of vaccine development.....	26
5.2.1 Expediting our CfP process.....	26
5.2.2 Sustainable manufacturing and clinical trials	27
5.3. Develops contingency plans to reduce risk so that successful products are available to support outbreak response	27
6. Finance.....	29
3.1. 5-Year plan.....	29

3.2 Contribution from Investors	30
3.3 Direct Investments.....	31
3.4 Operating expenses (OPEX)	32
3.5 Procurements.....	33
7. Risk Management	35
A1 Organisational Issues	37
A1.1 Organisational Management:.....	37
A1.2 Human Resources:	38
A1.3 Board	39
A1.4. Scientific Advisory Committee members	42
A1.5. Joint Coordination Group	42
A2 Risk Register	43
A3 Results Framework for the reporting.....	47
A4 Finance.....	52
A4.1 5-Year plan	52
A4.2 Direct Investments.....	53
A4.3 Operating costs (OPEX).....	54

I. Introduction

Dr Richard Hatchett, Chief Executive Officer

I'm pleased to present CEPI's first progress report since we were officially launched in 2017. This 2018 report highlights significant results and progress; and after a year of being in start up mode, CEPI is now fully operational, actively managing the resources entrusted to us to advance vaccines for populations in need.

We have moved quickly over the past year entering into 8 partnership agreements that together encompassed 17 vaccine candidates against some of the world's most deadly emerging infectious diseases in development. At the end of 2018 we had 11 vaccines being developed against our initial 'priority pathogens': Lassa, Nipah and MERS, and two innovative platforms technologies—each being tested against three different pathogens, to enable rapid development of new vaccines against new known or unknown pathogens.

These platforms represent a new approach to developing vaccines against emerging epidemic diseases. We have also recently launched a third call for proposals for vaccines against Chikungunya and Rift Valley Fever viruses, expanding our efforts to tackle diseases that cause human suffering and economic devastation.

The urgency of advancing candidates within our portfolio has never been greater. 2018 saw multiple outbreaks of emerging infectious diseases across the world. Cases of MERS continued to be reported in the Arabian Peninsula; an outbreak of Nipah in Kerala, India, killed 19 people before it was contained; and in Nigeria the largest recorded outbreak of Lassa Fever caused around 3500 infections and took over 170 lives. At the time of writing this introduction, we are also faced with a severe Ebola outbreak in eastern Democratic Republic of Congo, which is now the second largest outbreak in history, and is still not under control. To help address this potential catastrophe, CEPI has been asked to take a leading role in coordinating a clinical trial for a second vaccine candidate.

To support the development of vaccines against our priority pathogens we have also funded the development of biological standards and assays, enabled the implementation of targeted epidemiological studies, and provided catalytic support for the development of needed diagnostics. Importantly, we have extended our collaboration with scientists and government entities in affected countries, both in our portfolio governance and in planning and implementing country activities.

Organisationally, we have further strengthened the Secretariat to ensure we have the needed competencies to deliver on our mission in a complex environment. Our new governance structure has been in place since March, 2018, when our new permanent Board first met in Addis Ababa, Ethiopia.

The 10 members of the new permanent Joint Coordination Group (JCG) met for the first time February 2018 in London to work towards alignment between end-to-end partners with respect to CEPI's evolving portfolio. The reconstituted Scientific Advisory Committee (SAC) has provided guidance on the prioritisation of pathogens and platforms, made technical assessments of proposals, and made recommendations to the Board. Jointly, the members of our governing bodies ensure that there is a global coalition delivering on CEPI's mission and ensuring alignment of priorities between organisations in the end-to-end scope of vaccine R&D for emerging infectious diseases (EIDs).

As a young organisation we are of course on a steep learning curve and will continue to strive to improve all areas of our work. While we can point to a successful year with many achievements, there are lessons to be learned.

- i) Careful review followed by an extensive due diligence have allowed CEPI to grow its portfolio in a prudent manner, though not with the rapidity we will need if called to

respond to future public health emergencies. Using learnings from CfP1 and CfP2 to streamline the process around CfP3 is a first step in achieving the speed and efficiency the world will demand in a crisis.

- ii) Our governance arrangements and secretariat structure are established and seem to be working well, but I anticipate further improvements and fine tuning in the years to come. Coordination between the SAC and JCG and within and between elements of the Secretariat can be further strengthened.
- iii) CEPI must be able to respond rapidly and flexibly. The Secretariat is using the recent experiences with the outbreaks of Lassa and Ebola viruses to develop detailed plans and procedures to put the organisation in a better position to adapt quickly and effectively.

CEPI is a coalition and the Secretariat can only fulfil its mission when working closely with all our partners. Over the next year we will be striving to broaden and deepen our coalition—increasing our work with affected countries and building on the relationships we have with our existing partners and investors.

There is still much to do but this is also a moment to extend my deepfelt gratitude, on behalf of CEPI, to all our partners and investors for their vision, wise counsel and continued support.

Sincerely,

Richard

2. CEPI Mission and Strategic Objectives

Over the course of 2018 and in consultation with the Board, CEPI made some updates to its vision, mission and organisational strategy based on concrete experience from being an established organisation.

The key outcomes of this exercise were:

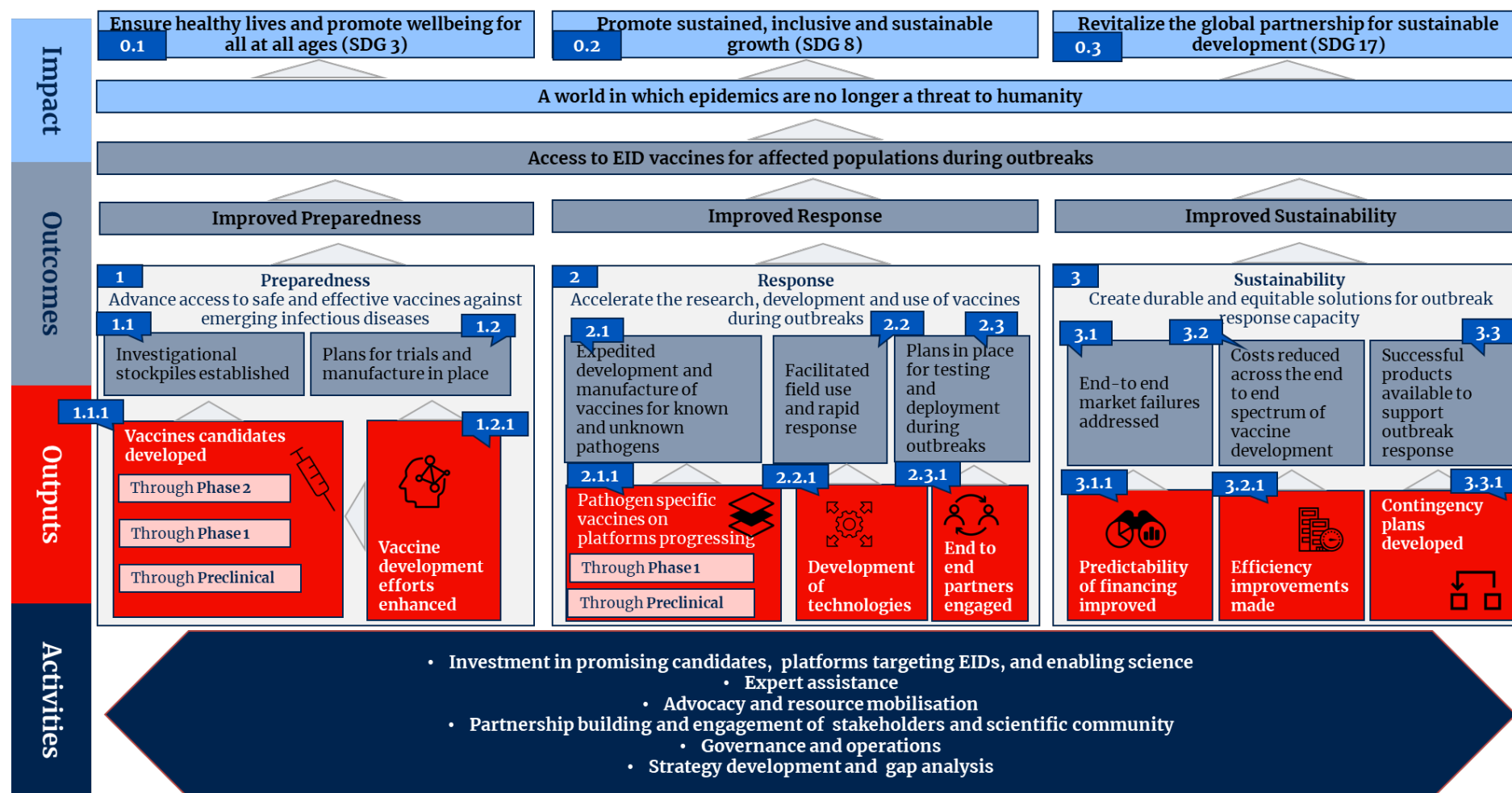
- To elevate equitable access to CEPI's core mission thus ensuring its centrality to all CEPI's activities
- To finetune the three key Strategic Objectives under which CEPI's work will be prioritised and which will ensure CEPI delivers on its mission: Preparedness, Response and Sustainability
- To devise an associated set of indicators to allow CEPI to measure progress and provide investors and our Board with reliable and objective data to assess our performance.

The next section therefore uses this structure to demonstrate activity and progress against these Strategic Objectives. These are summarised in **Figure 1**, which also shows CEPI's Theory of Change and how CEPI's activities will lead to outputs and then in turn higher level outcomes before supporting the achievement of impacts¹. The figure contains numbers which are referenced in all our indicators so that the reader can easily identify what they refer to.

In the following chapter, each Strategic Objective is depicted under three different sub-sections reflecting different areas of work – each one including outputs and/or outcomes as depicted in the figure below. Each of these sections include table(s) at the end showing indicators and progress towards targets. A “Status” box is included for each indicator using a colour coding of green, yellow and red, depicting the Secretariat's overall assessment of whether we're on track to achieving out-year targets. In 2019, we will further develop a monitoring plan to increase accountability.

¹ While CEPI's mission supports the achievement of Sustainable Development Goals 3, 8 and 17, this progress report does not discuss these in particular. For a more systematic overview of CEPI's Theory of Change, please see the CEPI Programme Document.

Figure 1: CEPI's Theory of Change



3: Preparedness

“Advance access to safe and effective vaccines against emerging infectious diseases”

Our ability to advance vaccine candidates against our priority pathogens is the ultimate test of our ability to deliver on our mission. However, vaccine development is a lengthy process. Advancement of vaccines – and especially so for epidemic diseases – is a complex endeavour requiring active involvement by industry, academic and public health experts. To support preparedness against emerging infectious diseases, CEPI

1. Invests in promising candidates targeting emerging infectious diseases to drive development of vaccines where markets incentives are insufficient
2. Facilitates the establishment and maintenance of investigational stockpiles and develops robust plans to allow for trials and eventual deployment of vaccines during outbreaks.
3. Provides expert assistance and funds enabling science and technologies to enhance vaccine development efforts.

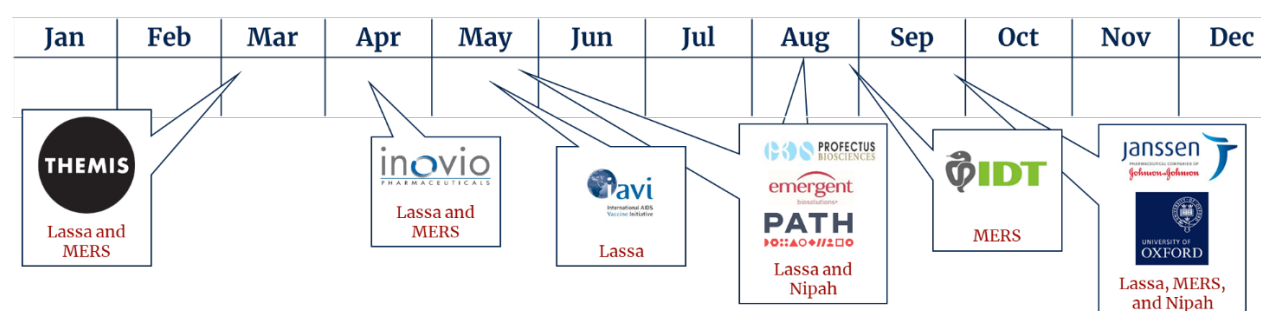
Our progress under Preparedness is summarised under these three areas of work in the following sub-sections.

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

3.1.1. Establishing a portfolio of candidates through CFP1

In 2018 CEPI established a vaccine development portfolio – an important accomplishment in itself. The projects resulting from Call for Proposals 1 (CfP1) covering the initial priority pathogens² Lassa, Nipah and MERS underwent a substantial due diligence process and associated contract negotiations. These steps — which are replicated in other CfPs as well — provides an important opportunity for exchange of views with the applicants and increases the likelihood of success. By end 2018 we had signed partnership agreements covering 11 candidates with contractual values worth up to \$242 million, spread over a five-year period (see figure 2).

Figure 2: CFP1 Partnership Agreement signings



3.1.2 Expanding our list of priority diseases through the launch of CFP3

In addition to completing partnership agreements with CFP1 partners, 2018 was also the year when CEPI made the choice to extend its list of priority pathogens to include Rift Valley Fever (RVF) and Chikungunya virus (CHIKV). This decision was made following an assessment of the Scientific Advisory Committee, based on the feasibility of vaccine development and the potential public health impact of vaccines against these diseases. The European Commission has provided 70% co-funding for what would be our third Calls for Proposals (CFP3).

RVF disease is among the WHO R&D Blueprint list of priority pathogens and CHIKV presents a major public health risk requiring further R&D. Vaccines against both viruses appear to be technically feasible, yet the commercial prospects for vaccines against RVF are non-existent and for CHIKV, uncertain at best. Both diseases pose as severe threats for causing epidemic outbreaks, and their prioritisation is thus a step towards further prioritising CEPI's role in preparedness.

3.1.3 Continued work on Ebola

The Secretariat has assessed the remaining gaps to finish the job on Ebola vaccines and been in close contact with companies with existing Ebola vaccines under development, to improve understanding of areas that would warrant CEPI support. Informed by these conversations and analyses, the Secretariat developed a set of funding principles for potential work on Ebola. Following a discussion by the CEPI board in October, 2018, on accelerating the licencing of leading candidates, the Executive and Investment Committee decided that CEPI would enter into negotiations with 3 partners for extensions of clinical trials.

² The Scientific Advisory Committee engages in all major decisions related to vaccine development and enabling science ([see this link](#) for summaries of meetings).

TOC # 1.1.1, indicator # 8	Disease	Phase	Baseline	Target 2018	Actual 2018	Target				Status
						19'	20'	21'	22'	
Number of vaccine candidates – for each priority disease – advanced through preclinical, P1 and P2	Lassa	PreC	0	1	1	3	4	4		Action may be required
		P1	0	0	0	2	3	3		
		P2	0	0	0	0	0	2	3	
	Nipah	PreC	1	1	1	3	4	4		Action may be required
		P1	0	0	0	0	3	3		
		P2	0	0	0	0	0	1	3	
	MERS	PreC	1	1	1	2	3	4		Action may be required
		P1	0	0	0	1	2	3		
		P2	0	0	0	0	1	1	3	
Comment										
Inovio successfully passed its stage gate in January, 2019, for a Lassa fever vaccine. For Nipah, Profectus had existing data prior to CEPI funding that was reimbursed. For MERS, Oxford already had a candidate through preclinical and CEPI is now funding an additional cell line. All diseases are assigned an orange status as CEPI's attrition model is currently under review.										

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

3.2.1 Partnering with at-risk countries in planning for trials

An investigational vaccine can only help curb an outbreak if the vaccine can be accessed—either through clinical trials or emergency use provisions. That is why it's important to plan ahead so vaccine doses are available when needed to those that need it. To prepare, CEPI has begun work to gain a better indication of the size of stockpiles needed to support an adequate level of preparedness. For example, CEPI held a workshop in Ghana November, 2018, to discuss how targeted epidemiological studies in West African countries could help prepare for Lassa vaccines trials. This workshop was also an opportunity to engage affected countries from the first stages of development, which will help mitigate challenges when and if a vaccine goes to trial and thus also the potential to drive efficiencies downstream (see 5. Sustainability).

CEPI has been working closely with the European & Developing Countries Clinical Trials Partnership (EDCTP) to develop a jointly funded EDCTP call where a €10 million CEPI investment is matched by a €30 million EDCTP investment. The purpose of the call is to support preparing and conducting phase IIb and III clinical trials with the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of novel candidate vaccines against Lassa. Another important outcome of this investment is enhanced capabilities in affected countries to plan and conduct clinical trials.

To further support our response capabilities, all agreements include provisions that allow us to establish multiple stockpiles of experimental vaccines for use in an outbreak, which may be replenished as necessary through additional work packages agreed to with our partners. These will be available free of charge to public-sector agencies.

3.2.2 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. CEPI's original equitable access policy included a requirement that it be reviewed after one year. This would allow us to gain experience with the policy and to consult with multiple partners on how it should best be expressed and applied. As a result of our experience and these consultations, CEPI's Equitable Access Policy evolved in 2018 from a "rules-based approach" that was highly proscriptive as to how it should be implemented to a "principles-based approach" that provides a robust foundation for advancing equitable access and enables a broad range of approaches to do so.

The CEPI Board is fully informed as to the approaches being taken in our partnering agreements to advance equitable access. Moreover, CEPI has committed to provide summaries to the general public as to how CEPI enables equitable access by means of its partnership agreements.

TOC # 1.1, indicator # 5	Baseline	Target 2018	Target				Status
			19'	20'	21'	2022	
Number of vaccine candidates in investigational stockpile for outbreak situations and ready for efficacy studies and emergency use	0	0					Action may be required
	Actual ➡	0	0	0	0	4 candidates for at least 2 pathogens	
Comment							
Due to the same reasons listed under indicator 1.1.1, 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.							

TOC # 1.2, indicator # 6	Baseline	Target 2018	Target			Status	
			2019	2020	2021		
Percent of vaccine Partnership Agreements that have manufacturing plans in place to enable vaccine production in response to an outbreak.	N/A	100%*				On track	
	Actual ➡	N/A	100% *	100% *	100% *		
Comment							
All development partners have committed to have manufacturing plans in place when they reach phase II clinical trials or beyond. Since none of CEPI’s candidates have reached phase II, there is nothing to report at this time. However, the Secretariat will continuously review manufacturing plans and recommend changes to these based on assessments in stage gate reviews. The initiated JCG Working Group on sustainable manufacturing (see chapter 3) may also inform CEPI’s further approach to the issue. <i>*Subject to completion of phase 1 and transitioning to p2.</i>							

TOC # 1.2, indicator # 7	Baseline	Target 2018	Target			Status
			2019	2020	2021	
Percent of vaccine development partners agreeing to terms that are fully consistent with CEPIs Equitable Access Policy	N/A	100%	100%	100%	100%	On track
	Actual ➡	N/A				
Comment						
CEPI has committed to provide summaries to the Board and the general public as to how CEPI enables equitable access by means of its partnership agreements. These summaries will available by end of Q1 2019.						

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

3.3.1 Supporting the advancement of our portfolio

One of CEPI's core advantages as a funder is its significant engagement in the projects it funds. By taking an active role in the projects of our partners, CEPI adds value to its investments. In the first year of operations, our technical team focused on establishing a portfolio through CfPs, and over time, efforts will shift to hands on technical support for projects that are in place.

One of the most important achievements in 2018 was establishing the capabilities and mechanisms to support a large number of projects with different challenges including the Stage Gate Review Committee (SGRC), the Joint Monitoring and Advisory Group (JMAG) and the Vaccine Development Committee (VDC). The purpose of the JMAG is to carry out day to day project management and the VDC reviews alterations to agreed project plan. Both these two groups are internal to CEPI. In contrast, the STRC is composed of CEPI staff and external experts, including SAC and JCG members. The STRC makes recommendations on “go”/”no-go” decisions for progression into the next work-package. Together these three groups thus form integral parts of CEPI’s technical project management and support functions and enables early engagement with regulatory agencies. In addition, the Secretariat has worked with leading experts from affected countries to increase their representation in the STRC, including the Nigerian Centre for Disease Control.

3.3.2 Accelerating vaccine development through enabling science

Outside of project-specific support, 2018 has been the first year where we’ve actively pursued and implemented cross-cutting enabling activities to the benefit of our portfolio at large. An example of this is our work on Biological Standards and Assays³. Different laboratories tend to use different measurement assays/platforms for their vaccine evaluation and these may as such give different quantitative outcomes to the same immune response. Providing common Biostandards to the different developers for evaluation of vaccine responses (in particular during Phase II clinical trials) will facilitate and speed up development as well as enable CEPI to choose the best vaccine formulation and even make the regulatory process less challenging. As part of this work, CEPI has initiated several projects at the end of 2018 including partnering with the National Institute of Biological Standards and Control (NIBSC), Tulane University and International Vaccine Institute (IVI).

CEPI also intensified its support of diagnostics through a partnership with FIND. In response to the Lassa outbreak in early 2018 we provided \$1 m in funding, leveraging an additional \$4.2 million from the German government. Further, CEPI conducted a scoping exercise on diagnostics for all 5 priority pathogens to identify bottlenecks and plan for clinical trials. Planning epidemiological studies has also surfaced as a key priority for CEPI. Together with work in clinical-trial-site preparation and identification, getting a better understanding of the epidemiology of target populations will expedite clinical trials both during and outside of emergencies. By end of Q2 2019, we plan to have funded such studies.

Lastly, as part of its commitment to accelerating enabling science, CEPI continues to drive scientific advancements through dedicated working groups (see SO 3 section 3.3.).

³ Biological assays can be used for measuring the immune responses to vaccine candidates and is as such crucial for evaluating their protective potential.

TOC # 1.1, indicator # 5	Baseline	Target 2018	Target				Status
			19'	20'	2021	2022	
Number of available Biological Standards and validated assays (including Standard Operating Procedures) for evaluation of vaccine candidates against CEPI's priority pathogens	0	0	0	0	1 Biological Standard developed for each of priority pathogens	at least one validated assay available each of priority pathogens	On track
	Actual 	0					
Comment							
Three agreements have been signed, and another (BNITM) is expected to be in place by early 2019. If the current advancement continues, we expect to exceed our target for 2022.							

TOC # 1.2.1, indicator # 10	Baseline	Target 2018	Target	Status
			2019–22	
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%*	On track
	Actual ➡	N/A		
Comment				
While no projects as of yet required 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.				

4: Response

“Accelerate the research, development and use of vaccines during outbreaks”

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. Importantly, history has shown us that the R&D and delivery response will not be effective unless it has been tested and planned for in preparedness mode. To support response, 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

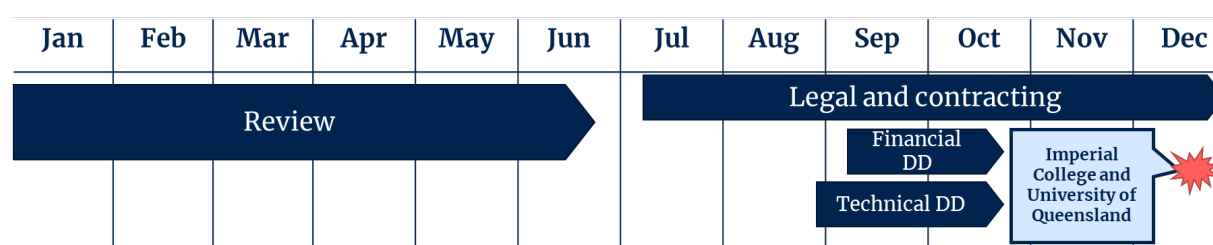
Our progress under Response is summarised under these three areas of work in the following sub-sections.

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

“Vaccine platform technologies” broadly 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 greatly speeds the development process.

CEPI’s second call for proposals (CFP2) supported the advancement of such platforms. Launched at the end of 2017, a review process then followed before a financial and technical due diligence was conducted. While 6 projects were selected to enter into financial and technical due diligence, it was decided not to enter into agreements with three of these—two due to technical issues that made them unsuitable for CEPI’s portfolio and third that was withdrawn by the applicant. Of the three that were taken forward, the first two partnering agreements were signed in December, 2018: one with Imperial College to develop a self-amplifying RNA platform (worth up to \$8.4 million) and another with the University of Queensland to develop a molecular clamp vaccine platform (worth up to \$10.6 m). All platform technologies will be tested against 3 pathogens, where at least one is on the WHO Blueprint list.

Figure 3: Establishing a CFP2 portfolio



While total current estimated contract values of the remaining projects total around \$50 million⁴, CEPI has made a long-term budgetary allocation of \$120 million, implying that the pipeline will be enlarged through a rolling call⁵.

TOC # 2.1, indicator # 11	Baseline	Target 2018	Target				Status
			19'	20'	21'	2022	
Number of vaccine platform technologies that can be rapidly adapted to develop vaccines against unknown pathogens for use in humans	0	0	0	0	0	2 or greater, including at least one novel (innovative) platform (i.e., that has no prototyped licensed vaccine)	Additional action required
	Actual ➡	0					
Comment							
This indicator is not expected to show any progress until 2022 when CFP2 vaccines move through phase I studies. However, because only 3 of the projects have been contracted to date, the Board has decided to initiate a rolling call for CFP2 to replenish the portfolio. This indicator may thus be revised or amended following implementation of the rolling call.							

⁴ Accounting for the third partnership agreement with Curevac (worth up to \$34 m), which was close to final end of 2018

⁵ As per March 2019 Board meeting, this is expected to be launched autumn 2019.

TOC # 2.1.1, indicator # 14	Baseline	Target 2018	Target				Status
			19'	20'	21'	2022	
Number CfP2 vaccine candidates progressing through preclinical and P1	0	0		8 products through preclinical	0	6 products through Phase I	Additional action required
	Actual ➡	0	0				
Comment							
Since only three of the original six projects made it through contract negotiations, the target is unrealistic within the current portfolio. The CEPI Board has approved the launch of a rolling call to replenish the portfolio, so mitigating actions are already ongoing forward. Per above, this indicator will be reviewed in 2019.							

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

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 have the ability to adapt when new solutions present themselves. While bilateral discussions with organisations like Gavi on innovative vaccine delivery solutions bear promise, more analysis must be conducted before commitments for support will be made. A few such technologies like patch technologies for vaccine delivery have been discussed by the Board, but are currently classified as outside of CEPI's core priorities. CEPI is also planning to set up a "tech watch" facility in 2019 tasked with scanning for new technologies to help assess where CEPI funding could be catalytic. This facility will also support the identification of viable candidates for a rolling call for platform technologies that will be launched later in 2019.

TOC # 2.2.1, indicator # 15	Baseline	Target 2018	Actual 2018	Target 2019–2022	Status
Annual analysis of available technologies and the gaps that currently exist	N/A	N/A	N/A	Annual update	On track
Comment					
This indicator was not due to be reported on in 2018. 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 will inform a thorough analysis in 2019 and beyond.					

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

4.3.1 Facilitating alignment and coordination

Having been launched as a coalition of partners in January 2017 on the basis of broad-based consultations with stakeholders ranging from civil society, multilateral organisations and vaccine developers, 2018 has been a year of establishing a sound and well-functioning organisation with a robust portfolio of vaccine candidates. In doing this, CEPI paid particular attention to establishing governance arrangements, policies, procedures and partnership agreements that reflected our commitment to working with the broadest set of actors. With this framework now in place, CEPI will continue to further manifest its position as a convener of organisations working within vaccine R&D.

4.3.2 The Joint Coordination Group

CEPI works with a broad set of partners. The Joint Coordination Group (JCG), an institutional roundtable made up of organisations who all have a vested interest in seeing CEPI's vaccines succeed, is the most important platform for coordination. The JCG met 3 times in over the past year for meetings that involved horizon scanning across CEPI's vaccine portfolio for potential challenges and problems the group can solve together.

Summaries of the meetings can be found [here](#). Highlights from some of the critical issues discussed include:

1. Community engagement is an integral part of vaccine delivery and for conducting clinical trials. Early engagement with local actors is therefore a prerequisite for doing vaccine R&D in fragile settings.
2. Developers must engage with local regulators and CEPI should work to enhance information sharing amongst national regulatory agencies.
3. Vaccination with unlicensed products is associated with considerable requirements for consent. CEPI should look at ways to improve procedures for getting consent in the field, and us of the expanded access provisions and the WHO Emergency Use Assessment and Listing procedure as potential solutions.

One of the main learnings from 2018 was how outside entities could help the JCG find practical solutions to identified problems by inviting outside entities to engage. In the September meeting, representatives from PREVENT⁶ presented on their work on inclusion of pregnant women in clinical trials, and meetings in early 2019 will focus on involving industry and affected countries⁷.

In addition to its own work, the JCG has the ability to recommend the establishment of dedicated working groups tasked to solve specific challenges that require added attention. Currently there are three such working groups, reporting to the JCG.

⁶ “Pregnancy Research Ethics for Vaccines, Epidemics and New Technologies”, a multi-year project funded by Wellcome Trust

⁷ In early 2019, the JCG met in Abuja Nigeria where developers and representatives from affected countries met.

Table 1: CEPI working groups

Name	Comment	Status
Regulatory	Having made important progress in 2017, the group was reconstituted in 2018. 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.	Reconstituted
Sustainable manufacturing	This group has been tasked with developing a proposal for a Sustainable Manufacturing solution for the EID's prioritised, considering issues like manufacturing/quality, people and infrastructure. The proposal will be presented to the Board September 2019.	Established
Biological standards	To stimulate consensus on essential assays, strive for harmonisation and increase the transparency in the field, CEPI has established an overarching Working Group on Biological Standards (co-Chaired with WHO), and disease specific Task Forces with regulatory experts, disease specialist and vaccine developers. These have in turn advised the Secretariat on defining the text for RfPs on Biological Standards.	3 established

Box 1: Other collaboration with end-to-end partners

While the WHO is a member of the JCG, the Scientific Advisory Committee and several working groups, it is also one of CEPI's most important partners bilaterally. In its function as the global normative and coordinating body for health, it plays a key role in guiding CEPI priorities. By providing technical expertise, the WHO has also supported the launch and advancement of CEPI's portfolio including on specifying target product profiles and fostering regulatory alignment.

A World Bank and CEPI vaccine development task force concluded its work in May 2018. The task force consisted of senior members from a wide range of institutions and geographies, and focused on how low-income countries could strengthen clinical research capacity, especially surge capacity to conduct clinical trials during an outbreak. A report can be [accessed here](#)—setting forth the task force's 15 recommendations.

TOC # 2.3, indicator # 12	Baseline	Target 2018	Actual 2018	Target 2019-22	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%	100%	On track
Comment					
All vaccine development partners had necessary agreements in place, thereby gives an indication of CEPI's ability and commitment to respond quickly.					

TOC # 2.3, indicator # 13	Baseline	Target 2018–22	Actual 2018	Status
Percent of vaccine development partners with plans in place for equitable access fully consistent with CEPI’s Equitable Access Policy.	N/A	100%	N/A	<i>On track</i>
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.				

5. 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. This means that CEPI will organise and prioritise such that the investments we make 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 of work in the following sub-sections.

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

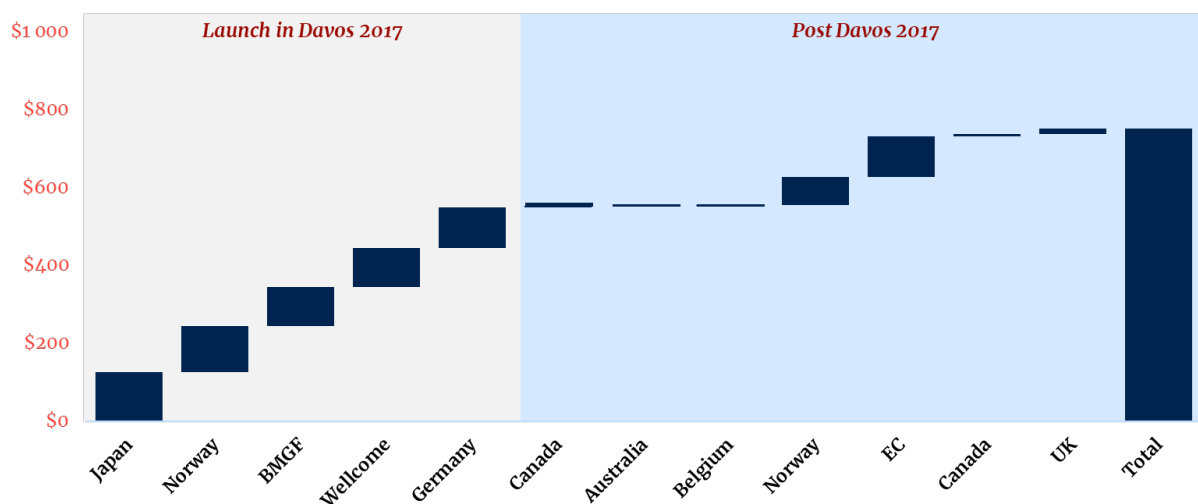
5.1.1 Strengthened resource mobilisation efforts

Although the establishment of CEPI represents an improvement in the predictability of financing for EIDs in itself, demonstrating progress and successes is key to mobilise continued financial support for our mission.

Building on the \$540 million of multi-year financial commitments announced in Davos by Norway, Germany, Japan, Wellcome, and the Bill & Melinda Gates Foundation, and subsequent announcements by Canada, Australia and Belgium, CEPI has continued to raise resources. A Resource Mobilisation task force was established among investors, dedicated to engagement of and collaboration between existing Investors in an effort to attract new ones.

In 2018, the EC awarded CEPI €30 million in funding through the Horizon 2020 program for RVF and CHIKV with potential for additional funding for this program in 2020⁸. Moreover, Canada expanded their single year investment to a two-year commitment of CAD\$10 million through 2020. The United Kingdom also joined the Coalition, becoming CEPI's newest Investor with a £10m single year commitment for 2018/19. Together, these investments have brought commitments up to \$750m⁹, making us \$250 million short of our \$1bn goal for 2019.

Figure 4: Contributions to CEPI by Investors before and after launch in January 2017



5.1.2 Alignment of funding and scope with other organisations

In terms of alignment with other organisations, an initial mapping exercise undertaken by CEPI's working group on Stockpiling (sunset in December 2017) has been taken forward by the JCG. Through the JCG, partners such as Gavi, UNICEF, IFRC, and MSF are mapping outbreak-related roles and responsibilities. These discussions aim to bring greater clarity along the end to end chain including on how the industry can be appropriately incentivised to support access for populations in need. CEPI is continuously working bilaterally with partners in the end-to-end scope to this purpose, and was closely engaged with the update of Gavi's Vaccine Investment Strategy in an effort to align priorities.

⁸ Final decision pending and expected to be made in 2019

⁹ Rounded number and subject to currency fluctuations. Includes additional anticipated funding of €60 from the EC, bringing total EC contribution up to €90.

Box 2: Other collaboration with end-to-end partners

In December 2018, the [Gavi Board approved](#) use of its International Finance Facility for Immunisation (IFFIm) as a mechanism for Norway to support CEPI. By issuing bonds backed by Norwegian pledges to CEPI in 2022–2025, CEPI will now be able to access these funds earlier, enabling urgently needed vaccine development. Use of the IFFIm substantially improves financial predictability for CEPI and is an excellent example of global health organisations leveraging existing capabilities to a common purpose.

TOC # 3.1, indicator # 16	Baseline	Target 2018	Target				Status
			19'	20'	21'	2022	
Agreements with downstream financing partners in place for each of CEPI's priority diseases.	0	0					Action required
	Actual ➡	0	0	0	0	3 agreements in place	
Comment							
One of CEPI's priorities for 2019 is strengthening its broader Coalition engagement. A positive development is Gavi's close involvement of CEPI in their process to update their Vaccine Investment Strategy in an effort to align priorities. This may serve as a test case for how CEPI may proactively engage with other organisations as to similar ends.							

TOC # 3.1.1, indicator # 17	Baseline	Target 2018	Target				Status	
			19'	20'	21'	2022		
\$1bn raised as multi-year contributions to CEPI	\$630m	0	\$1bn	0	0	0	Substantial action required	
	Actual	0						
								
Comment								
Current funds raised total around \$750m, with the exact number depending on exchange rates. While CEPI has gained momentum through renewed commitments from Australia and Canada, as well as positive signals of funding from new Investors, considerable action is required to meet the funding target.								

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

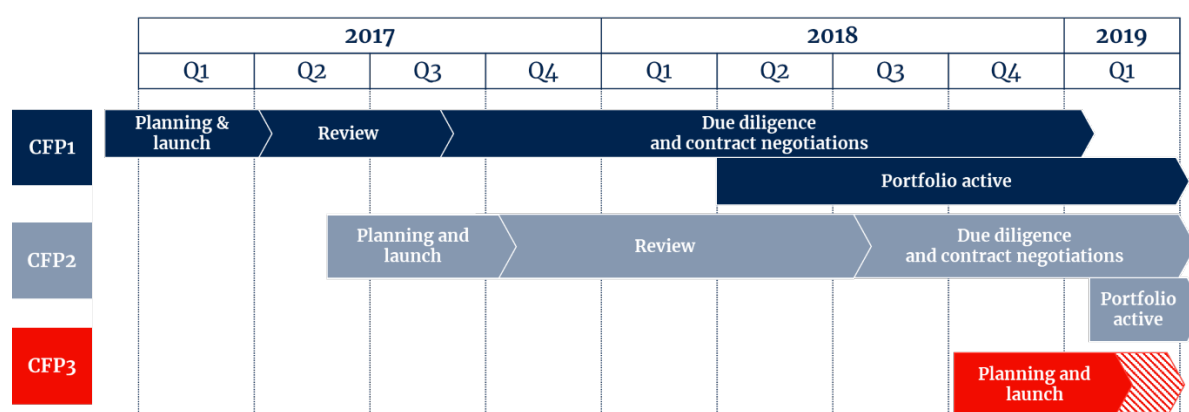
CEPI was established as a financing mechanism for vaccine development for EIDs, and tasked to try and do things differently; looking for opportunities and solutions that could make a lasting impact. This relates both to our organisational approach and our portfolio approach, making sure that the vaccines we help develop are effective and fit for purpose.

There are two areas that CEPI has worked on specifically in this regard in 2018; sustainable manufacturing and expediting our CfP process.

5.2.1 Expediting our CfP process

CEPI has undergone two full calls for proposals and initiated a third call. While the CFP1 process took more than two years in total, the CFP2 process proceeded more rapidly—in around 18 months. Specific efficiencies were made in the due diligence processes: the technical, financial, and legal due diligence processes were done in parallel. As for the recently initiated CFP3, it was launched just 3 months after a high-level proposal was made to the CEPI Board in October, 2018. And because of streamlined procedures, contracts are expected to be signed by early Q3, 2019.

Figure 5: Timeline for conducting Calls for Proposals



As a result of our in-depth project due diligence prior to signing of agreements, we have been able to achieve considerable costs savings. While the decision on which projects to fund are primarily based on the technical feasibility of developing the vaccines, all projects must adhere to CEPI's eligible cost guidance. Through the due diligence process we have been able to reduce costs by up to more than 40%, equivalent to more than \$300 million by challenging originally budgets figures¹⁰. While aggregate budgets were decreased after cost challenges, there were individual projects that saw increases—primarily due to increases in scope of activities suggested by the Secretariat to increase likelihood of success. In addition to cost savings, the due diligence process has also allowed CEPI to suggest alterations to product development plans so that the final product is more likely to match the needs on the ground—as specified in target product profiles.

5.2.2 Sustainable manufacturing and clinical trials

Since epidemics are by definition unpredictable, ensuring adequate manufacturing capacity that can be scaled up in the event of a crisis has been a costly endeavour. That is why CEPI is trying to look at innovative ways of bringing down costs across developers. As part of this workstream, in 2018 the Board endorsed a plan whereby in 2019 the Secretariat would develop a strategy for ensuring sustainable manufacturing based on an “end-to-end” supply chain model, engagement of end users, explore standardising for CEPI vaccine development project process development and explore possible new business models and funding/financing solutions.

TOC # 3.2.1, indicator # 18	Baseline	Target 2018	Actual 2018	Target 2019–2022	Status
Percent of priority actions taken to achieve efficiencies	0	0	N/A	50%	Action required
Comment					
This indicator cannot be reported on in 2018, since there were no priority actions identified prior to reporting. Priority actions for next reporting period will be identified by end of Q2 2019,					

5.3. 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

¹⁰ Figures based on potential total contract value. Actual contract value will be reduced following attrition.

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 2018	Actual 2018	Target 2019-2022	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.					

6. Finance

2018 was an important year for CEPI organisationally—including for Finance & Operation. The team has been substantially strengthened, and is now fully equipped to deliver on creating a diligent internal control environment and procuring goods and services in a way that ensures value for money. Many initiatives were launched and results from an audit in the fall of 2018 from Wellcome, UK Department of Health and EY, suggest CEPI is on the right track.

3.1. 5-Year plan

The following section gives a financial overview of all CEPI activities. The point of departure is the 5-year forecast (six when including 2017), depicting CEPI's projected cash flow over time. It consists of contributions (revenue) from Investors, Direct Investments going into funded projects, operational expenses (split between three sub-categories) and financial costs¹¹. Together these provide the cash balance per year and accumulated over time. Further detail can be found in subsections that follow and annex A4 Finance.

5 year plan	2017	2018	2019	2020	2021	2022	Total
	Actual	Actual	Budget	Plan	Plan	Plan	
<i>Figures in MUS\$</i>							
Contributions	82	113	237	185	130	0	747
Direct Investments	0	35	157	174	192	163	720
Indirect Investments (OPEX)	6	9	14	15	15	16	75
Resource Mobilisation (OPEX)	1	1	2	1	2	2	8
Administration (OPEX)	2	8	10	10	10	10	50
Financial costs	0	-4	5	-1	-1	-1	-1
Cash balance	73	64	50	-15	-87	-189	-104
Accumulated Cash balance	73	137	187	172	85	-104	

Operating expenses (OPEX) can be viewed either by activity, or by type. By *activity* refers to whether the expense is channelled towards Administration¹², Indirect investments or Resource Mobilisation¹³. This provides insight into where operating expenses are directed towards managing the organisation, raising funds, and adding value to the portfolio of investments through technical support. By type refers to the kind of expense that is budgeted/incurred depending on the nature of the expense irrespective of activity (see Figure 6). Both ways of viewing the operating expenses provide the same total.

¹¹ See annex for an explanation of financial costs

¹² Includes IT, Office facilities, Finance, HR and Senior Management costs.

¹³ Consist of work on investor relations, and the negotiations of agreements with the various investors.

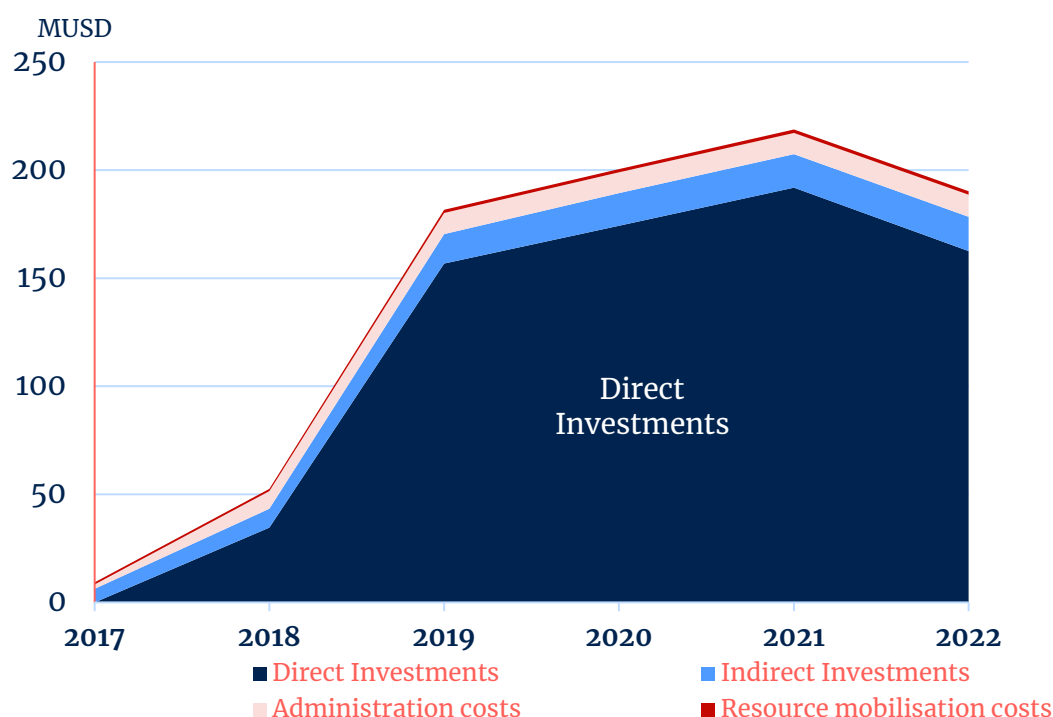
Figure 6: Operating expenses by activity vs type

Activity	=	Type
Indirect investments		Salary & Social
Administration		Consultancy
Resource mobilisation		Travel
		Infrastructure
		Service providers/Other

Investment costs are split between *indirect* and *direct*. Indirect refers to the above-mentioned operating expenses associated with supporting the portfolio. Direct refers to payments made to awardees through the calls for proposals (CfP1, CfP2, CfP3) and investments made in enabling science projects.

Figure 7 below gives a figurative depiction of the expenses in the 5-year plan, where operational expenses are depicted by activity. It shows that investment costs is by far the largest expense category—and even more so when including the indirect investment costs that add value to direct investments. The figure also shows that operational expenses declines as a share of total expenses over time, as indirect investment costs increase while operational expenses remain stable.

Figure 7: Operational expenses and investment costs over time



3.2 Contribution from Investors

As per 31.12.2018 the investors had committed contributions of \$747,4 million to CEPI. Table 2 shows how much different investors have committed over time. See “5. Sustainability” for more detail on resource mobilisation.

Table 2: Overview of financial commitments to CEPI

Contributions	2017	2018	2019	2020	2021	2022	TOTAL
MUSD*	Actual	Actual	Plan	Plan	Plan	Plan	
Norway (MNOK 1600)	11,9	17,1	93,8	30,0	45,0	-	197,8
Wellcome (MUSD 100,4)	1,7	20,0	38,7	20,0	20,0	-	100,4
BMGF (MUSD 100)	22,0	20,0	20,0	20,0	18,0	-	100,0
Germany (MEUR 90)	18,7	16,3	22,4	22,4	22,4	-	102,2
Japan (MUSD 125)	25,0	25,0	25,0	25,0	25,0	-	125,0
Australia (MAUD 2)	-	1,4	-	-	-	-	1,4
Belgium (MEUR 0,5)	-	0,6	0,0	0,0	0,0	-	0,6
Canada (MCAD 14)**	2,8	0,3	6,7	0,7	-	-	10,6
UK (GBP 10)	-	12,6	-	-	-	-	12,6
EC CfP3i/ii (MEUR 90)	-	-	33,5	67,0	0,0	-	100,5
TOTAL	82,2	113,3	240,1	185,1	130,4	-	751,1

* Subject to currency fluctuations. ** Annual statements did not factor in the last CAD 5 million due to timing issues, making the total \$747,4 m

CEPI has also received a number of in-kind contributions. This includes pro-bono services provided by Norwegian Institute of Public Health (NIPH) for office space at an estimated value of \$0,45 million. In addition to its cash contribution, Wellcome has also provided office space, meeting rooms and other services. Also the Research Council of Norway (RCN) has provided technical solutions and administrative services to assist CEPI in hosting the calls for proposals, and a web-based platform to facilitate the application process for CEPI funding. The value of these services has not been possible to quantify.

3.3 Direct Investments

Table 3 shows CEPI's direct investment cost categories, comparing the 2018 actuals with the budget. The overall variance reflects that the establishment of a portfolio took longer time than anticipated. A detailed breakdown of direct investment costs can be found in annex A4 Finance.

Table 3: CEPI's Direct investments

Figures in MUSD	Actual 2018	Budget 2018	Variance	Budget 2019
Priority diseases	34,2	98,9	65 %	83,8
Platform Technologies	-	32,8	100 %	37,3
Enabling Science	0,5	10,0	95 %	21,9
Finishing Ebola	-	6,5	100 %	10,1
EDCTP	-	-	-	3,7
	34,7	148,2	-77 %	156,8

Priority diseases

Investments in priority diseases includes projects covered under CFP1 and CFP3. Due to delays in completing contract negotiations and subsequent postponement of project start dates for CFP1, actual investments were far below what was budgeted. This variance can thus be understood as a change in timelines rather than scope of the call and remaining funds are now rolled over to 2019.

Platform technologies

As with CFP1, there were delays in CFP2 because of due diligence processes and requirements.

Enabling Science

Because Enabling science projects primarily relate to activities that supports advancement of CEPI's portfolio (i.e. assays, epidemiology, animal models), their initiation requires an active portfolio. The delays with completing CFP1 and CFP2 contracts have therefore created ripple effects for enabling science projects, shifting these into 2019.

Finishing Ebola

CEPI did not invest directly in any Ebola clinical projects during 2018. This will be a priority in 2019. See "3.1. Invests in promising candidates targeting emerging infectious diseases to drive development of vaccines where markets incentives are insufficient" for more detail.

EDCTP

In addition to its co-funding commitment, the European Commission has also committed to support CEPI through the European and Developing Countries Clinical Trials Partnership (EDCTP) through matching funds whereby CEPI Investments of €10m are coupled with €30m from EDCTP. Although no date has been set, CEPI has budgeted in anticipation for a call to be completed in 2019.

3.4 Operating expenses (OPEX)

CEPI's operational expenses reflect that 2018 has been a build-up period to manage an investment portfolio of up to USD 1 billion. The total operating expenditures in 2018 amounted to \$17.883 million—higher than the original approved budget of \$15.315 million. The variance was primarily driven by unanticipated support required to initiate CEPI's portfolio of projects, as well as lack of comparison years for benchmarking budgeting.

Salary and social costs were lower than budgeted in 2018 due to a lower pace in hiring than planned. Conversely, this led to an increased need for consultants—a need which was further amplified by a more extensive due diligence processes, awardee contracts negotiations and organisational support following awards. The delay in hiring did not result in travel cost savings, as consultancy travel is included in the travel category. Setting up full time operations was also more costly than planned in particular with regard to hardware and office costs, reflected in the higher than budgeted infrastructure expenses. Service providers/other also shows an overspend compared to the amount budgeted, mainly due to high insurance costs and the rebranding of CEPI. Below is the breakdown of CEPI's operating expenses by type.

Table 4: Operational expenses by type, actual and budget 2018

OPEX	Actual 2018	Budget 2018	Variance
<i>Figures in KUSD</i>			
Salary & Social	6 272	7 432	1 159
Consultancy	7 521	4 443	-3 078
Travel	2 105	2 134	29
Infrastructure	1 107	756	-351
Service providers/Other	878	550	-328
Total	17 883	15 315	-2 569

The operating expenses above are depicted by type, but presenting by activity would show that Indirect Investments (technical support to projects) represented 84% of the total variance in operating expenses compared to budget. The remaining 16% variance was associated with higher cost for Administration and Resource mobilisation.

The below table compares the 2018 actuals with the 2019 budget and reflects a projected increase in operational costs of 28% in 2019. This is primarily driven by an increase in staffing, growing from an average FTE of 33 in 2018 to 60 in 2019 (Table 6). The main increase in FTE will be in the Scientists category, working on Investment project support. As the size and complexity of CEPI's portfolio has increased, the skills and expertise required to manage it has risen. This will increase the expected consultant costs, as shown in Table 5. Together with continued hiring, the increase in use of consultants will also increase travel costs. Infrastructure costs will be at the same level as in 2018. The Service providers/other category will increase because of the requirement to set up an internal audit committee and a need to increase Media & Communication spend. See annex A4 Finance for additional in-depth details on operating costs.

Table 5: Operational expenses by type, actual 2018 and budget 2019

OPEX	Actual 2018	Budget 2019	Increase
<i>Figures in KUSD</i>			
Salary & Social	6 272	10 507	4 235
Consultancy	7 521	8 822	1 301
Travel	2 105	3 063	958
Infrastructure	1 107	1 049	-58
Service providers/Other	878	1 477	600
Total	17 883	24 919	7 035

Table 6: CEPI staffing 2018 and 2019

FTE Average	Actual 2018	Budget 2018	Budget 2019
	33	42	60
Senior Management, incl CEO	7	7	8
Advocacy, Communication & Resource mobilisation	5	6	9
Scientists	10	16	24
Finance, Operations, Admin Support & HR	9	11	15
Legal, Contract & Business Development	2	2	5

3.5 Procurements

Procurement Governance

CEPI places great emphasis on creating value for money in all areas of its business, including when procuring goods and services. In line with establishing the Secretariat and hiring of staff, CEPI has increasingly formalised its principles and procedures for buying goods and services¹⁴; in November 2017 the CEPI Board approved the [CEPI Procurement Policy](#) and the associated procedure was adopted 22.06.2018.

¹⁴ Partnership agreements executed between CEPI and its Awardees, and their Sub-Awardees, are evaluated via the CfP due diligence process. Similarly, agreements or Memoranda of Understanding (MOU's), between CEPI and CEPI's Implementing Partners fall outside the scope of the CEPI procurement procedures.

The policy outlines how CEPI commits to conduct procurements 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 shall 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 CEPI procurement procedure includes general rules and principles, eligibility criteria for tenderers, specification of tender procedure types and duration of contracts. It also defines a set of thresholds that trigger different procurement processes (Direct procurement/simple tender/full tender), whereby the number of steps and scrutiny undergone reflects the value and type of procurement.

Together, the policy and the procedure reflect international best standards and EU directives. They were also drafted in close consultation with our Investors, ensuring that our approach was in line with legal requirements.

Implementation and lessons learned

In transitioning into more formalised arrangements for procurement, KPMG was engaged by CEPI in the beginning of the year, to help systematise the documentation of the procurements that had been undertaken as well as develop the CEPI procurement procedure. Additional compliance staff was also hired, including an Operations and Procurement Manager with dedicated responsibility for implementing the procedure and overseeing that procurements were made according to its guidance. As part of this effort, staff trainings were conducted across the Secretariat in the autumn of 2018.

Over the course of 2018, 54 procurements were undertaken and completed in accordance with CEPI's Procurement Procedure. Table 7 below gives an overview of how these were distributed across the different procurement processes, according to estimated value.

Table 7: Overview of procurement made under different thresholds

Type of procurement process	#
Direct Procurement (value below NOK 100')	22
Simple Tender (value between NOK 100' - 500')	20
Full tender (value above NOK 500')	4
Full tender (value above NOK 1 000')	8

While the process for completing these procurements has marked a substantial improvement in CEPI's ability to identify providers of goods and services that provide the best value for money, there are also lessons to be learned. Specifically, we have seen that an overly detailed process may cause undue delays in carrying out our mission and that the managerial process for documentation may well be a barrier to compliance rather than an enabler. To this effect, an evaluation and update of CEPI Procurement Procedure is planned to be performed in Q2 2019. The ambition is to make the procedure less cumbersome, reducing the administrative resources and cost required, enabling CEPI to act faster and more agile. At the same time, the requirements must be proportional in relation to expected value and compliance with applicable rules and regulations ensured. CEPI is currently in the process of planning a new information management system, where automation of key processes is within the scope. The procurement process is one such the key processes.

7. Risk Management

CEPI places great emphasis on risk management and has, since 2017, employed an encompassing approach to risk management. This has been further strengthened in 2018, including through adopting a revised [risk management policy](#) and the hiring of a Governance Risk and Compliance Manager. Another important achievement was the establishment of an Audit and Risk committee of the Board that reviews CEPI's budget and monitor the integrity of the financial statements, oversee external and internal audit work and reviews the internal controls and risk management approach of CEPI. Also, an Internal Audit Function of CEPI was established and an internal audit plan is approved for 2019.

Over the course of the year, CEPI developed and implemented a number of policies¹⁵ in response to legal/regulatory requirements, industry standards and investor requirements, and to mitigate against identified risks. The implementation and operationalisation of these policies is accomplished through introducing practical procedures and communicated through training sessions and all staff information activities.

CEPI's approach to risk management acknowledges that it is not possible to avoid all risks. However, it is necessary to be aware of relevant risks and try to mitigate them to an acceptable level. The organisational highest level risks (H) are highlighted in Table 8 as are the results of associated mitigating actions. These risks are covered in more detail in annex A2 Risk Register .

Table 8: CEPI's top risks

Category	Risk description	Risk prior to mitigating	Risk after mitigation
Reputational, Financial, Legal, Operational risk	CEPI not developing safe and effective vaccines five years after launch	H	M
Operational risks	Understaffing in Secretariat leading to too high workload, reduced quality, delays and not delivering on CEPI's mission	H	M
Financial risks	Loss of political interest and willingness to fund	H	M
Operational risks	Insufficient collaboration with central partners (e.g., WHO, GAVI) leading to lack of coordination of resources related to outbreaks	H	M
Operational risks	Leakage of sensitive information	H	M
Reputational risk	Abuse of power, misuse of public funds	H	M

H=high; M=medium

Project risks

In addition to the organizational risks, CEPI also manages risks on a project level. CEPI implemented a thorough due diligence process in 2018 with a mandate to investigate all potential risks for each project, respectively. Together with the introduction of internal project risk management guidelines, risks are considered across the entire life cycle of the project – both prior to and after grant signature. The awardees of CEPI funded projects are required to identify key technical, financial, legal and

¹⁵ See <https://cepi.net/about/governance/> for a complete overview of our policies

integrity risks to their development projects. These risks are monitored by both CEPI's project management team and the Joint Monitoring and Advisory Group. Risks and mitigating measures are part of each milestone review and ultimately overseen by CEPI's leadership team.

CEPI requires that its awardees conduct their programmes according to CEPI's policies and to abide applicable laws and standards in the relevant territories and jurisdictions where the CEPI-funded activities are undertaken. As an example CEPI has a specific [policy for clinical trials](#), in which CEPI requires awardees to have all relevant regulatory and ethical approvals, and appropriate governance mechanisms in place before the clinical trial is initiated. Under this policy, CEPI assesses the clinical trials risks and oversees that appropriate risk monitoring and risk mitigating plans are implemented before a trial is initiated.

Fraud and corruption

CEPI has a zero-tolerance policy with regard to fraud and corruption. The discovery, reporting and documentation of acts of fraud and corruption, which are covered in more depth within the Procedures for Anti-Corruption, are established for the protection of all parties. CEPI is committed to principles of due process in addressing allegations of fraud or corruptions. If an allegation of fraud or corruption is sustained, CEPI will take appropriate disciplinary action, up to and including termination of employment, repayment of funds, restitution of losses and securing any remedies available through legal process. CEPI requires that its awardees and their subcontractors conduct their CEPI-funded programme according to similar principles and will abide by applicable laws and standards on fraud and corruption in the relevant territories and jurisdictions where the CEPI-funded activities are undertaken.

CEPI conducts internal anti-corruption training for staff as a part of wider training session on values and ethics. CEPI also maintains a gifts and hospitality register and has implemented internal control systems which are operated in a way that allows early detection and prevention of corruption, fraud and other financial irregularities. A reporting line to investors and the Board is also established in case of credible allegations of corruption or fraud or other financial irregularities.

At the end of 2018 CEPI launched a [electronic reporting](#) channel to facilitate reporting of misconduct, fraud, corruption and business crime. The solution is provided by an external and independent third party specialised in integrity and compliance, and supports CEPI's compliance work and ability to prevent, and act in case of any, wrongdoings.

No instances of fraud or corruption identified.

Vulnerable groups and unintended consequences

CEPI is committed to achieving the highest standards possible in our activities, and ensuring they meet the expectations of our partners, funders, other stakeholders, and the public. All decision-making and actions related to selecting external partners aim to be impartial and unbiased, meaning CEPI strives to be open, fair, and non-discriminatory in engaging with all external partners.

Our people are our most important asset and the key to CEPI's success. We encourage a culture that embraces inclusiveness, respect, accountability, and opportunities for continuous improvement. CEPI's recently approved Code of Conduct defines the standards we expect our employees, consultants, and others we work with to follow. And we expect partners and suppliers to adhere to the same high standards.

Appendices:

AI Organisational Issues

A1.1 Organisational Management:

CEPI made considerable changes to its organisational structure following the start-up phase (2016–2018). The changes reflect that the Secretariat had reached a higher level of maturity capable of taking a more active role in program implementation and management. Figure 9 and 10 depicts these changes, with the Secretariat now assuming a more central role in CEPI operations, with Board serving an executive rather than operational function. Permanent Secretariat teams have also been established across the 3 locations; Oslo, London and Washington D.C.

Figure 8: Interim Governance structure

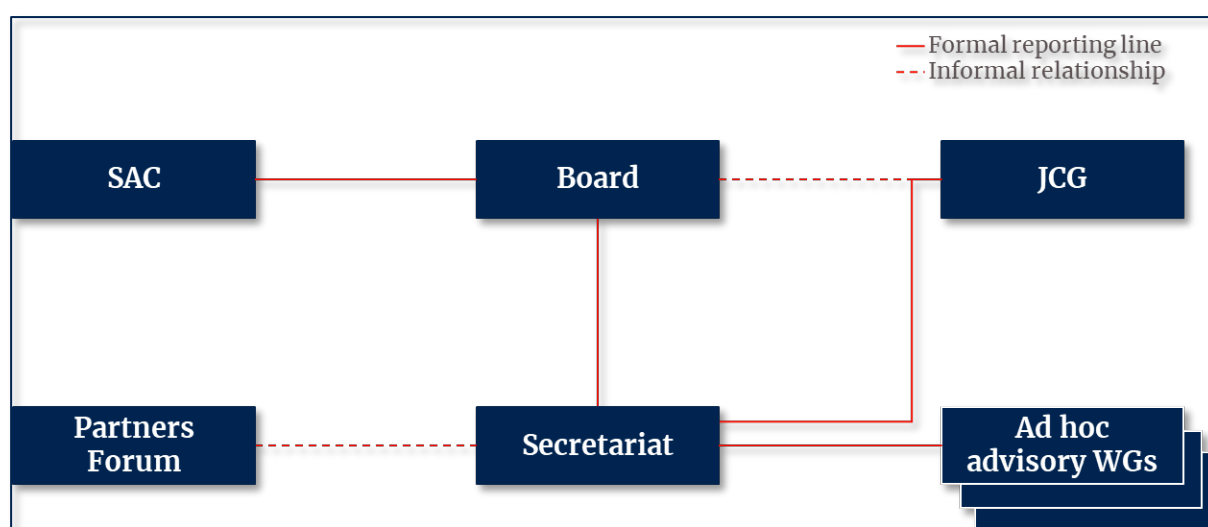
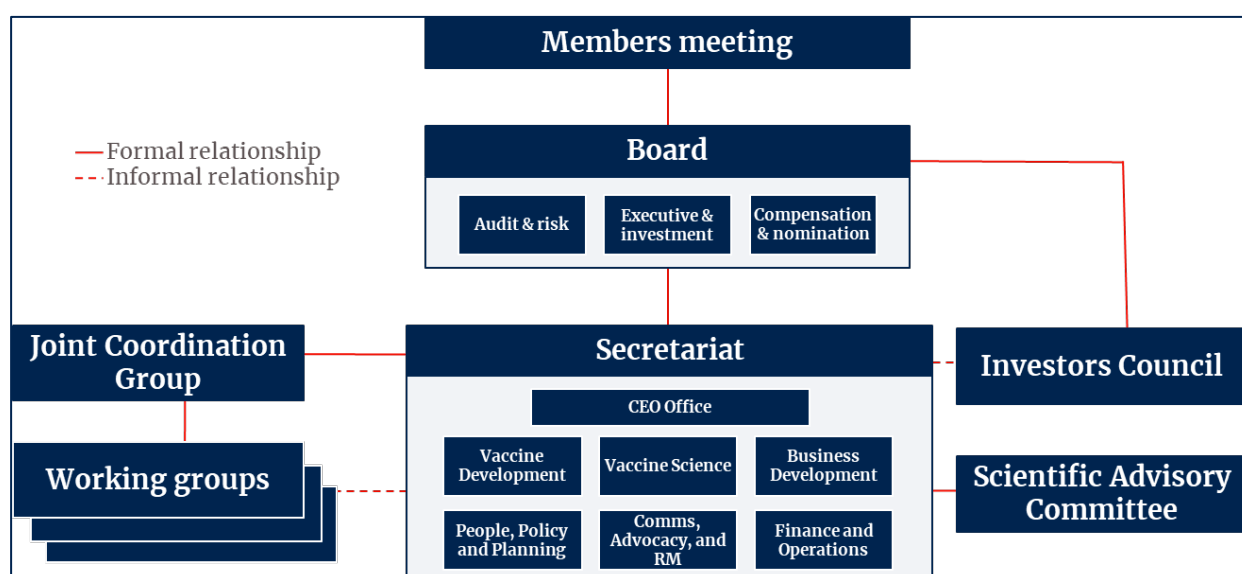


Figure 9: Permanent Governance Structure



A1.2 Human Resources:

In 2018, CEPI has focused on development job descriptions, hiring staff and implementing performance management systems. Achievements in the area of human resource management include:

- Three offices (Oslo, London, DC) were effectively set up with payroll and a defined, global employee benefits scheme was established providing for pensions, health and life insurance, travel insurance, parental leave, and professional training, among other benefits.
- A job level structure, with accompanying salary bands, was established for both leadership and individual contributor roles. Salaries are aligned with market norms (private, not-for-profit, and public sector)
- Job descriptions have been developed for all identified roles.
- Effective recruitment processes are set up.
- On-boarding and off-boarding mechanisms are established.
- A Board approved global HR policy, accompanying procedures, and employee manuals have been developed and are available to all staff.
- 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 our organisational culture.
- A Performance Management and Salary Review System has been developed; it was partially implemented in 2018 and will be fully implemented in 2019. All staff have been trained and have been part of developing this system. Specific training for the line managers has been delivered 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. CEPI advertises widely and compose interview panels with care.

Current composition of the CEPI Secretariat:

- As of today the Secretariat has 52 (permanent and temporary) employees
- Gender balance Secretariat: 50% female
- Gender balance Sr Management: 45% female
- The 52 Secretariat employees are from 16 different countries; 7 (13,5%) employees are from affected countries.
- Of the 21 employees in scientific roles, 6 (29%) are from affected countries

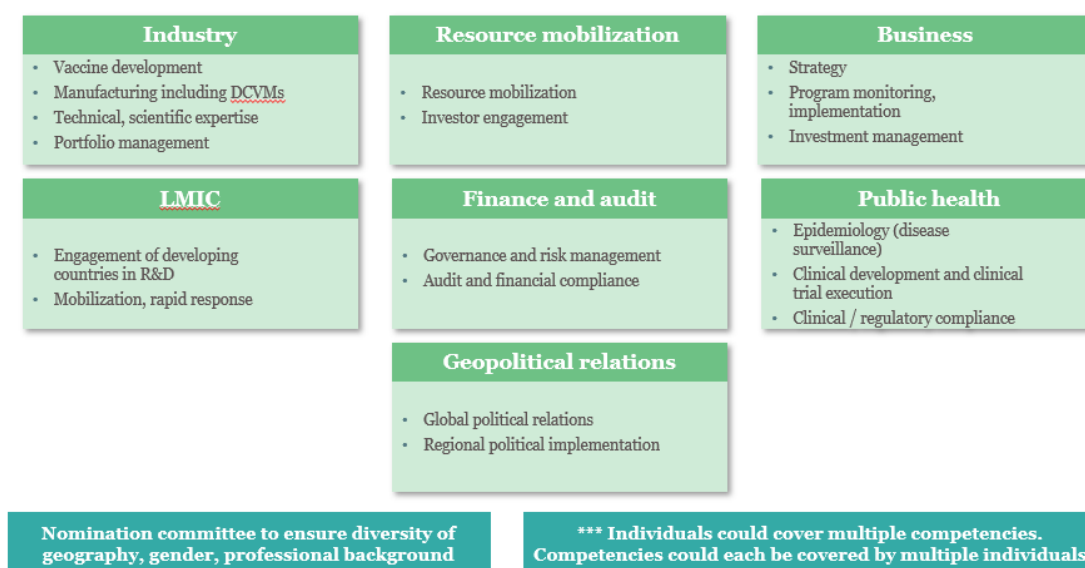
Hires at senior level in 2018

- Mads Høgholen—Director Finance and Operations (March 1, 2018)
- Richard Wilder—General Counsel and Director Business Development (March 1, 2018)

A1.3 Board

As part of the revised governance structure, CEPI implemented a new Board structure. The structure reflects a desire for a nimble and effective organisation and adequate representation from experts in vaccine development, multilateral institutions, affected countries and Investors. As part of the revised governance structure, three Board committees were also established, each consisting of 4 Board members each: Audit and Risk Committee, Executive and Investment Committee, Nominations and Compensation Committee (NCC). The NCC has a key role in ensuring an appropriate balance and range of skills.

When nominating the permanent Board at the Board meeting in November 2017, the following illustrative competencies were presented for consideration



Useful links

- [CEPI Board Charter](#), adopted in March 2018
- For current composition, see [this link](#).

CEPI Interim Board Members (from November 2017 meeting)

K. Vijay Raghavan (Chair)

Secretary, Department of Biotechnology
Ministry of Science and Technology,
India

Peter Piot (Vice Chair)

Director of the London School of
Hygiene and Tropical Medicine

Adar Poonawalla

CEO and Executive Director
Serum Institute of India

Arnaud Bernaert

Head of Global Health and Healthcare
Industries, World Economic Forum

Christopher Whitty

Chief Scientific Adviser
Department of Health, UK

Ichiro Kurane

Director-General, National Institute of
Infectious Diseases, Ministry of Health,
Labour and Welfare, Japan

Jane Halton

Adjunct Professor
University of Canberra

Jeffrey Mphahlele

Vice President
South African Medical Research
Council

Jeremy Farrar

Director
Wellcome Trust

Joachim Klein

Deputy Head of Division Health
Research, Federal Ministry of
Education and Research, Germany

Joanne Liu

International President
Medecins sans Frontieres

Julie Gerberding

Executive Vice President
Merck

Line Matthiessen

acting Director of Directorate for
Health Research
European Commission

Luc Debruyne

President Global Vaccines
GSK

Marco Krieger

Vice –President of Production and
Innovation, Fiocruz

Nima Farzan

President and CEO
PAXVAX INC.

Tore Godal

Special Adviser on Global Health
Ministry of Foreign Affairs,
Norway

Trevor Mundel

President Global Health Division
The Bill & Melinda Gates
Foundation

Victor Dzau

President of the Institute of
Medicine
National Academy of Sciences

Yah Zolia

Deputy Minister of Health and
Social Welfare, Liberia

Yifru Berhan

Minister of Health
Ethiopia

Observers

Mark Feinberg

President & Chief Executive Officer
IAVI

Peggy Hamburg

Foreign Secretary of the Institute of
Medicine
National Academy of Sciences

Peter Salama

Executive Director
WHO Health Emergencies Programme

Richard Hatchett

CEO of CEPI

CEPI Board Members (from December 2018 meeting)

INDEPENDENT MEMBERS

Jane Halton *(Chair)***Cherry Kang** *(Vice-Chair)*Executive Director
Translational Health
Science & Technology
Institute**John Nkengasong**Director
Africa Centres for Disease
Control and Prevention**Peter Piot**Director
London School of
Hygiene and Tropical
Medicine**David Reddy**Chief Executive Officer
Medicines for Malaria
Venture**Rajeev Venkayya**President
Vaccine Business Unit
Takeda

INVESTOR REPRESENTATIVES

Tore GodalSpecial Adviser on Global Health
Norwegian Institute of Public
Health**Joachim Klein**Deputy Head
Division Health Research
Federal Ministry of Education
and Research, Germany**Ichiro Kurane**Director-General
National Institute of Infectious
Diseases, Japan**Trevor Mundel**President Global Health Division
The Bill & Melinda Gates
Foundation

NON-VOTING MEMBERS

Richard HatchettChief Executive Officer
Coalition for Epidemic Preparedness
Innovations**Helen Rees** *(Chair of the SAC)*Executive Director
Wits Reproductive Health and HIV
Institute**Peggy Hamburg** *(Chair of the JCG)*President-elect
American Association for the
Advancement of Science**Peter Salama** *(WHO representative)*Executive Director of Health
Emergencies Programme
World Health Organization**Tim Evans** *(World Bank representative)*Senior Director
Health, Nutrition and Population
World Bank

A1.4. Scientific Advisory Committee members

<u>Beginning 2018</u>	<u>End of 2018</u>
Voting members	Voting members
Alan Barrett	Alash'le Abimiku
Alash'le Abimiku	Christian Bréchet
Christian Bréchet	Christian Happi
Christian Happi	Connie Schmaljohn
Connie Schmaljohn	Daniel Brasseur
Daniel Brasseur	Delese Mimi Darko
Delese Mimi Darko	George Fu Gao
George Fu Gao	Helen Rees (Chairperson)
Helen Rees (Chair)	Inger Damon
Inger Damon	James Robinson (co-chair)
Jim Robinson (Vice Chair)	John Edmunds
Johan von Hoof	Kathleen Neuzil
John Edmunds	Kenji Shibuya
Kathleen Neuzil	Michel De Wilde
Kathrin Jansen	Myron Levine
Myron Levine	Paula Bryant
Paula Bryant	Penny Heaton
Penny Heaton	Peter Smith
Peter Smith	Phil Krause
Phil Krause	Ralf Clemens
Stanley Plotkin	Stanley Plotkin
Tom Kariuki	Thomas Kariuki
Yves Lévy	Yves Lévy
Non voting members	Non voting members
Ali Allouche	Ali Allouche, Takeda
Jean Lang	Jean Lang, Sanofi
Vasee Sathiyamoorthy, WHO	Johan van Hoof, J&J
	Kathrin Jansen, Pfizer
	Vasee Sathiyamoorthy, WHO

A1.5. Joint Coordination Group

The JCG was reconstituted in February 2018. All members are thus new. Go to the “Joint Coordination Group” tab using [this link](#) for a complete overview of members and summaries of meetings.

A2 Risk Register

TOP RISKS CEPI								
Category	Risk description	Probability	Consequence	Risk prior to mitigating	Mitigating measures	Risk after mitigation	Risk Owner	Status progress on mitigating measures
1	Reputational, Financial, Legal, Operational risk CEPI not developing safe and effective vaccines five years after launch	M	H	H	1. Ensure partner contracts are agreed in a timely manner. Procure suitable insurance coverage for legal risks related to use of vaccines. 2. Rigorous assessment of funded projects by Secretariat, SAC and independent expert reviewers in advance of start 3. Close follow up of projects through JMAG, milestones and stage gate reviews. Since the selected CEPI partners are small biotech companies in consortia with academic partners and CROs, this requires significant staff increase to allow close follow up of all projects. 4. Balancing portfolio of development projects 5. Project failure hedged against through investment strategy and portfolio review 6. Ensure clarity about what CEPI is responsible for and where there are dependencies on others	M	CEO	1. The first partner contracts are signed. Legal risk related to future vaccine use considered and will be insured against in due time. Insurance needs currently under review. 2. CfP1 and CfP2 processes have been very thorough on technical assessment. Financial and integrity due diligence performed on all awardees. CfP3 due diligence planned. 3. Principles agreed in partner contracts and need for additional staff estimated based on realistic number of projects. October 2018 Board approved staff increase, recruitment process ongoing, expected completed Q4 2019. 42 of 66 hired pr Feb 2019. 4. Assessment of re-opening/rolling calls initiated, to be raised at the March Board meeting. 5. Investment strategy signed off by Board, portfolio review principles under development. First annual potfolio review planned Q3-Q4 2019. 6. Continuous alignment with CEPI stakeholders, complexities included in business plans and contingency arrangements. Note: risk stays red until staff increase is in place, may then be downgraded to orange.

2	Operational risks	Understaffing in Secretariat leading to too high workload, reduced quality, delays and	H	H	H	1. Hire leaders with clear roles and responsibilities2. Organisational and operational planning. Avoid people working unreasonable hours over a long time and make sure that people take vacations 3. Hiring of necessary/planned staff, including external help temporarily. Avoid loss of institutional memory by relying too much on consultants.4. Input/assistance from hosting organisations and partners to the Coalition to learn from experience and best practices5. Strengthen forecasting of HR needs to match planned workload and get Board approval for proposed increase in staff6. Tracking of staff engagement	M	Deputy CEO	1. Completed. Close follow up of employees from line managers to avoid burnout.2. Organisational plan for 2019 planned finalised Feb 2019, individual key priorities defined for 2019. Clear messages on importance of taking vacations have been communicated.3. Ongoing. Staff increase will reduce need for external consultants.4. Ongoing5. Staff increase approved by the Board October 2018, recruitment ongoing.6. Staff survey performed January 2019, ongoing follow-up.
3	Financial risks	Loss of political interest and willingness to fund	M	H	H	1. Diversification of funding base and implementation of innovative financing mechanisms 2. Reporting and communication of achievements and progress 3. Establish MoU and contract requirements for investors to inform about future funding in a timely manner 4. Ensure good governance to build trust 5. Revision of business plan 6. Replenishment from investors	M	Director Advocacy , Comms and Resource Mobilisation	1. Ongoing, resource mobilisation strategy developed - under implementation. 2. Signing of partner contracts have been communicated. Proactive communication in media. Standardised investor reporting in process. 3. Agreements in place, frontloading of MUSD from Norad work in progress. 4. Ongoing, continuous work with stakeholders and governments on global health security. 5. Board approved for 2019. 6. Preparatory considerations started.

4	Operational risks	Insufficient collaboration with central partners (e.g., WHO, GAVI) leading to lack of	M	H	H	1. Mapping and prioritising key partners and to formalise collaboration, including through MOUs 2. Partner participation in development of strategies, including through representation in Board and JCG 3. Task team collaboration. Dedicated staff in place working on stakeholder engagement and management 4. Internal coordination of external relations	M	Deputy CEO	1. Mapping and prioritisation in process. MOUs signed with a number of critical partners, with many reps serving on JCG or SAC. Considering update to WHO MOU. 2. Funders and key partners included in Board, Investors forum and JCG 3. Task teams/WGs (e.g. JCG WG) have representation from key partners, including WHO (including regional offices), Gavi, UNICEF. Interlocutor at strategic level with WHO and other central partners. Discussions with GAVI around investment strategy and criteria for epidemic diseases. Resource Mobilisation strategy developed, under implementation. 4. Continuous collaboration between CEPI departments to have coordinated approach to partners. Developing internal coordination mechanisms with "key account managers" (e.g. for WHO). Recruitment ongoing to employ policy manager and investor relations resource.
5	Operational risks	Leakage of sensitive information	H	H	H	1. Increase awareness and anchor best practice on handling of sensitive information within the secretariat 2. Develop standard operating procedures (SOPs) for handling sensitive information and responding to leakages. 3. Refrain where possible from sharing documents and rather use links 4. Non-Disclosure Agreements (NDA) to be signed by all CEPI awardees 5. Have external assessment of IT security and implement mitigating measures, including through having insecure email network with sensitive information to be moved to safe area 6. Establish and monitor a SharePoint with access control to be used for sensitive information	M	Director Finance and Operations + General Counsel	1. Information on how to handle sensitive information shared by mail. IT security training completed for all employees in June 2018. Includes training on protection of personal data and update on GDPR regulations. Cyber risk review/audit planned for 2019 focusing on both insider risk and external threats. 2. In process. Information Security Policy approved Feb 2019. Procedures under development and to be implemented as a part of Information Management Project. 3. Communicated, mandatory training performed of all staff. 4. Included in partner contracts 5. Completed. Audit verifying that all specifications given Intility have been implemented initiate and planned finalised Q1 2019. 6. Completed CEPI Intranet site with access control. Ongoing work to further strengthen access control (ref Information Security Policy)

6	Reputational risk	Abuse of power, misuse of public funds	M	H	H	1. Best practice Governance, prevent and control activities. a. Tone from the top: CEPI values b. Code of Conduct c. Policies d. Procedure e. Training and awareness f. Control activities g. Establish channels for report of concerns (whistleblowing)	M	CEO	a. CEPI values defined and communicated, needs to be repeated continuously b. Code of Conduct implemented. Summarises the existing policies which have been approved by the CEPI Board. c. Policies completed and approved by the CEPI Board. d. Most procedures completed, some in final review and targeted to be signed off in Q1 2019. e. Mandatory IT security and GDPR training completed in June 2018. Mandatory anti-corruption, whistleblowing and conflict of interest training performed. New employees to be trained during Q1 2019, then continuously refresh work. f. Project control routines - ongoing work. Internal Audit plan 2019 approved. g. Whistleblowing policy approved by the CEPI Board. Whistleblowing procedure approved. External whistleblowing channel implemented Dec 2018.
---	-------------------	--	---	---	---	--	---	-----	---

A3 Results Framework

This annex provides a collated overview of all the indicators and their targets covered in this progress report. CEPI's Programme Document provides more detail on how each indicator is monitored and measured. To complement this Framework, CEPI will develop a monitoring and evaluation plan by the end of 2019 to support timely and accurate follow-up of achievements towards our strategic objectives. This is deemed particularly important for the Theory of Change levels 2.2, 2.3.1, 3.2 and 3.3 which currently do not have dedicated indicators.

Indicator number	TOC number	Indicators	Baseline Y0	Target 2018	Target 2019	Target 2020	Target 2021	Target 2022	Status
1	0,1	3.B.2 Development assistance to medical research & basic healthcare	N/A	N/A	N/A	N/A	N/A	N/A	
2	0,1	3.D.1 Health emergency preparedness	N/A	N/A	N/A	N/A	N/A	N/A	
3	0,2	8.1.1 GDP per capita growth rate	N/A	N/A	N/A	N/A	N/A	N/A	
4	0,3	17.6.1 Science and technology cooperation	N/A	N/A	N/A	N/A	N/A	N/A	On track
5	1,1	Number of vaccine candidates in investigational stockpile for outbreak situations and ready for efficacy studies and emergency use	0	0	0	0	0	4 candidates for at least 2 priority pathogens	Action required
6	1,2	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%	100%	100%	On track
7	1,2	Percent of vaccine development partners agreeing to terms that are fully consistent with CEPI's Equitable Access Policy and implementation guidance	N/A	100%	100%	100%	100%	100%	On track
8	1,1,1 a	Number of vaccine candidates advanced through preclinical trials	Lassa: 0	Lassa: 1	Lassa: 3	Lassa: 4	Lassa: 4		Action required
8	1,1,1 a	Number of vaccine candidates advanced through preclinical trials	Nipah: 1	Nipah: 1	Nipah: 3	Nipah: 4	Nipah: 4		Action required
8	1,1,1 a	Number of vaccine candidates advanced through preclinical trials	MERS: 1	MERS: 1	MERS: 2	MERS: 3	MERS: 4		Action required
8	1,1,1 b	Number of vaccine candidates advanced through P1 trials	Lassa: 0	Progress towards	Lassa: 2	Lassa: 3	Lassa: 3		Action required

				targets reported					
8	1,1,1 b	Number of vaccine candidates advanced through P1 trials	Nipah: 0	Progress towards targets reported	Nipah: 0	Nipah: 3	Nipah: 3		Action required
8	1,1,1 b	Number of vaccine candidates advanced through P1 trials	MERS: 0	Progress towards targets reported	MERS: 1	MERS: 2	MERS: 3		Action required
8	1,1,1 c	Number of vaccine candidates advanced through P2 trials	Lassa: 0	Progress towards targets reported	Progress towards targets reported	Lassa: 0	Lassa: 2	Lassa: 3	Action required
8	1,1,1 c	Number of vaccine candidates advanced through P2 trials	Nipah: 0	Progress towards targets reported	Progress towards targets reported	Nipah: 0	Nipah:1	Nipah:3	Action required
8	1,1,1 c	Number of vaccine candidates advanced through P2 trials	MERS: 0	Progress towards targets reported	Progress towards targets reported	MERS: 1	MERS: 1	MERS: 3	Action required
9	1,2,1	Number of available biological standards and validated assays (including standard operating procedures) for evaluation of vaccine candidates against CEPI's priority pathogens	0	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	1 biological standards developed for each of priority pathogens	at least one validated assay available each of priority pathogens	On track
10	1,2,1 a	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. (End preclinical/move to phase I (Stage Gate 1): Scientific advice for CTA/Pre-IND package)	0	Subject to successful completion of preclinical: 100%	Subject to successful completion of preclinical: 100%	Subject to successful completion of preclinical: 100%	Subject to successful completion of preclinical: 100%	Subject to successful completion of preclinical: 100%	On track

10	1,2,1 b	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 (End of phase I, type C meeting/scientific advice,)	0	Subject to successful completion of P1 100%	Subject to successful completion of P1 100%	Subject to successful completion of P1 100%	Subject to successful completion of P1 100%	Subject to successful completion of P1 100%	On track
10	1,2,1 c	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. (for phase II, submission of CTA to NRAs in affected countries)	0	Subject to successful completion of P2 100%	Subject to successful completion of P2 100%	Subject to successful completion of P2 100%	Subject to successful completion of P2 100%	Subject to successful completion of P2 100%	On track
11	2,1	Number of vaccine platform technologies that can be rapidly adapted to develop vaccines against unknown pathogens for use in humans	0	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	2 or greater, including at least one novel (innovative) platform, i.e., that has no prototyped licensed vaccine	Action required
12	2,3	Percent of vaccine development partners with necessary agreements in place for vaccines to be deployed and tested during an outbreak	0	100%	100%	100%	100%	100%	On track
13	2,3	Percent of vaccine development partners with plans in place for equitable access fully consistent with CEPI's Equitable Access Policy.	0	100%	100%	100%	100%	100%	On track
14	2,1,1 a	Number of pathogen specific vaccines progressing using CEPI funded platforms, through preclinical.	0	Progress towards targets reported	Progress towards targets reported	8 pathogen specific vaccines			Action required
14	2,1,1 b	Number of pathogen specific vaccines progressing using CEPI funded platforms, through P1	0	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	6 products progressed through Phase I		Action required

15	2,2,1	Annual analysis of available technologies and the gaps that currently exist	N/A	Annual update	Annual update	Annual update	Annual update	Annual update	On track
	2.2	The outcome level on “Facilitated field use and rapid response” does currently not have an indicator. The reason for this is that without having defined which technologies CEPI will support under this priority, it is difficult to define an indicator that accurately reflects the associated outcome. When priority areas here are identified, CEPI will amend its results framework to capture this.							
	2,3,1	The Secretariat did not find a telling indicator for the output level. Engaging end-to-end partners could arguably be defined as an indicator, but the framing here suggests that it could also be an output. An indicator on meetings held etc was considered, but not deemed as helpful in this context							
16	3,1	Agreements in place with downstream partners on life-cycle financing a of CEPI-funded products, by disease area.	0					3 agreements in place	Action required
17	3,1	\$1bn raised as multi-year contributions to CEPI	\$630 m	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	Progress towards targets reported	\$1 bn	Substantial action required
	3,2	The difficulty with defining this indicator up-front relates to the multitude of areas that can potentially be a source of reductions in costs or timelines. As is reflected in the section “5.2 ”, CEPI was able to drive reduction in both timelines and costs as part of its CFP process in 2018. 2019 however will likely not see efficiencies in the same areas as the portfolio will be established. As such, CEPI will – for the time being – consider from time to time which areas make sense to report on. The process for this will be further detailed in a monitoring and evaluation							

		plan. As part of this exercise CEPI may also be able to identify appropriate indicators for this outcome level.							
	3,3	Availability of products is supported by a multitude of activities and the associated complexity was difficult to depict in a theory of change. Moreover, availability will ultimately depend on other actors than just CEPI, who will deliver the vaccine in the field and help define target populations.							
18	3,2,1	Percent of priority actions taken to achieve efficiencies	0	0	50%	50%	50%	50%	Action required
19	3,3,1	Percent of vaccine Partnership Agreements in place that contain contingency plans for manufacturing	N/A	100%	100%	100%	100%	100%	On track

A4 Finance

A4.1 5-Year plan

Financial items are shown as Financial costs in CEPI's 5-year plan and is a net of Financial income and costs. In 2018 CEPI had a gain of USD 3,5 million due to World Bank Investment income and currency exchange effects. The 2019 budget shows a net cost of USD 5 million due to expected costs of the frontloading of funds from Norway.

Financial items	Actual 2018
<i>Figures in KUSD</i>	
World Bank Investment return	1 808
World Bank fee	-227
DNB Interests	194
Agio	1 773
Bank charges	-12
Total	3 535

A4.2 Direct Investments

<i>Figures in MUS\$</i>	Actual 2018	Budget 2019
Priority diseases (CfP1 & CfP3)	34,2	83,8
Lassa	20,2	32,2
MERS	11,8	14,6
Nipah	2,2	16,1
Rift Valley Fever & Chikungunya	-	16,0
Contingency & Reserves	-	5,0
Platform Technologies (CfP2)	-	37,3
Recombinant viruses	-	14,3
Recombinant proteins	-	3,9
Nucleic acids (DNA and RNA)	-	13,8
Contingency & reserves	-	5,3
Finishing Ebola	-	10,1
Supporting Clinical Trials	-	7,1
Unprogrammed	-	3,0
Enabling Science	0,5	21,9
Lassa	0,2	7,8
Assays and Standards	-	3,0
Epidemiology	-	2,3
Diagnostics	-	1,0
Animal models	-	1,3
Workshops, Conferences and meetings	0,2	0,2
MERS	-	4,3
Assays and Standards	-	2,0
Epidemiology	-	1,0
Diagnostics	-	0,0
Animal models	-	1,3
Workshops, Conferences and meetings	-	0,0
Nipah	-	4,5
Assays and Standards	-	2,0
Epidemiology	-	1,0
Diagnostics	-	0,0
Animal models	-	1,3
Workshops, Conferences and meetings	-	0,2
Cross cutting	0,3	5,2
Academic engagement	-	0,5
Capacity Strengthening	-	0,3
Manufacturing related research	-	2,3
Facilitating Clinical Trials	-	0,6
Systems immunology	-	0,0
Workshops, Conferences and meetings	0,3	1,4
EDCTP	-	3,7
Total Investments	34,7	156,8

A4.3 Operating costs (OPEX)

CEPI has made changes to how operating costs are categorised. Accounting, Audit and Media/Communication costs are moved from the Consultancy to the Service providers/Other category, and some adjustments have been made between the Infrastructure and Service providers/Others. Below, CEPI has amended the 2018 figures accordingly, to make them comparable to 2019. Totals remain unchanged.

Operation costs	Actual 2018	Budget 2019
<i>Figures in KUSD</i>		
Salary & Social	6 272	10 507
Senior Management & BoD remuneration	2 440	2 724
Advocacy, Communication & Resource mobilisation	1 065	1 169
Scientists	1 335	4 084
Finance, Operations, Admin Support & HR	1 088	1 837
Legal, Contract & Business Development	344	693
Consultants/Consultancy/Seconded	7 521	8 822
Vaccine Science	394	504
Vaccine Development	793	2 463
Due Diligence	927	1 407
Resource Mobilisation	191	597
Strategy/Governance	667	477
Portfolio Management	223	420
Communication	207	184
Legal & Contract Management	2 822	1 850
Finance and Operations	1 120	599
HR	147	120
IT	29	200
Travel	2 105	3 063
Travel	1 998	2 798
Board meetings	25	70
Committees (SAC & JCG)	83	195
Infrastructure	1 107	1 049
Hardware	366	84
Software	50	90
IT Operation costs and maintenance fees	267	391
Telephony	62	164
Office costs	362	320
Service providers/Other	878	1 477
Accounting fees	238	234
Audit (External and internal)	107	300
Media & Communication	146	284
Recruitment	224	377
Meetings	123	238
Staff social	40	44
Total	17 883	24 919

CEPI