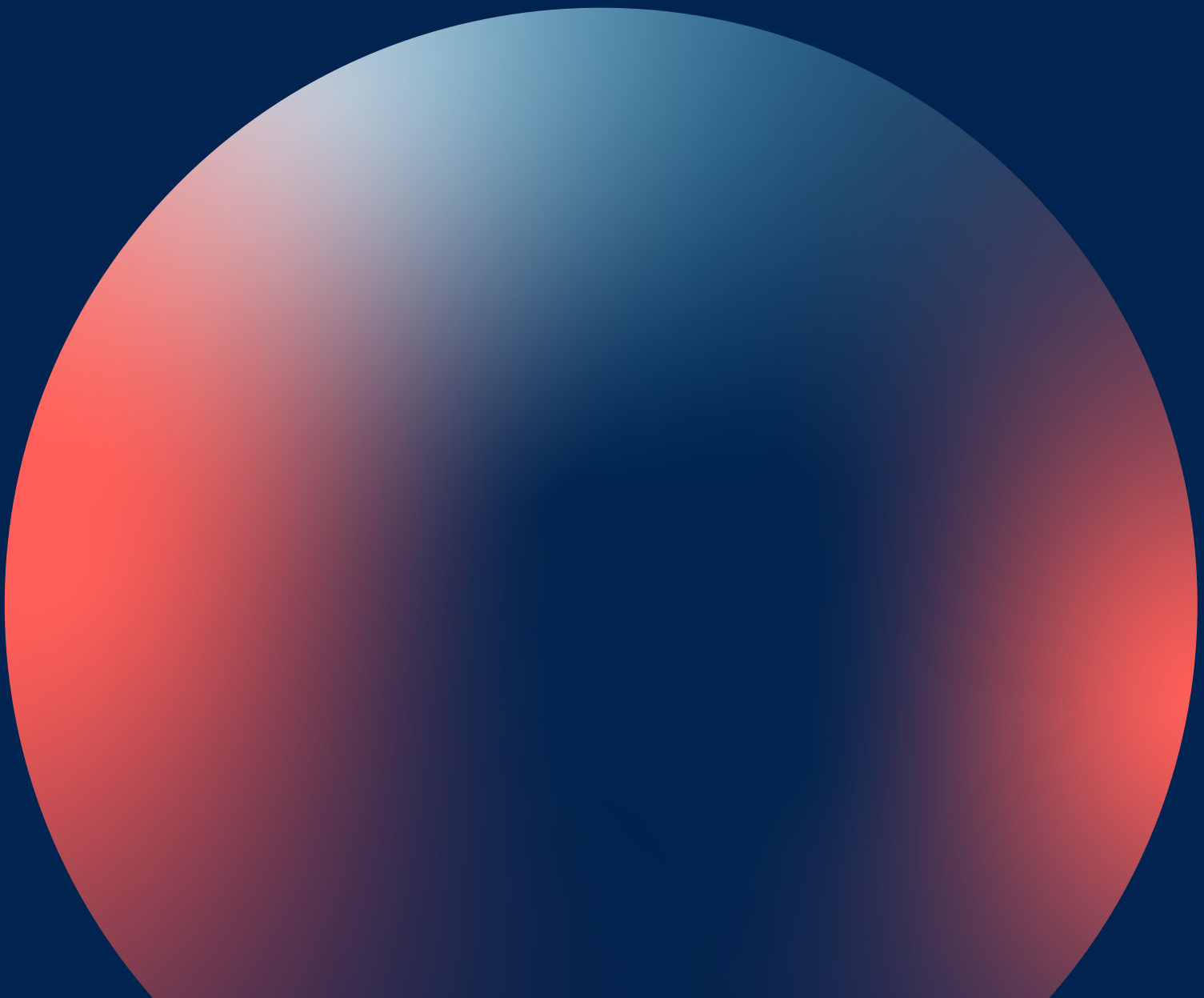
CEPI

2020 Annual Progress Report

Covering the period from:
1 January – 31 December 2020



2020 ANNUAL PROGRESS REPORT

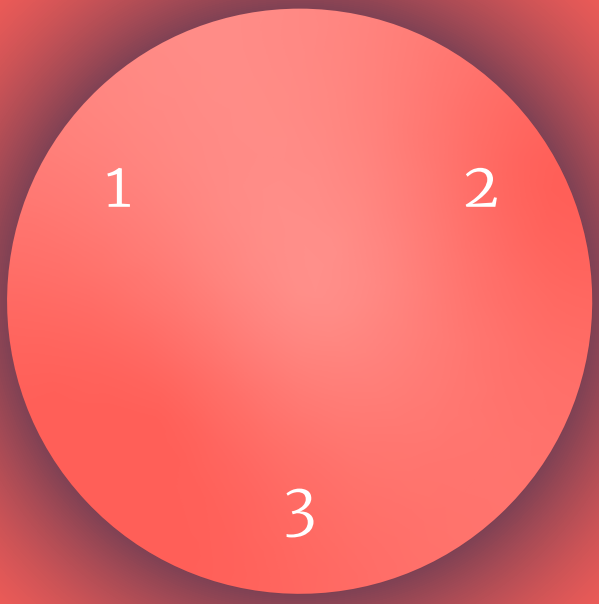
Coalition for Epidemic Preparedness Innovations (CEPI)

Reporting Period	1 January 2020 – 31 December 2020
Date report submitted	31 March 2021
Contact Name:	Samia Saad, Director of Resource Mobilisation & Investor Relations
Postal address:	Gibbs Building, 215 Euston Rd, London NW1 2BE
Email:	samia.saad@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

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

LIST OF ABBREVIATIONS

AAS	The African Academy of Sciences
AVAREF	The African Vaccine Regulatory Forum
ACT-A	Access to COVID-19 Tools - Accelerator
AZ	AstraZeneca
BMGF	Bill and Melinda Gates Foundation
CEPI	Coalition for Epidemic Preparedness Innovations
CfP	(CEPI) Calls for Proposals
CfP1	CfP for vaccine candidates against Lassa, Nipah and MERS
CfP2	CfP for platform technologies against an unknown pathogen
CfP2R	Rolling CfP for platform technologies
CfP3i	CfP for vaccine candidates against CHIK and RVF
CfP3ii	Follow on call for CfPi, not launched
CHIKV	Chikungunya virus
COVAX	The Vaccine Pillar of ACT-A
COVID-19	Coronavirus Disease 2019 (due to SARS-CoV2 virus)
CSAG	(CEPI) Cyber Security Advisory Group
CSL	Commonwealth Serum Laboratories (Australia)
EDCTP	European & Developing Countries Clinical Trials Partnership
EIC	(CEPI) Executive Investment Committee
EID	Emerging Infectious Diseases
EMA	European Medicines Agency
EDQM	European Directorate for the Quality of Medicines
FDA	United States Food and Drug Administration
FDD	Financial Due Diligence
FCPA	United States Foreign Corrupt Practices Act
GAVI	GAVI, the Vaccine Alliance
GISAID	Global science primary source that provides open-access to genomic data of influenza viruses and the coronavirus responsible for the COVID-19 pandemic
GRC	(CEPI) Governance, Risk, and Compliance function
IFFIm	International Finance Facility for Immunisation
IDD	Integrity Due Diligence
IMT	Incident Management Team

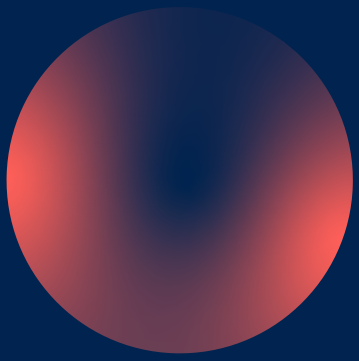
IOPN	Increased Outbreak Preparation Need
IPG	(COVAX) Independent Product Group
IVI	International Vaccine Institute
JCG	(CEPI) Joint Coordination Group
JMAG	(CEPI) Joint Management and Advisory Group Composition
KPI	Key performance indicator
LMICs	Low- and Middle-Income Countries
MERS	Middle East Respiratory Syndrome
NCC	(CEPI) Nomination and Compensation Committee
NCDIC	(CEPI) Nominations Compensation Diversity & Inclusion Committee
NIPH	The Norwegian Institute of Public Health
NHP	Non-Human Primates
NIBSC	(UK) National Institute of Biological Standards and Control
P1	Phase 1 clinical trials
P2	Phase 2 clinical trials
PATH	Program for Appropriate Technology in Health
PreC	Preclinical Trials
PREVAC-UP	Partnership for Research on Ebola Vaccinations – Extended Follow-up
PSMB	(CEPI) Portfolio Strategy and Management Board
RAG	(COVAX) Regulatory Advisory Group
R&D	Research and Development
RDMIC	(COVAX) Research, Development and Manufacturing Investment Committee
RVF	Rift Valley Fever
SAC	(CEPI) Scientific Advisory Committee
SARS n-COV-2	Severe acute respiratory syndrome coronavirus 2
SDGs	UN Sustainable Development Goals
SGRC	(CEPI) Stage Gate Review Committee
SPEAC	Safety Platform for Emergency vaccines
SWAT	(CEPI) Support Work to Advance Teams
TRG	(CEPI) Technology Review Group
TT	Technology Transfer
UMICs	Upper Middle-Income Countries
UNICEF	United Nations International Children's Emergency Fund
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
WHO	World Health Organisation

INTRODUCTION

In 2017, when CEPI was founded, some might have discounted the threat of emerging infectious diseases and wondered whether that threat had been overblown. Today this is no longer the case. For more than a year, COVID-19 has dominated the lives of every person on the planet, in a way rivalled only by the great wars of the 20th century. COVID-19 represents the greatest global public health crisis in more than a century and the greatest economic crisis since the Great Depression.

At the time of publication, the news that long-awaited vaccines have begun to roll out gives much needed hope, while new vaccines are also on the way. Where vaccines have begun to be widely administered, hospitalisations and death rates are falling. The world has begun to reduce the equity gap. Through COVAX the world has embarked on the largest vaccine rollout in history. By early March, 2021, more than 30 million doses of vaccine had been delivered to more than 60 countries on 4 continents in just 10 days, bringing hope to millions of people. CEPI is proud to have been instrumental in conceiving and establishing COVAX and the ACT Accelerator and to have secured more than a billion doses for COVAX. We are proud to have enabled cooperation and action through CEPI's funding of extraordinary scientific achievements in the face of a global disaster. COVAX is an expression of global solidarity against pandemic disease and an improbable model that embodies what can be accomplished when we all work together.

This report reflects CEPI's progress against targets that we set ourselves for core activities and COVID activities. 2020 was a remarkable year for CEPI. We matured as an organisation and as a coalition while responding to the pandemic. We have broader global partnerships and more technical collaborations than ever before. We have tripled the number of countries that have joined the coalition and almost doubled the number of CEPI employees. Even while fighting the pandemic, CEPI has continued to progress vaccine development against other emerging infectious diseases. CEPI's investments are starting to bear fruit and in 2020 we achieved a number of firsts including the first phase 3 trial of a Chikungunya vaccine and the advancement of the first ever Nipah and Lassa virus vaccines into phase 1 trials. Much work remains to be done.



> **Through COVAX the world has embarked on the largest vaccine rollout in history**

As we look toward the future, CEPI is fully engaged in addressing the questions of how the world can end the pandemic and emerge stronger, more united, and more prepared for known future threats. To address these challenges and guide our replenishment efforts, we have developed a new strategy for CEPI 2.0 that was approved by our Board in December, 2020. The strategy focuses on strengthening our defences against COVID-19 and reducing the risk of future coronavirus pandemics; developing vaccines for known threats; working to compress vaccine development timelines to 100 days; producing a library of vaccines against prototype pathogens; establishing global networks for lab capacity, assays, and preclinical models; and supporting the efforts of low- and middle-income countries to take full ownership of their national health security. We look forward to implementing this ambitious programme in the coming years.

I hope you find this report a useful account of our activities in an extraordinary year.

Yours sincerely,

Richard Hatchett

Chief Executive Officer

Coalition for Epidemic Preparedness Innovations

2020 KEY HIGHLIGHTS

CEPI's leading role in COVID vaccine R&D preparedness and response: CEPI was one of the first organisations to begin development of COVID-19 vaccines in January 2020, when the genetic sequence of the novel coronavirus was first made public. Prior to the COVID-19 pandemic—and in recognition of the threat posed by Disease X and coronaviruses in particular—CEPI had allocated over $50 million to develop vaccine platform technologies that could enable the development of rapid-response vaccines against newly emerging pathogens and over $140 million to develop vaccines against MERS, a virus related to SARS-CoV-2. CEPI was able to be agile and start making investments in SARS-CoV-2 vaccine R&D within two weeks of the publication of the sequence of the virus. During 2020, CEPI was able to pivot most of CEPI's MERS and platform technology partners to work on COVID-19 and rapidly built a portfolio of 11 vaccines. By end of year, two of these vaccines had demonstrated high efficacy in preventing severe COVID-19 disease and had received emergency use authorizations, enabling roll out of vaccine doses in early 2021. CEPI has invested in one of the world's largest portfolio of vaccines against COVID-19 which continues to grow and be strengthened during the start of 2021, has awarded forgivable loans in 2020 to expand global manufacturing capacity, has established a global network of laboratories to standardise vaccine assessment, and has emerging viral strains on vaccine effectiveness.

Enabling equitable access to COVID-19 vaccines: COVAX, the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A), was initiated and co-led by CEPI, Gavi and WHO. COVAX has fundamentally altered the global conversation around access. By bringing together 191 countries and economies, including 92 LMICs, in just a few months to accelerate the development, manufacture, and distribution of COVID-19 vaccines, COVAX has emerged as the largest multilateral undertaking since the Paris Agreement on climate change. CEPI secured first right of refusal to over 1 billion doses for COVAX and by December 2020, COVAX had put agreements in place to enable access in 2021 to nearly 2 billion doses of several promising vaccine candidates. The COVAX rollout of COVID-19 vaccine has now begun, with the first doses arriving in Cote d'Ivoire and Ghana at the end of February, with tens of millions of doses subsequently delivered to date to over 60 countries at the time of writing. Both the ACTA and COVAX are promising initiatives and, while there is room for improvement, will likely serve as models for how to address development and distribution challenges in the future.

Driving R&D advances against priority pathogens: CEPI has also overseen a number of scientific "firsts" in 2020, including the first phase 3 trial of a Chikungunya vaccine and the advancement of the first ever Nipah and Lassa virus vaccines into phase 1 trials. The advances that have been made in this short period simply would not have been possible without CEPI. To date, CEPI has entered into partnership agreements with a total investment value up to $725 million, including investments in support of enabling science, to develop more than 20 vaccine candidates against Ebola, Lassa, MERS, Nipah, Rift Valley Fever, and Chikungunya—diseases which disproportionally affect those living in LMICs

A truly global coalition, a broader set of investors, and a clearly defined future: In 2020, the coalition expanded significantly, in terms of the numbers of both investors as well as research and manufacturing partners. Members of the Investors Council increased from nine in 2019 to 24 in 2020, bringing an additional USD$1.5 billion in financial commitments for CEPI's COVID-19 work, primarily from the public sector, alongside some philanthropic and private sector funding.

In line with investor requirements, CEPI initiated an independent mid-term review. Carried out by external consultants, the review captured CEPI's progress from inception in 2017 to January 2020 in addition to a review of the first six months of CEPI's response to the COVID-19 pandemic. The findings from both reviews fed into the strategy development process.

CEPI's next five year strategy for 2022-2026 was developed during the second half of 2020. This process included intense consultation with over 60 external key stakeholders across multiple sectors, geographies and parts of the vaccine R&D value chain. The Board approved the new five year strategy in Dec 2020 and CEPI is currently developing the implementation plan, with the Investment Case for $3.5 billion launched on 10th March 2021.

CEPI'S MISSION AND THEORY OF CHANGE

CEPI's mission, vision and strategy

Since its launch in 2017, CEPI has established itself as a key player in the global health security ecosystem with its mission to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks, building upon initial successes along the pillars of:

1. improved **preparedness**,

2. improved **response and**

3. improved **sustainability**.

These three pillars support our mission of **a world in which epidemics are no longer a threat to humanity**.

In 2020 CEPI had acted on all three priorities and adapted Key Performance Indicators (KPIs) in all three strategic objective areas to track our progress in responding to the COVID-19 pandemic.

Early in 2020, and in line with the original mission and strategic objective to improve response during outbreaks, CEPI gradually pivoted to responding to COVID-19 as a newly emerging pathogen with epidemic – and pandemic – potential. As the pandemic has unfolded over the year, its impacts have transformed the vaccine development landscape and transformed CEPI as an organisation. The response to the pandemic also revealed what more the world must do to improve national and global health security. In 2020 CEPI found itself well positioned to both respond to the pandemic in kick starting vaccine development, as well as playing a key role in helping to catalyse a global consensus, by weaving together the capabilities and expertise of public and private sectors to enhance global response capacity.

In March 2020, CEPI outlined its ambition in respect of COVID-19 along axes of speed, scale, and access with the aim to develop vaccines against COVID-19, making hundreds of millions of doses available globally. In the second half of 2020, guided by CEPI's experience in priority pathogen and platform technology vaccine development and building on the learnings from the COVID-19 vaccine development efforts, CEPI , together with our coalition partners, developed an ambitious strategy for CEPI's future value proposition in its second business cycle commencing in 2022. The CEPI 2.0 strategy was approved by the Board in December 2020 with an updated vision of a world in which epidemics and pandemics are no longer a threat to humanity and related mission to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. This updated vision and mission statement underpin a new theory of change for CEPI's activities. The next five-year plan (for the period from 2022-2026) sets out the strategic priorities to:

- **prepare** for known epidemic and pandemic threats,
- **transform** the response to the next novel threat, and
- **connect** and enhance global collaboration to build a world that is better equipped to deal with these devastating diseases.

At the time of publication, CEPI had already started work on implementing this strategy, which includes the development of a new results framework. Furthermore, in light of the continuing COVID-19 pandemic and emergence of variants, CEPI has commenced some elements of the new strategy including launching a call for proposals for a broadly protective beta coronavirus vaccine.

[1] Call to Action for funding Rapid COVID-19 Vaccine Development To develop vaccines against COVID-19.

Theory of Change

This report highlights CEPI's progress towards the strategic objectives for the period from 1 January to 31 December, 2020. The following section describes key activities carried out and progress against targets as set out in the results framework for CEPI's core/pre-COVID-19 portfolio (priority pathogens and platform technologies). It also outlines indicators for and CEPI's progress toward objectives in the COVID-19 portfolio which has featured as the dominant programme of activity in 2020.

Figure 1 describes the Theory of Change to support CEPI's mission from 2017 through to 2021 and illustrates how CEPI's activities contribute to higher level objectives such as the UN Sustainable Development Goals (SDGs) through activities, outputs and outcomes. CEPI has developed Key Performance Indicators (KPIs) to track and measure the COVID-19 activities. This was done using the core portfolio KPIs as a guide and adapting for areas that were also applicable for COVID-19. The results framework to capture COVID-19 activities was developed in May-June, 2020. It should be noted that many KPIs from CEPI's pre-COVID-19 portfolio are also relevant to and contribute toward the development of a vaccine against COVID-19, for example those relating to platform technologies, engaging with end-to-end partners or driving efficiencies in the end-to-end spectrum of vaccine development[2].

This report is structured as follows:

- Section 1 describes how CEPI has progressed against the three strategic objectives (namely, improved preparedness, response and sustainability) and the associated indicators. A report on the "core" indicators is followed by a report on progress for COVID-19 indicators under each strategic objective. For each indicator, a Status Box is provided depicting an assessment of whether the 2020 targets have been reached. Supplementary information is provided in a commentary box.
- Section 2 provides a summary of financial information
- Section 3 outlines CEPI's approach to risk management
- Appendices 1-5 provide information on CEPI's organisational structure, human and financial resources, and key governance bodies.

[2] Changes in ACT-A and COVAX will likely require changes to the CEPI COVID-19 related KPIs into the future, given the scope of these structures includes partners to support allocation, distribution and delivery of vaccines which are beyond CEPI's mandate and sphere of influence

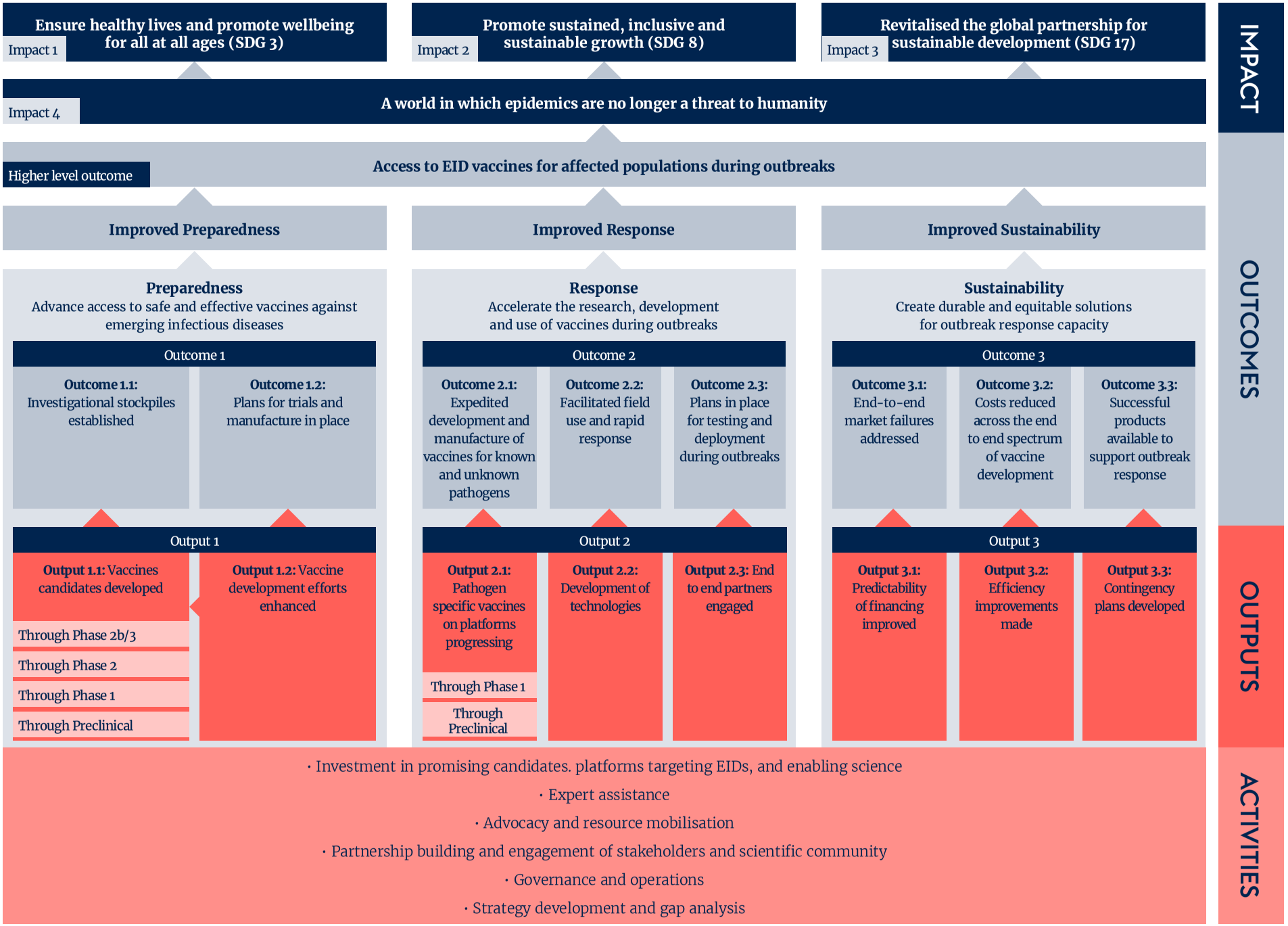


Figure I: CEPI's Theory of Change

1. PROGRESS AGAINST THE STRATEGIC OBJECTIVES

1.1 STRATEGIC OBJECTIVE 1: PREPAREDNESS

CEPI is delivering against its promise to work towards a world in which epidemics are no longer a threat to humanity. CEPI has pioneered the development of vaccines against emerging infectious diseases (EIDs) identified and prioritised in the WHO R&D Blueprint for action to prevent epidemics. By the end of 2020,CEPI had made investments in: 20 vaccines candidates against its five priority pathogens[3], three rapid response platforms to develop vaccines against Disease X, 10 COVID-19 vaccines, and an array of enabling science projects. Through targeted investments in R&D, CEPI has also overseen a number of scientific "firsts", including the first phase 3 trial of a Chikungunya vaccine and the advancement of the first ever Nipah and Lassa virus vaccines into phase 1.

CEPI's funding of priority pathogens and rapid-response vaccine platforms, as well as an agile approach to portfolio management to select and advance vaccine portfolios, enabled the organisation to kick-start vaccine development efforts in response to the emergence of the Covid-19 pandemic in early 2020. As a consequence, CEPI has been able to develop and support one of the world's largest and most diverse COVID-19 vaccine candidate portfolios. In 2020, CEPI, alongside GAVI and the WHO co-established COVAX, which became the vaccines pillar of the ACT-Accelerator (ACT-A). This section highlights the efforts CEPI has undertaken in 2020 to advance access to safe and effective vaccines against emerging infectious diseases. Under this pillar, CEPI's effort includes both the pre COVID/core and COVID portfolio and related activities as follows:

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

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

1.1.1.1. Advance access to safe and effective vaccines against emerging infectious diseases

As of end 2020, CEPI's R&D portfolio consisted of 29 vaccine candidates (for details, see figure 2). This includes: nine active vaccine candidates for COVID-19 including candidates from CEPI's rapid response platform project portfolio; six vaccine candidates for Lassa including a Lassa pilot pathogen candidate from CEPI's rapid response platform project portfolio; five vaccine candidates for MERS including a MERS pilot pathogen candidate from CEPI's rapid response platform project portfolio; four vaccine candidates for Nipah; three vaccine candidates for Chikungunya; and two vaccine candidates for Rift Valley Fever. CEPI's current R&D portfolio also includes three rapid response platforms tested in additional pilot pathogens (figure 2), along with a range of pathogen-specific and cross cutting enabling science activities that support vaccine development and funding activities for Finishing Ebola. As of end 2020, a total of 16 emerging infectious disease vaccine candidates in CEPI's vaccine candidate portfolio were actively being advanced through clinical trials that were either CEPI or self-funded, including: five COVID-19 vaccines in phase II/III or phase III pivotal trials, two of which have received Emergency Use Authorisation (EUA) as well as three COVID-19 vaccines in phase I/II[4] ; three Chikungunya projects in phase II/III; three MERS projects in phase I; two Lassa projects in phase I; one Nipah project in phase I.

[3] Includes: Six Lassa vaccine candidates including one pilot pathogen vaccine candidate through the CureVac rapid response platform project; five MERS vaccine candidates including one pilot pathogen vaccine candidate through the U/Queensland rapid response platform project; four Nipah vaccine candidates; three Chikungunya vaccine candidates; two Rift Valley Fever vaccine candidates.

[4] One of the 11 CEPI-funded COVID-19 vaccine candidates in 2020 was discontinued in December 2020 following the completion of phase 1 trials.

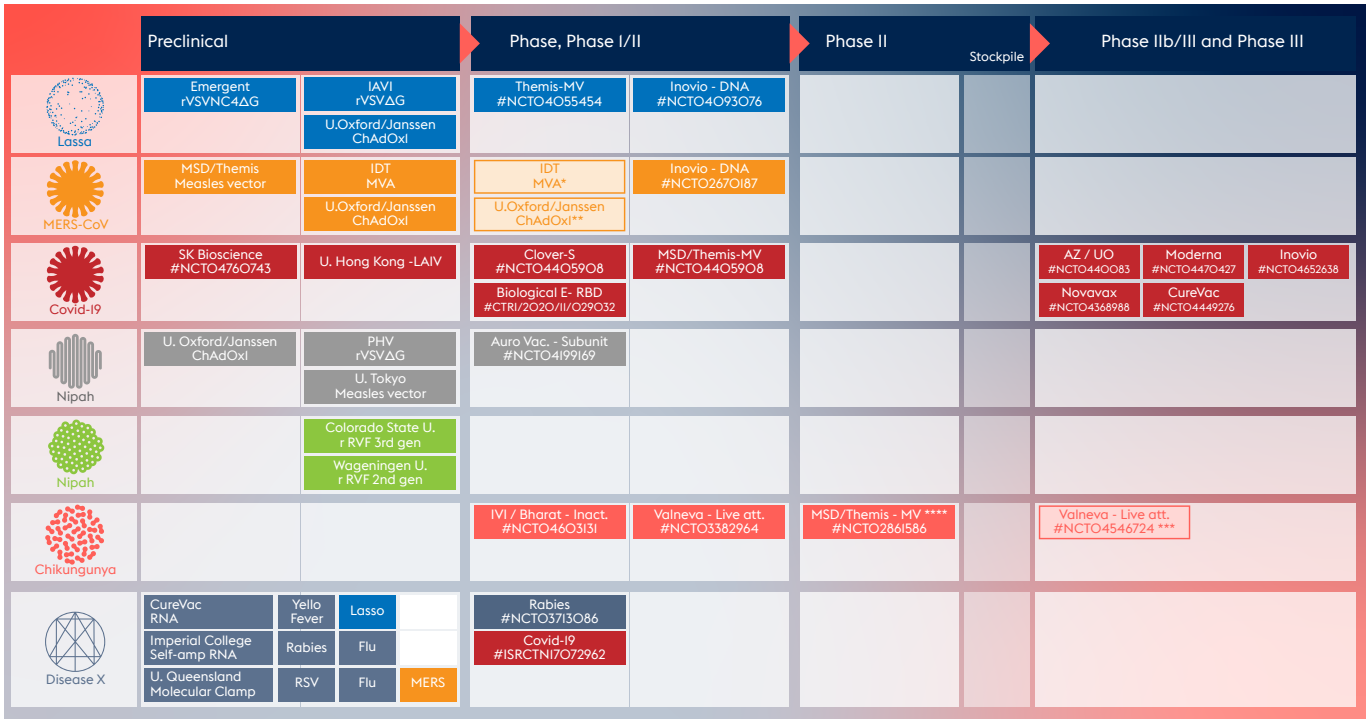
Notable developments for the CEPI-funded pre-COVID-19/core portfolio in 2020 include:

- **Three major vaccine candidate progressions through the clinic:** Valneva initiating a pivotal Phase III study in the US for their Chikungunya candidate; Auro Vaccines (previously Profectus) starting enrolment for a Phase I trial for Nipah; Inovio starting its Phase Ib trial for Lassa in Ghana[5].
- **Five successfully concluded stage gate reviews for vaccine candidate progressions into new clinical development phases**: Inovio-MERS to Phase II; Themis-Lassa to Phase II; IDT-MERS to Phase Ib; IAVI-Lassa to Phase I; Oxford-Nipah to Phase I.
- **Clinical validation of CEPI's rapid response platform portfolio**: CureVac and University of Queensland have received additional funding from CEPI to develop COVID-19 vaccine candidates; while some of the funding provided to Imperial College under CfP2 has been reallocated to Imperial's COVID-19 development efforts. All three projects have accelerated and further advanced the clinical validation of their platforms through COVID-19 vaccine development, despite some delays to their original plans observed due to the pandemic.
- **Expansion of enabling sciences programmes**, including; identification and selection of central coordination partners for the Lassa epidemiology programme and extending the programme to Sierra Leone and Guinea, with ongoing enrolment of subjects in Nigeria since December 2020; signing partnership agreements with BSL-3 and BSL-4 labs for animal model studies; entering into an implementing partner agreement with CSIRO for COVID-19 animal model development; completion of the first MERS antibody working standard; completion of Lassa serological panel and interim reference standard and preliminary validation of Lassa serology assay achieved.
- **Extension of support to "Finishing Ebola" clinical trials and follow-up activities:** Continued commitment to Finishing Ebola in response to the 2019 outbreak, extending support to follow-up activities for both MSD and Janssen vaccines in children (through PREVAC-UP) and for the Janssen vaccine in pregnant women in Rwanda, which has recently been initiated.
- **New project entries & partnerships established, including:** a partnership agreement with IVI-Bharat signed for a third vaccine candidate for Chikungunya, arising from CfP3 with a funding contribution from IndCEPI; MSD acquisition of Themis in June requiring a review of Themis' pipeline and re- alignment with CEPI on vaccine development priorities for Lassa, MERS, and Chikungunya; technology transfer agreement endorsed by CEPI for signature with Instituto Butantan to support LMIC manufacturing of Valneva's Chikungunya vaccine candidate; partnership agreement signed with Integrum for RVF large volume serum collection and serological panel; continued commitment to Finishing Ebola through agreement with Merck for follow-up activities in children (through PREVAC-UP).

On top of its core portfolio milestones, CEPI has made unprecedented progress in advancing a diverse COVID-19 vaccine candidate portfolio through clinical development at pandemic speed (for details see section 2.2.2).

[5] Preparation for dosing, since first dose in patient took place in January 2021

Figure 2: CEPI's portfolio of active R&D projects by development phase as of 31 December 2020



* Funded by the German Center for Infection Research (DZIF)
** Funded by the UK Department of Health

*** Self-funded phase 3 in US
**** Phase III FSFV start depends on the strategic review between Merck and Themis

CEPI is ahead of its overall portfolio targets for 2020 per development phase and, in particular, of its objective of delivering four phase 3 ready vaccine candidates against two or more priority pathogens by end of CEPI's first 5-year funding period (see Table 1). This is despite the delays experienced by CEPI's pre COVID-19/core portfolio projects due to the COVID-19 pandemic, against which CEPI has developed and implemented mitigation strategies and reinforced portfolio monitoring and review efforts. Cognisant of the ongoing impact of the COVID-19 pandemic and of CEPI's transition towards CEPI 2.0, CEPI is currently undertaking a strategic review of its R&D portfolio that will enable it to reinforce portfolio oversight and to anticipate portfolio prioritisation and successful transition towards CEPI 2.0 throughout 2021.

Table 1: Summary of CEPI's vaccine candidate portfolio

Pathogen	Phase	Target 2020	Actual 2020 (+additional successful stage gate reviews)[6]	Comment
"Core" Priority pathogens	Pre-clinical	14	17	The pipeline is progressing broadly as expected but experiencing delays due to the impact of Covid-19.
	Phase 1	8	5 (+4)	
	Phase 2	1	1 (+2)	
	Phase 3/ Licensure	1	1	
Covid-19	Pre-clinical	NA	2	In 2020, CEPI had an additional 9 active Covid-19 vaccine candidates, 7 of which were in clinical development. Some of these projects have upsides for CEPI's "core" priority pathogen pipeline.
	Phase 1/2	NA	3	
	Phase 2/3	NA	2	
	P3/Licensure	NA	3	
Total	Pre-clinical	14	19	Taking into account "core" priority pathogen projects and Covid-19 projects, CEPI is ahead of its 2020 targets.
	Phase 1	8	8 (+4)	
	Phase 2	1	3 (+2)	
	Phase 3/ Licensure	1	4	

[6] Numbers outside the brackets in the 'Actual 2020' column reflect the total number of vaccine candidates being active or having successfully completed development in a given phase by the end of this year. Numbers in brackets in the 'Actual 2020' column indicate the total number of vaccine candidates endorsed by CEPI for progression into the given phase, following on a successful stage gate review during 2020 or previous years, but which have not yet formally initiated this phase in terms of dosing study subjects.

Indicator Output 1.1 (KPI 8)	Pathogen	Phase	Baseline	Target 2020	Actual 2020*	Target 2021	Target 2022	Status
Number of vaccine candidates advanced for each priority pathogen	Lassa	Pre-clinical	0	4	6	4		***On track***
		P1	0	3	2 (+2)	3		
		P2	0		0 (+1)	2	3	
	Nipah	Pre-clinical	1	4	4	4		***Action may be required***
		Phase 1	0	3	1 (+1)	3		
		Phase 2	0	0	0	1	3	
	MERS	Pre-clinical	4	3	5	4		***On track***
		P1	0	2	1 (+1)	3		
		P2	0	1	0 (+1)	1	3	
	CHIKV	Pre-clinical	3	1	0			***On track***
		Phase 1	2		1	1		
		Phase 2	0		1		1	
		Phase 3	0	1	1			
		Licensure.	0		0	1		
	RVF	Pre-clinical	0	2	2	1		***On track***
		Phase 1	2		0	1	2	
		Phase 2	0		0			

Comment on progress in 2020:

For Lassa, Nipah, MERS and RVF, the pipeline is progressing broadly as expected but experiencing delays due to the impact of Covid-19. Based upon successful Stage Gate Reviews in 2020, the PSMB endorsed recommendations to progress: the Inovio-MERS project to Phase II; the Themis-Lassa project to Phase II; the IDT-MERS project to Phase Ib; the IAVI-Lassa project to Phase I; the Oxford-Nipah project to Phase I. The PSMB had also endorsed the progression of Emergent Lassa into phase 1 following on a successful stage gate review in late 2019, but which is yet to start phase 1 because of project delays. Valneva (CHK) initiated self-funded phase 3 in US, while CEPI-funded phase 3 study in adolescents in Brazil to start in 2021.

Overall progress in CEPI's "core" vaccine candidate portfolio has been delayed as a consequence of the COVID-19 pandemic for a number of reasons, including:

(1) supply chain problems / access to materials;

(2) technical/ R&D problems related to access to animal or human trial subjects;

(3) temporary business continuity problems because of Covid-19 response measures and/or re-direction of project resources to Covid-19 response.

Based on an initial impact assessment presented to the Board, providing an understanding of the nature and scale of those impacts, as well as a recently completed scientific and technical review, CEPI is currently undertaking a systematic strategic review of its "core" vaccine candidate portfolio that will enable CEPI to reinforce portfolio oversight and to anticipate portfolio prioritisation and transition towards CEPI 2.0 throughout 2021.

**NB: There are some vaccine candidate development projects that have successfully passed the stage gate to enter the next development phase but have not yet initiated the next phase in terms of dosing study subjects. For a complete overview, these numbers are added as (+SG) in the table above.*

1.1.1.2. Continued work on Ebola

A trigger for CEPI's establishment in 2017 was to support the work towards finishing the job on Ebola with the overall goal of attaining licensure for two or more Ebola vaccines. CEPI's efforts in this area are in line with the following investment principles:

- Aim to achieve the overall goal of attaining licensure for two or more vaccines
- Facilitate licensure through data collection and analysis needed by advancing scientific understanding of immune response and supporting novel or flexible approaches to authorisation and licensure
- Support clinical trials in affected countries including in an outbreak situation when they aim for licensure in certain risk groups and subpopulations, and advance or simplify delivery of vaccine in the field through vaccine-related innovation
- Support a generalisable approach to sustainable manufacturing that includes Ebola vaccines.
- Not to exclusively fund the deployment or delivery of vaccine.

With the COVID-19 pandemic, 2020 was a particularly challenging year in containing the Ebola outbreak in the Democratic Republic of Congo (DRC). In 2020, there were over 3400 cases of Ebola and over 2250 deaths in DRC. In line with the mounting safety of the situation, CEPI continued its work as part of the established global consortium in supporting the DRC Government to introduce a second investigational Ebola vaccine developed by Janssen. After the COVID-19 pandemic hit DRC with the first case confirmed in Goma on 31 March 2020, many activities were paused for up to 6 months. All resumed before end of 2020.

In a major achievement, on 01 July 2020, Janssen received the marketing authorisation from the European Commission[7]. 20 427 people received the first dose, and 14 232 received the second dose of the Janssen Ebola vaccine. On 25th June 2020, the 10th Ebola epidemic was declared over, and its end was celebrated in all of North Kivu. On 1st June 2020 an 11th Ebola outbreak was declared in Equateur province by the Ministry of Public Health of DRC and the WHO. The end of this outbreak was declared on 18th November 2020.

CEPI is also continuing to support from 2018 a trial of the Janssen vaccine in healthcare and frontline workers in Uganda, as well as two trials from 2019 in the Innovative Medicines Initiative (IMI) EBOVAC3 consortium[8] in DRC, Sierra Leone, and Guinea in healthcare workers and infants, respectively. In Uganda, 800 Front Line Workers (FLWs) were enrolled for Janssen vaccine study with 2 years follow-up in Mbarara. For the IMI funded EBOVAC3 consortium, 107 subjects were enrolled for the first study of an Ebola vaccine on infants in Sierra Leone and Guinea, and 700 Health Care Workers (HCWs) as subjects were given the vaccine in DRC.

[7] In 2019, a second vaccine from Janssen was introduced following recommendation from the WHO Strategic Advisory Group of Experts on Immunization (SAGE).

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

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

1.1.2.1. Partnering with at risk countries in planning for clinical trials

Epidemiological studies - such as cross-sectional, case-control, or prospective cohort studies, and mathematical modelling - are essential to addressing key issues in vaccine development. Among many other insights, such studies contribute to our current knowledge of burden of disease, correlates of immunity, strain circulation, and vaccination impact, and facilitate the design and inform the location of vaccine trials. In addition, these studies offer an opportunity to strengthen capacity in priority pathogen-endemic countries by building on national surveillance and ongoing research – while also providing a framework for enhanced laboratory diagnostics and good clinical practice for future vaccine trials.

Anticipating Lassa vaccine candidates to be ready for advanced stage clinical development in 2021/2022, CEPI has made significant progress towards the implementation of a multi-country prospective cohort study in five West African countries[9]. This programme, also known as the Enable Lassa Research Programme, is the result of years of effort by CEPI and its partners in these five countries to address a critical knowledge gap impairing our ability to deliver a vaccine for Lassa fever.

Through the Enable programme, timely pre-COVID-19 investment in laboratory and data management staff/infrastructure capacity - together with improved regional collaboration and coordination and flexible use of CEPI-funded equipment and supplies - has already improved readiness for laboratory activities including COVID-19 analyses and yellow fever. Having such improved diagnostic facilities will not only improve clinical research on these diseases, but also contribute to actionable data for public health decisions in the five countries.

Other key achievements of the Enable programme in 2020 include:

- Signed contracts with all five West African countries
- Completed migration of project implementation from CEPI to four coordination/implementing partners (P-95, Margan Clinical Research Organization, Bernhard Nocht Institute for Tropical Medicine, Epicentre)
- Final preparations for the Enable programme launch in all five countries while also facilitating COVID-19 public health response with use of study supplies and personnel
- Public launch of the Enable programme and study enrolment activities in Nigeria

An anticipated outcome of the investment into the Enable programme is enhanced capability to plan and conduct clinical trials in Lassa fever-affected countries and then inform vaccination strategies.
These capabilities can then be leveraged or amplified, for example by the joint call on vaccines for Lassa fever launched by CEPI and the European & Developing Countries Clinical Trials Partnership (EDCTP) in November 2019. This call aims to support the preparation and conduct of phase 2b/3 clinical trials with the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of novel Lassa virus vaccine candidates in Lassa fever-affected countries.

An investigational vaccine can only help curb an outbreak if the vaccine can be accessed— either through clinical trials, or emergency use provisions. Developing accurate estimates for vaccine manufacturing for stockpile needs and outbreak response for CEPI target pathogens strategies is therefore crucial.

In 2019, CEPI released a CfP for "Epidemiology and vaccine demand curve modelling for CEPI target pathogens" to support our Sustainable Manufacturing efforts for CEPI's priority pathogens. The information gleaned from these reports helped CEPI to better understand potential vaccine impact and paves the ground for more in-depth modelling to inform CEPI's 2.0 Priority Pathogens methodology and manufacturing strategy.

In 2020, CEPI released a tender for a Rift Valley fever (RVF) systematic literature review to inform the RVF vaccine development strategies. Results of this review will be made available in 2021.

[9] The study will estimate age and sex specific incidence of disease and infection in five Lassa fever-affected countries (Benin, Guinea, Liberia, Nigeria, and Sierra Leone)

1.1.2.2. Provisions fit for purpose to support equitable access

CEPI works in many ways to support equitable access: from supporting enabling science that benefits the entire field; enabling manufacture in multiple geographies or at lower cost; to striving for ease of delivery in low-resource settings, CEPI looks at every way possible to develop vaccines in a manner that enables them to be available, affordable and appropriate. From its program selection through development to licensure to manufacturing and in line with its equitable access policy, CEPI requires commitment to actions by its partners which enable affordability and availability of appropriate products to those who need them most. CEPI also works together with other stakeholders in the value chain to pass on the value of those commitments, in particular to those responsible for negotiating price, volume purchase and allocation agreements, as well those engaged in last mile delivery.

With every investment, CEPI's commitment to access focusses on enabling the ultimate delivery of doses to those that need them the most through outcomes that are within CEPI's scope:

- Data available to scientific community on an open access basis
- Enabling science to expedite a broader research agenda
- Products available at an affordable price as close to cost as is sustainable and developed in line with target product profile
- Adequate availability of supply of appropriate products for lower- and middle-income countries
- Manufacturing capacity adequate to meet demand at an affordable price and where possible local to areas where the disease is most likely

To achieve these outcomes, CEPI relies on partners. It can be difficult to tie partners to measurable access commitments early in the development process as not all characteristics of the final product and its manufacturing are known in early stage development, or the partners may have other funding which exceeds CEPI's contribution. CEPI's influence depends on its level of investment, the stage of development of the product in which it invests, and the presence or absence of other investors who may have their own conditions and requirements with regard to access. CEPI therefore reviews its access provisions with partners at pre-determined decision points on continued funding and adds or renegotiates terms, as appropriate, before investing further in development.

CEPI's approach to supporting equitable access is grounded in the following activities:

1. **End –to-end coverage** – coordinating development partners and manufacturers to facilitate procurement and delivery;
2. **Funding and access to development tools** – providing tools and knowledge for developers all over the world to accelerate timelines and make smarter decisions;
3. **Clinical and regulatory advancement** – facilitating regulatory and clinical collaboration across products and geographies;
4. **Manufacturing and supply of doses** – providing for "scale-up" of a developer's existing capacity and "scale-out" to build local capacity and de-risk supply continuity, through expansion of production to other geographies, in particular UMICs and LMICs as well as clinical trial ready-reserves for rapid response to an outbreak even before product licensure;
5. **Pricing** – driving down costs of production through innovation, streamlining development and signing agreements with development partners for affordable pricing of vaccines;
6. **Project continuity** – retaining a public health licence for use if a partner decides not to continue with product development or is in breach of access agreements; and
7. **Access to data and materials** – requiring data sharing, public disclosure of results on an open access basis, and sharing of project materials including animal models to accelerate the field.

Table 2: Examples of CEPI actions that increase access

Affordability for end purchaser	Affordability clauses; where feasible cost or cost plus requirements; risk sharing agreements; commercial benefits sharing agreements; investment in cost–efficient manufacturing platforms; facilitation of voluntary licensing and tech transfer.
Accessibility of science and technologies developed with CEPI investment	Inclusion of tech transfer; sharing of project materials (animal models, standardised assays, biological samples, candidate vaccines; lab structures); sharing of clinical data and results in a timely manner; sharing of lab structures; open access publishing requirement; public health licence;
Availability in LMICs	Requirements for sales to public procurement agents; right to redirect excess capacity; investment in scale out and scale up of high capacity manufacturing; regulatory harmonisation and support for product registration and licensing; investment in ready reserves; requirement that development partners for Phase III trials complete registration in at least one country and have a path to WHO pre-qualification; tech transfer and stand up of local manufacturing; purchase of ancillary supply
Appropriate for target populations	Research and development based on patient need informed target product profiles; attention to storage conditions, methods and routes of administration; user-centred design (fewer injections, thermostability); expansion of clinical trials networks to include low-income countries.

To enable transparency around what is included in its agreements, CEPI regularly publishes access summary reports for its core portfolio and for COVID-19 related investments.

As early as March 2020, CEPI had circulated a concept note for a Fair Allocations of Innovations for Pandemic Relief (FAIR) system to establish a globally fair system for allocating COVID vaccines, which ultimately led to CEPI co-establishing COVAX. Since this early advocacy around equitable access of COVID vaccine, CEPI has continued this access-related work with its investments in COVID-19 vaccines. CEPI's focus has been on starting projects rapidly, securing first rights of refusal to doses for fair allocation, reasonable pricing, and procurement to be passed onto the COVAX Facility. CEPI has also worked to expand manufacturing capacity in multiple geographic regions to provide the greatest hedge against vaccine nationalism, which could prevent countries—without manufacturing capability or resources to purchase vaccine— from having access. The lessons learned from this experience on a global scale will be gathered and used to improve in future.

Indicator Outcome 1.1 (KPI 5)	Baseline	Target 2020	Actual 2020	Status
Number of vaccine candidates in investigational stockpile for outbreak situations and ready for efficacy studies and emergency use	0	0	0	***Action may be required***
Target 2021 0	**Target 2022** At least 4 candidates (total) for at least 2 priority diseases (Lassa, MERS, Nipah, RVF)			

Comment on progress in 2020:

The COVID-19 outbreak has resulted in delays to the 2020 development plans being encountered. Planned commencement of clinical trials were postponed, partners staff re-deployed to focus on COVID-19 programmes and access to manufacturing facilities all contributed to the delays. During 2021 a number of the development projects are scheduled to start Phase II and build stockpiles for outbreak situations. Due to these reasons action may be required to reach the targets for 2022 and this will remain a focus for the Secretariat.

Indicator Outcome 1.2 (KPI 6)	Baseline	Target 2020	Actual 2020	Status
Percent of vaccine Partnership Agreements that have manufacturing plans in place to enable vaccine production in response to an outbreak.	NA	100%*	100%	***On track***
Target 2021 100%	**Target 2022** 100%			

Comment on progress in 2020:

Some Chikungunya programmes have reached this stage of development. Access elements of Chikungunya funding agreements include:

(i) technology transfer to local endemic manufacturing partners to increase vaccine security through additional secondary manufacturing capacity,

(ii) the provision of a rolling stockpile for use at CEPI's direction in an outbreak situation free of charge with replenishment paid at cost; and

(iii) a proportion of doses from any manufacturing run to be used as CEPI directs.

** Subject to completion of phase 1 and transitioning to phase 2.*

Indicator Outcome 1.2 (KPI 7)	Baseline	Target 2020	Actual 2020	Status
Percent of vaccine development partners agreeing to terms that are fully consistent with CEPI's equitable access policy and implementation guidance	**CORE**			
	0	100%	100%	*On track*
	Target 2021 100%		**Target 2022** 100%	
	Comment on progress in 2020: All Core Portfolio vaccine development partners have agreed to terms fully consistent with CEPI's Equitable Access Policy and implementation guidance.			
	COVID-19			
	0	100%	90%	*On track*
	Target 2021 100%		**Target 2022** 100%	
	Comment on progress in 2020: For COVID projects in particular, CEPI's leverage, in terms of access and affordability, is generally related to the phase of development / timing of investment (degree of risk taken on board) and the amount of investment relative to other funding sources and to the company's own investment. In one particular case, the availability of other funding and market opportunity for COVID projects, and a lack of alignment on more specific access provisions, led to CEPI not following its original investment.			

1.1.3. Provides expert assistance and fund enabling science and technologies to enhance vaccine development efforts

1.1.3.1. Accelerating vaccine development through enabling science

Progress within the cross-cutting Enabling Sciences portfolio including the initiation of the multi-country Lassa epidemiology study, initiation and completion of further standards and assays projects, and signing partnership agreements to set up a laboratory network for animal studies. Due to the COVID-19 pandemic CEPI and CEPI partners faced a need to deprioritise many Enabling Science activities initially planned for 2020.

A key achievement in 2020 was the establishment of a first international antibody standard against MERS, in collaboration with International Vaccine Institute and the UK National Institute for Biological Standards and Control. Standard material and assays for Lassa was made available to developers. Collection of Lassa serum for the international standard was achieved despite challenging travel restrictions.

All ongoing projects in the core portfolio continued with minor delays, except for the Nipah serum collection. In addition to COVID-19 related delays, important discussions on sample access and benefits sharing for the Nipah project took longer time than anticipated. Mitigation plans, including collection in multiple countries, was elaborated as back-up. However, delays in this Enabling Science deliverable did not impact the vaccine development projects as these were equally delayed.

Other critical activities were maintained in 2020. These included:

- Task Forces for Lassa, Nipah and MERS continued to be engaged throughout the year;
- a Task Force for Rift Valley Fever was established in January and held regular meetings;
- a Call for Proposals for the collection of Rift Valley fever serum was conducted, led to the initiation of two new projects.
- Regular interactions with members of the Standards and Assays Working Group reporting to the Joint Coordination Group.

Indicator Output 1.2 (KPI 9)	Baseline	Target 2020	Actual 2020	Status
Number of available biological standards and validated assays (including standard operating procedures) for evaluation of vaccine candidates against CEPI's priority pathogens	0	Necessary Biological Standards for evaluation of immune responses against Lassa fever, Nipah and MERS will be developed	Established Biological Standards for Lassa and MERS. Delays in standard development for Nipah	*On track*
Target 2021 First International standard for Lassa adopted by WHO Expert Committee on Biological Standardisation	**Target 2022** Necessary Biological Standards for evaluation of immune responses against Rift Valley Fever; at least one validated assay for each of Lassa fever, Nipah, MERS and Rift Valley Fever will be used for evaluation and comparative measurements of the CEPI supported vaccine projects			
Comment on progress in 2020: Delays in standard development for Nipah is mainly related to discussions on sample access and benefits sharing and has not affected the vaccine development projects.				

On top of the enabling science activity milestones for its core portfolio, CEPI has made substantial progress in developing animal models, developing and validating assays and international antibody standards, and establishing animal testing facility and centralised laboratory networks (for details, see section 2.2.2.).

<table>
<tr><th>Indicator Output 1.2 (KPI 10)</th><th>Baseline</th><th>Target 2020</th><th>Actual 2020</th><th>Status</th></tr>
<tr><td rowspan="8">Percent of vaccine candidates in clinical development (e.g. being tested in humans), with relevant engagement from regional and/or national authorities—including regulators—in at-risk countries</td><td colspan="4">CORE</td></tr>
<tr><td>0</td><td>100% for each disease at every stage</td><td>100%</td><td>On track</td></tr>
<tr><td colspan="2">Target 2021
100% for each disease at every stage</td><td colspan="2">Target 2022
100% for each disease at every stage</td></tr>
<tr><td colspan="4">Comment on progress in 2020:

Despite the impact of COVID-19, a number of projects progressed through to clinical development in at risk countries. It remains a priority to attain the 2021 target</td></tr>
<tr><td colspan="4">COVID-19</td></tr>
<tr><td>N/A</td><td>100% for each disease at every stage</td><td>100%</td><td>On track</td></tr>
<tr><td colspan="4">Target 2021
N/A</td></tr>
<tr><td colspan="4">Comment on progress in 2020:

N/A</td></tr>
</table>

1.2. STRATEGIC OBJECTIVE 2: RESPONSE

Accelerate the research, development and use of vaccines during outbreaks

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

1. Invests in platforms to speed the development and manufacture of vaccines.
2. In 2020 this includes CEPI's response work connected to the COVID-19 pandemic
3. Supports the development of technologies to facilitate field use and rapid response.
4. Engages end-to-end partners to plan for the testing and deployment of vaccines during outbreaks.

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

Vaccine platform technologies refers to a system that uses the same basic vaccine components as a backbone, which can be adapted or built upon for use against different pathogens by inserting new generic or protein sequences. Prior to COVID-19, CEPI had supported the development of new and innovative platform technologies that have the potential to radically accelerate the development and manufacture of vaccines to rapidly respond to future outbreaks of emerging infectious diseases and unknown pathogens, known as "Disease X".

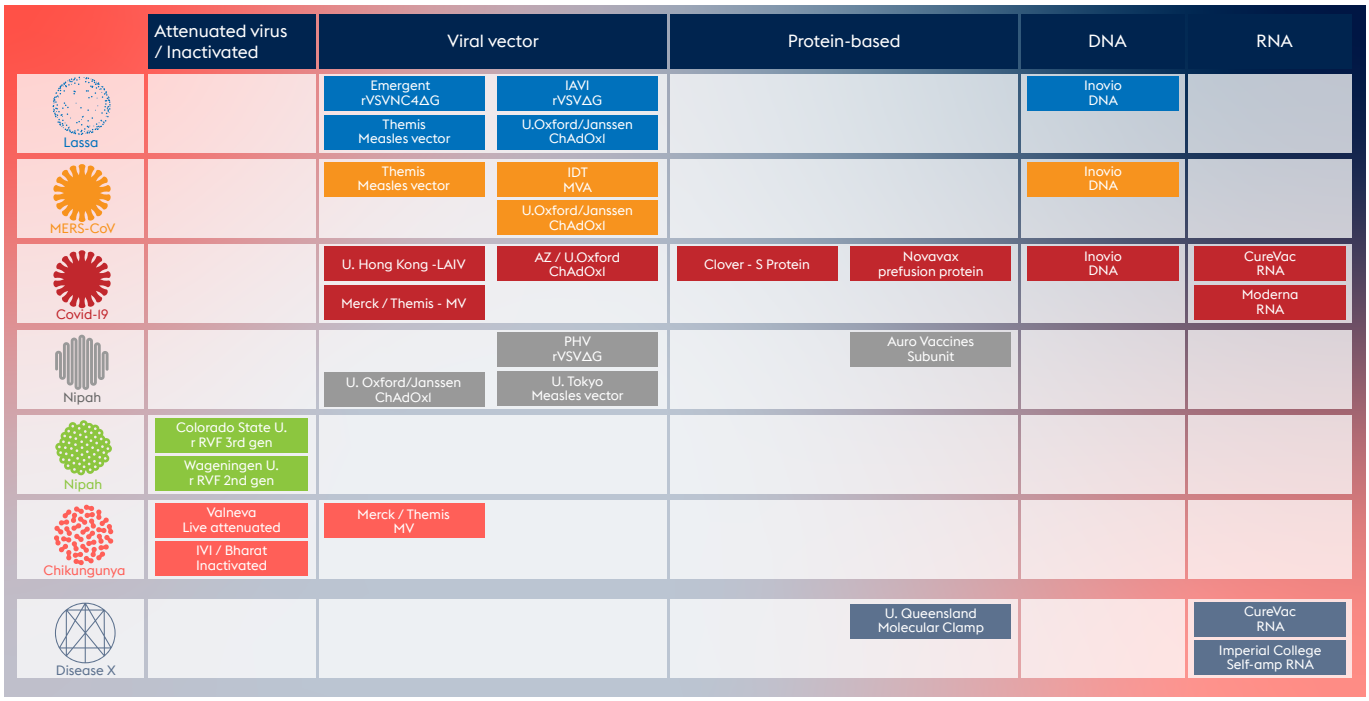
CEPI's "Disease X" portfolio comprised three rapid response platform technologies which have potentially broad application potential with each platform being tested through phase 1 for three diseases. In addition to developing the platform as such, these platforms have the potential for additional vaccines being produced against: influenza (2); rabies (2); MERS (1); Marburg (1); Lassa (1); Respiratory Syncytial Virus (1); yellow fever (1).

In 2020 CEPI leveraged these innovative vaccine approaches as well as technology platforms employed for the development of core pathogen vaccines to advance COVID-19 vaccine development. All three of CEPI's rapid response platform technologies funded through Call for Proposals 2 (CfP2) as well as three platform technologies funded through CfP1 and CfP3 underpinning CEPI's core portfolio were pivoted toward COVID-19 vaccine development. Having the contractual agreements already in place allowed CEPI to rapidly switch their focus to COVID-19 vaccine development early in 2020.

The benefits of this investment should not be underestimated: recent data including from COVID-19 vaccines that use RNA vaccine technology (e.g. BioNtech-Pfizer and Moderna) established proof of concept for the technology including demonstrating up to 95% efficacy. This advancement is paradigm-shifting and has been achieved in record time. These successes are also the result of early investment in MERS coronavirus research, including that funded by CEPI, and two decades of research which has enabled the world to have effective COVID-19 vaccines in less than a year from the time the sequence of the SARS-CoV2 virus was first published.

Standardised platform systems allow the same basic components to be used as a backbone for producing vaccines against different pathogens. Given some of these innovative platforms have resulted in the successful development of safe and effective COVID-19 vaccines at speed, there is a good chance that they can also be used to quickly develop vaccines against other known, and unknown, infectious diseases. Looking to the future, the world needs to expand the breadth of focus and investment beyond coronaviruses extending into all 25 virus families. Starting from 2021 and moving into CEPI's next strategic period (2022-2026) CEPI will focus our efforts on whole virus families – including development of a beta-coronavirus vaccine.

Portfolio overview - CEPI-funded technology platform portfolio



Indicator Outcome 2.1 (KPI 11)	Baseline	Target 2020	Actual 2020	Status
Number of vaccine platform technologies that can be rapidly adapted to develop vaccines against unknown pathogens for use in humans	0	0	0	*On track*

Target 2021 0	**Target 2022** 2 or greater, including at least one novel (innovative) platform (i.e., that has no prototyped licensed vaccine)

Comment on progress in 2020:

Platform technologies underpinning CEPI's core portfolio were utilised for the COVID-19 vaccine development. Having the platform technology agreements in place allowed CEPI to switch focus of those to COVID-19 vaccine development early in 2020. Six projects developing vaccines for CEPI's core pathogens on four of the five platforms currently comprising CEPI's core vaccine R&D portfolio were repurposed to accelerated the development of COVID-19 vaccines.

Standardised platform systems allow the same basic components to be used as a backbone for producing vaccines against different pathogens. With some of the CEPI-funded innovative platforms being shown to have successfully developed safe and effective COVID-19 vaccines at speed, there is a good chance that they can also be used to quickly develop vaccines against other known, and unknown, infectious diseases. The clinical validation of vaccine platforms in CEPI's portfolio represent major upside opportunities, and there will be a focus on leverage knowledge we have now gathered through the work on COVID on CEPI funded platform technologies also for other pathogens.

Indicator Output 2.1 (KPI 14)	Baseline	Target 2020	Actual 2020	Status
Number of vaccine candidates progressing through preclinical and P1 using CEPI funded platform technologies	0	0	3 through preclinical 2 started and 1 successfully finished P1	***On track***
Target 2021 0	**Target 2022** 8 products through preclinical and 6 products progressed through phase 1 by 2022			

Comment on progress in 2020:

CEPI funded platform technologies all diverted to COVID-19 in 2020. Throughout the year, three platform technology developers were able to progress COVID-19 candidates on CEPI-funded platforms through preclinical, and two started and one successfully finished Phase 1. (University of Queensland's COVID-19 vaccine candidate was not progressed into Phase 2/3 clinical trials due to unsuitability for broad deployment; Imperial completed 1 phase 1 study with alternative source of funding and started preparatory activities for phase 1 with funding from CEPI)

*NB: the wording of this Indicator has been slightly modified, from "Number of **CfP2** vaccine candidates" to "Number of vaccines candidates progressing through preclinical and P1 using **CEPI funded platform technologies**, to reflect all platform technologies CEPI is supporting.*

1.2.2. CEPI's response work connected to COVID-19

CEPI's progress under Response is relayed in the following sections and focuses particularly on the work done in CEPI's COVID portfolio in 2020. CEPI has invested in a diverse portfolio of COVID-19 vaccine platform technologies and large-scale manufacturing capabilities with the objective of delivering up to 2 billion doses of vaccine for use globally through COVAX by the end of 2021.

During 2020 CEPI signed 11 partnering agreements to support COVID-19 vaccine candidate development and manufacturing programmes (ten still active, one terminated in December 2020); redirected funds from the Imperial College Disease X / platform project to support Imperial College's COVID-19 vaccine development efforts; and signed a further 17 partnering agreements for cross-cutting enabling sciences activities that support vaccine development. The size and complexity of these R&D investments has been large and given the novelty of the virus and the need to respond at pandemic speed, many investment decisions were taken with a higher tolerance for risk than under traditional circumstances. As CEPI's COVID-19 portfolio transitioned into the COVAX pillar of the ACT-Accelerator, as of July 2020 investment decision-making for the COVID-19 portfolio moved under the responsibility of the Research & Development and Manufacturing Investment Committee (RDMIC) within the COVAX structure.

Notable developments related to CEPI's COVID-19 vaccine R&D portfolio in 2020 include:

- **Accelerated advancement of COVID-19 vaccines through pivotal trials for Emergency Use Authorisation (EUA)**: Throughout 2020, CEPI and its COVAX partners managed to support the unprecedently accelerated development of nine "Wave 1" COVID-19 vaccines through the clinic (i.e. vaccine candidates anticipated to deliver doses to COVAX by December 2021); two of which received EUA, five candidates in phase II/III or Phase III pivotal trials, and one of which was discontinued following completion of phase 1 (CSL/University of Queensland).
- **Optimisation of COVID-19 vaccines to maximise global access potential:** A "Wave 2" portfolio of translational candidates has been established with investment from CEPI and the Bill & Melinda Gates Foundation. By end of 2020, 194 applications for funding had been reviewed, as part of CEPI's second Call for Proposals for COVID-19 (CfP-C2), with two Wave 2 candidates selected by end 2020 with the potential to deliver optimised vaccine profiles (e.g., high volumes, cost advantages, improved thermostability). Funding is intended to progress projects through to clinical validation (end of Phase I), at which stage further investment proposals for full development of promising candidates will be considered by RDMIC.
- **Establishment of a Technology Transfer Oversight group** as a sub-group of the TRG tasked with providing expert technology transfer oversight and input to de-risk technology transfers for current portfolio candidates.
- **Endorsement of a number of enabling activities in support of vaccine development**, including; establishment of a global laboratory network to provide standardized assessment of COVID-19 vaccines; critical support for GISAID to monitor sequence diversity in SARS-CoV-2 by collecting and publishing >100K sequences; harmonized vaccine safety assessments and vaccine safety monitoring standards and tools; pilot project and testing of multidose vaccination solution for pandemic use; investments to secure adequate quantities of medical glass for up to 2 billion doses; funding of LMIC site readiness.

Towards the end of 2020 an increasing number of new variants of SARS-CoV-2 were observed in different regions of the world. CEPI recognised the need to assess the impact of these new variants on vaccine efficacy including variants of the B1.1.7[10] and B1.351 lineages that have rapidly spread to other countries and regions and have overtaken the previous forms to become the dominant lineage circulating in some areas.

CEPI rapidly identified the need to strengthen genomic and antigenic characterisation of SARS-CoV-2 to support vaccine development. To support this, in mid-2020, CEPI made strategic investments in support of genomic surveillance and rapid assessment of emerging variants of SARS-CoV-2 through the setup of two complementary projects:

- GISAID Initiative: to support global genomic surveillance, sharing and analysis of sequencing data (1.3 MUSD)
- Agility: Rapid assessment of biological impact of variants of concern (1.3 MUSD)

[10] Variant of concern 202012/01. Lineage B.1.1.7, also known as 20I/501Y.V1, Variant of Concern 20DEC-01 or commonly as the UK variant, British variant or Kent variant, is a variant of SARS-CoV-2

KPI Outcome & Output 1.1	Baseline	Target 2020	Actual 2020	Status
Number of COVID-19 vaccine candidates advancing through Phase I, Phase II/III, and authorised for distribution (COVID PORTFOLIO)	0	Progress 2 candidates into phase II/III by end 2020, one candidate primary readout by end 2020	5 candidates progressed into phase II/III or phase III (Moderna, Inovio, Novavax, AZ/Uni Oxford, CureVac), two projects that received early funding from CEPIhad primary readouts and received emergency use licensure in 2020 (Moderna and AZ/Uni Oxford)	***On track***

Target 2021
- Progress 10 vaccine candidates through primary analysis of phase I end Q1/2021
- Progress 3 additional with primary readouts by Q3/2021 (based on primary endpoint analysis of pivotal trial)
- Licensed / emergency use - up to 4 by end 2021

Comment on progress in 2020:

Throughout 2020 CEPI signed 11 partnership agreements to support a diverse portfolio of COVID-19 vaccine platform technologies and large-scale manufacturing capabilities. Nine candidates funded under the first wave of investments (Wave 1, i.e., vaccine candidates anticipated to deliver doses by December 2021) entered clinical development in 2020. Five candidates entered advanced clinical development and two were approved for emergency use by the end of 2020. One Wave 1 candidate (CSL/University of Queensland) was terminated after completion of phase 1 in December 2020. Two Wave 2 candidates were actively in preclinical development as of end December 2020.

CEPI has defined and reviewed on an ongoing basis the target composition, diversity, investment allocation and risk profile of the portfolio of COVAX-funded vaccine candidate projects and cross-cutting enabling projects.

Indicator Outcome 1.2	Baseline	Target 2020	Actual 2020	Status
Plans for manufacture of up to hundred million doses for emergency use by end 2020, and up to 2 billion COVID-19 vaccine doses by end 2021	N/A	100%* of partnership agreements have manufacturing plans in place Plans for manufacture of up to hundred million doses for emergency use by end 2020 Manufacturing of clinical trial material for phase II/III trials for 4-6 vaccine candidates by Q3/2020 Initial investment to expand global manufacturing capacity for up to 6 vaccine developers by Q3/2020 Enhancing global manufacturing capacity with tech transfer to scale out geographically distributed locations of up to 3 candidates by Q4/2020	100%* of partnership agreements have manufacturing plans in place Right of first refusal for 1B vaccine doses (as of end 2020) 8 candidates started manufacturing of clinical trial material by Q3 2020. Funding of four candidates specifically included support for the manufacture of clinical trial materials Investments made to 3 vaccine candidates to expand global manufacturing capacity by Q3. Investments made to 3 vaccine candidates to expand capacity with tech transfer to scale out to geographically distributed locations by Q4 Conducted deep-dive tech transfer risk reviews of Novavax, AZ/Oxford and Clover and established Technology Transfer Oversight Team which reports to TRG, with escalation route to RDMIC as needed	***On track***

Target 2021
- 100% of partnership agreements have manufacturing plans in place;
- Plans for manufacture of up to 2 billion doses by end 2021

Comment on progress in 2020:

CEPI is on track to help COVAX secure 2 billion vaccine doses by end of 2021. At the end of 2020, CEPI's investments in the COVAX R&D portfolio could potentially secure right of first refusal for 1B vaccine doses (non-risk adjusted) for the COVAX Facility by the end of 2021[11]

A technology transfer (TT) oversight team was established to evaluate tech transfer plans, risks and mitigation strategies, to conduct routine monitoring of TT progress issues and clinical/regulatory alignment, and to provide oversight/advice for critical TT projects. In 2020, the team conducted deep-dive assessments of three projects (Novavax, AZ/University of Oxford and Clover Biopharmaceuticals).

Complexity of vaccine supply chains requires an overall risk analysis of the vaccine supply chains that will deliver doses to COVAX Facility.

** Subject to completion of phase 1 and transitioning to phase 2.*

[11] https://cepi.net/news_cepi/covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021/

Indicator Outcome 2.2	Baseline	Target 2020	Actual 2020	Status
Number of CEPI-funded vaccine candidates accepted for (rolling) regulatory review (COVID PORTFOLIO)	0	Rolling review/ Regulatory consultation on advanced stage development started for at least 2 vaccine candidates Q4/2020	2	***On track***
Target 2021 Rolling review/Regulatory consultation on advanced stage development started for 4 more vaccine candidates Q2/2021				
Comment on progress in 2020: Two CEPI-funded vaccine candidates progressed through rolling regulatory reviews and received emergency use licensure: by the end of 2020 both Moderna and University of Oxford/ AstraZeneca were licensed under temporary use authorisation in some countries. In 2021, EUL continued to be granted for these two vaccines in many jurisdictions. In the case of University of Oxford/ AstraZeneca, the WHO granted EUL.				

Throughout 2020, an ongoing desk-based exercise took place to keep abreast of the vaccine development landscape across CEPI's core portfolio priority pathogen (MERS, Lassa, Nipah, Chikungunya, RVF).

At the very start of the pandemic, and as part of CEPI's response, a coronavirus vaccine landscape analysis was conducted to identify key platforms and relevant key stakeholders for the COVID-19 response effort. After the initial exercise focusing on MERS and SARS coronavirus, a COVID-19 vaccine landscape exercise (in collaboration with BMGF) was initiated and is being updated on the ongoing basis to:

- Keep abreast of the overall COVID-19 vaccine development landscape, capture key information regarding platform technologies, consortium partners, development stage and other key relevant project profile and plan information.
- Provide inputs/background analysis to the COVID -19 portfolio management cycle, in particular during portfolio monitoring and seeking for new investment opportunities.
- Share the landscape analysis with CEPI key coalition stakeholders and external communications.

This work included publishing high impact research articles using established methodology and insight from COVID-19 landscape exercise (for example "The COVID-19 vaccine development landscape"; and "Evolution of the COVID-19 vaccine development landscape").

The COVID-19 enabling science programme goals for 2020 were met by a large margin. With a global outreach and close collaboration with key partners we signed 17 new implementing partnership agreements to deliver 3 animal models, 5 animal facilities, 7 labs, 3 validated assays, 1 international antibody standard. A Centralised Laboratory Network for standardised assessment of immune response was established with labs in Canada, US, UK, Netherlands, Italy, India and Bangladesh, and is available to any COVID-19 developer. The network laboratories are set up to test pre-clinical and clinical samples using the same methods, key reagents and standards, therefore, removing much of the inter-laboratory variability and allowing for head-to-head comparisons of immune responses induced by multiple vaccine candidates. The network will expand in 2021 for a larger global footprint and with additional assays, notably for new SARS-CoV-2 variants.

Pre-existing partnerships and working relations were critical to rapidly initiate collaborative efforts, such as the development of the international antibody standard with NIBSC. In 2021 we will expand this work to develop working standards for a panel of SARS-CoV-2 variants. A Request for Proposals for animal model laboratories conducted late 2019 was also a huge advantage to rapidly establish the animal model network in 2020. Five of CEPI's vaccines under development for COVID-19 were supported by preclinical studies performed through the animal model network, as well as research into vaccine mediated enhanced disease and basic model refinements. New partnerships are working on COVID-19 and will also contribute to other CEPI-priority pathogens.

In addition to the set goals, CEPI supported global molecular surveillance through the GISAID collaboration and monitoring of virus mutations relevant for vaccines and diagnostics. In a partnership with PHE and NIBSC we set up a framework to evaluate the biological significance of new SARS-CoV-2 variants as a tool to make decisions on the need to develop alternative vaccines. This framework will be further developed in 2021.

The COVID response is characterised by many institutions and countries working on same or similar activities. CEPI has contributed with secondment of scientists to WHO to lead and coordinate WHO working groups. CEPI has close interaction with key partners, such as WHO, BMGF, Path, Operation Warp Speed and members of the Standard and Assays Working Group[12], to coordinate efforts and avoid duplications.

Indicator Output 1.2 (KPI 9)	Baseline	Target 2020	Actual 2020	Status
Number of CEPI-funded validated enabling science programmes available to accelerate preclinical development and evaluation of vaccine candidates against COVID-19	0	1 animal model by end Q3/2020 At least 3 animal testing facilities by end Q2/2020 At least 2 centralised laboratory networks for testing of pre-clinical and clinical samples for CEPI supported vaccine candidates and others by end of Q3/2020 At least 1 validated assay by Q4 2020	3 animal models available in our network (NHP, Hamster, Ferret) 5 animal testing facilities in the Animal Model Network 7 labs in the Centralised Laboratory Network (North America, Europe and Asia) 3 assays validated 1 international antibody standard	***On track***
Target 2021 1 international antibody standard by end Q1/2021				
Comment on progress in 2020: The COVID-19 enabling science programme goals for 2020 were met by a large margin. With a global outreach and close collaboration with key partners we signed 17 new implementing partnership agreements. A Centralised Laboratory Network for standardised assessment of immune response was established with labs in Canada, US, UK, Netherlands, Italy, India and Bangladesh, and is available to any COVID-19 developer. The network laboratories are set up to test pre-clinical and clinical samples using the same methods, key reagents and standards, therefore, removing much of the inter-laboratory variability and allowing for head-to-head comparisons of immune responses induced by multiple vaccine candidates. The network will expand in 2021 for a larger global footprint and with additional assays, notably for new SARS-CoV-2 variants.				

[12] A subgroup of CEPI's JCG (Joint Coordination Group)

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

Throughout 2020, TechTalks have been an informal interaction with developers presenting their technologies, current results of vaccine development in particular vaccine technology platforms. With the COVID-19 pandemic, the main focus has been discussion with developers working on vaccines against SARS-CoV-2. The TechTalks have mainly been around sharing and shaping of ideas and plans and discussions to potentially shape applications or expressions of interest for the active announcement of funding opportunities by CEPI in the form of Call for Proposals. TechTalks have also brought more awareness and understanding of the technologies available globally. For 2021, the TechTalks will continue, and ideally serve as a more regular check in with developers to understand and learn about their technology and results during the development, giving a deeper and more longitudinal understanding and acquaintance with particularly promising technologies and the environments behind them.

Indicator Output 2.2 (KPI 15)	Baseline	Target 2020	Actual 2020	Status
Regular analysis of available technologies and the gaps that currently exist	N/A	Regular analyses on basis of identified need	Regular analyses on basis of identified need	***Not applicable***
Target 2021 Regular analyses on basis of identified need	**Target 2022** Regular analyses on basis of identified need			

Comment on progress in 2020:

In line with the adjusted wording for this indicator, activities in this area are undertaken on the basis of identified need. In 2020, activities included desk-based monitoring of core portfolio priority pathogens; coronavirus landscape mapping and relevant platform input to the early response effort; COVID-19 vaccine landscaping; TechTalks with developers, video/teleconference interaction, CfP preparations, Q&A, awareness.

With the COVID-19 pandemic in 2020, and challenges with new viral mutations, CEPI's focus on Technology Platforms that are versatile and can be modified at speed has shown to be an important feature for the future vaccines we would support to stop new emerging infectious viral diseases.

NB: the wording of this Indicator has been slightly modified. ***Regular analyses*** *are being conducted when required on the basis of an annual portfolio review, new pathogen or new funding opportunity/call for proposal, as opposed to previously aimed for on an* ***annual basis****.*

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

Engaging in end-to-end work has been an ongoing part of CEPI's core portfolio, but the experience of responding to COVID-19 has pushed CEPI to engage in this way as never before. Early in 2020, CEPI advocated for the need for an integrated global solution, to meet the COVID-19 vaccine needs of all countries be they low, middle, or high income.

COVID-19 has changed the world. The global response to the current COVID-19 pandemic clearly revealed the health, social, economic and political consequences of persistent gaps in Emerging Infectious Disease (EID) preparedness and response, particularly with regard to the financing required to secure rapid at-scale and at-risk manufacturing capacity and mechanisms to enable fair and equitable access of vaccines, diagnostics, therapeutics and other critical equipment. COVID-19 has also reshaped the global health ecosystem and also the way CEPI has engaged with end-to-end partners.

Through ACT-A, organisations with related but separate missions are collaborating towards the common goals of accelerating development, production, and equitable access to COVID-19 tests, treatments, and vaccines. Through the vaccine pillar (COVAX), CEPI, alongside Gavi and the World Health Organisation, has offered an 'end-to-end' solution to the challenge of vaccine development, manufacture, and supply. Within COVAX, CEPI holds the primary responsibility for creating an R&D portfolio of COVID-19 vaccines and supporting technology transfer and manufacturing to provide the right of first refusal to vaccines for procurement by the COVAX Facility through its partnering agreements. Over the course of the pandemic, CEPI has played an evolving role throughout the different phases of the response. In line with its mandate and as requested by its Board and Investors, CEPI broadened its funding scope to support late-stage clinical trials and manufacturing, hence engaging in the end-to-end spectrum in an extended manner.

ACT-A and COVAX represent unprecedented level of global cooperation both between multilateral organisations, between multi-lateral organisations and industry, as well as among countries. However, several challenges remain, and COVID-19 will provide useful learnings for the architecture of the ecosystem and end-to-end collaboration in future preparedness and response. Health security is now on the agenda for all governments and all key stakeholders, and it is clear that future preparedness and response will benefit from a clearly financed, coordinated ecosystem with pre-positioned R&D elements as well as clearly defined roles and responsibilities for the various entities.

The global pandemic has impacted CEPI's core portfolio, causing delays to many projects, but also offering opportunities to accelerate progress for some areas of the portfolio, most notably in accelerated clinical validation of rapid response platforms. Moreover, CEPI's close collaboration with all end-to-end partners through COVAX has and will impact also on our broader work with the core portfolio; the strength of our Coalition; as well as our ability to drive the post-pandemic consensus and play a key connecting role within a future ecosystem.

1.2.4.1. Facilitating alignment and coordination

CEPI engages with partners relevant to its mission. This includes work on vaccine development, both those developing the vaccines and upstream and downstream partners. The range of partners CEPI works with extends from our grant awardee partners, to academic and public health institutions, governments, philanthropic, industry, civil society and others.

Of the myriad of end-to-end activities CEPI carried out in 2020, some of the most notable are:

- A continued focus on enabling science, including standardisation of standards and assays as well as establishing an animal model network. Furthermore, CEPI has established a global network of laboratories to centralise assessment of COVID-19 vaccines, with value for future collaboration (the Centralised Laboratory Network).
- As part of CEPIs sustainable manufacturing project, CEPI conducted a global survey of vaccine manufacturers capacity for COVID-19. CEPI is currently exploring a global drug product manufacturing network for future preparedness, with sites in UMICs and LMIC currently being considered.
- Collaboration with the Wellcome Trust and The African Academy of Sciences (AAS), to establish a community engagement project (CEPINET) to strengthen communities and research institutions to expand and deepen existing partnerships, and forge new ones, with the goal of facilitating effective community engagement in Epidemiology studies towards vaccine development against EIDs.
- Collaboration with the European and Developing Country Clinical Trials Partnership (EDCTP) on a project to strengthen regulatory capabilities in 5 West-African countries, with particular focus on general clinical trials capabilities and capacity.

- Collaboration with GISAID to support genomic sequence database for SARS-CoV-2 with improved global outreach and dedicated support to African countries, with potential spillover to core portfolio/ future preparedness.
- CEPI has made its service provider, the Safety Platform for Emergency vaccines (SPEAC) Project of the Task Force for Global Health, available to developers to enhance their regulatory strategy and submissions to licensing agencies as well as to obtain an overall safety database for clinical trials.
- The ENABLE-Lassa fever research programme has established a large, well-functioning and trusted research consortium in West-Africa that can be leveraged for any future clinical trials and capacity strengthening in the region

On stakeholder engagement, highlights include:

- Through COVAX, CEPI has collaborated closely on a day-to-day level with WHO, GAVI, UNICEF, PAHO and regularly with civil society to co-create the best joint mechanisms to enable rapid development, sustainable manufacturing and financing and equitable access
- CEPI has significantly increased its engagement with political leadership both on regional and national levels, with multiple meetings and parliamentary events with key CEPI G7 and G20 investor countries and the African Union and the EU,CEPI has also engaged with the UNITE Parliamentarian network to drive awareness of EID preparedness and response.
- CEPI has strengthened its engagement with multiple industry partners, including International Federation of Pharmaceutical Manufacturers & Association (IFPMA), Developing Countries Vaccine Manufacturing Network (DCVMN), Biotechnology Innovation Organization (BIO) and multiple MNCs.
- CEPI has increased engagement with funders and financial institutions including BMGF, World Economic Forum (WEF), World Bank, regional development banks and the Global Fund for AIDS, TB and malaria.
- CEPI has significantly increased its engagement with Civil Society through COVAX, ensuring CSO representation in 4 CEPI-led scientific workstreams on vaccine development in addition to 6 COVAX workstreams led by WHO and GAVI. Moreover, CEPI contributes to driving the COVAX CSO briefings that gathers ~200 CSO representatives on a regular basis.
- Informing the development of CEPI's strategy for the next business period from 2022-2026, CEPI undertook over 60 external consultations across governments (investors, non-investors, HICs and LMICs), industry, civil society, global health key stakeholders.

Joint Coordination Group

CEPI's key coalition platform for end to end coordination is the Joint Coordination Group (JCG). An institutional roundtable comprised of organisations that have a vested interest in seeing CEPI's vaccines succeed, the JCG met 3 times in 2020 to discuss and troubleshoot the development, licensure and delivery of CEPI's vaccine candidates, as well as the general evolution and gaps in the preparedness and response ecosystem. A thorough analysis and discussion of challenges and gaps in JCG in March 2020 provided very useful insights and contributed to the establishment of ACT-A and COVAX. CEPI has been working closely with most of the JCG partners through COVAX and ACT-A. The regulatory advisory group has been heavily engaged in issues related to Good Manufacturing Practice (GMP), packaging, labelling, barcoding and other Chemistry, manufacturing and Control (CMC) issues. No doubt, the JCG will continue to learn from the lessons of COVAX and ACT-A, including recognising the need to broaden representation on the JCG going forward. The table below outlines the purpose of the JCG working groups (regulatory, sustainable manufacturing and biological standards) and provides an update of their activities in 2020:

Table 3: CEPI's JCG Working Groups

JCG Working Groups	
Purpose of regulatory group	**2020 update**
The primary objective of the CEPI regulatory function, over the course of 2020, has been to build, develop and facilitate regulatory dialogue between industry, regulators and the WHO.	The Regulatory team's active participation and leadership in the following activities have delivered directly to this objective: · direct dialogue has been established with key country and regional regulatory authorities, including the US FDA, European Medicines Agency, WHO, African Vaccines Regulatory Forum etc. · Regulatory advice and guidance are provided to CEPI funded COVID and non-COVID projects via project teams and joint monitoring and assessment groups (JMAGS) · Core membership of all COVAX SWAT teams · Support, leadership and presentation at multiple professional conferences and COVAX workshops Importantly, the gathering of product related issues and insights into developmental challenges has ensured the level of expertise, knowledge and regulatory leadership to establish the COVAX Regulatory Advisory Group (RAG). The RAG has members from Regulatory Agencies covering all regions, including Argentina, Australia, Brazil, Canada, Europe (EMA & EDQM), Ghana, Japan, Singapore and USA and observers from Gavi and UNICEF. The RAG gives feedback on regulatory science questions of a product agnostic nature raised by the COVAX SWAT teams and CEPI's regulatory network, and promotes regulatory preparedness among COVID-19 vaccine developers. The first meeting was held in August 2020 and monthly thereafter. Meetings are co-chaired by CEPI Regulatory Affairs and the WHO, with deliverables published as technical briefs on the WHO website.
Purpose of sustainable manufacturing working group	**2020 update**
This group has been tasked with developing a proposal for a Sustainable Manufacturing solution for the CEPI pathogens taking into account manufacturing/quality, people and infrastructure.	**Accomplishments in the core portfolio:** · Development of epidemiology modelling on 5 CEPI target pathogens: Lassa, MERS, Chikungunya, Rift Valley Virus, Nipah · Development multi-pathogen/multi-facility vaccine supply chain modelling **Accomplishments in the COVID-19 portfolio:** · Launch of an expression of interested (EoI) for mapping Drug Substance/Drug Product (DS/DP) manufacturing capacity · Identification of DS/DP sites with capacity and capabilities to support COVID-19 vaccine manufacturing, facilitate matchmaking with vaccine developers and reserve capacity to ensure fungibility across the portfolio · Reserve vial capacity to ensure vial supply to COVID-19 vaccine manufactures (with priority to COVAX doses) · COVID-19 Manufacturing EoI helped identify a manufacturers corium that forms a network of CEPI contract development and manufacturing organisation (CDMO) collaborators: Biofabri (Spain), Biofarma (Indonesia), Biovac (South Africa), Green Cross Corporation (South Korea), Instituto Butantan (Brazil), LG Chem (South Korea), Thermo Fisher (Italy). Through 2021 the master EoI list (114 Drug Substance and 65 Drug Product CDMOs) will support a Manufacturing Innovation/Capacity working group landscaping of LMIC manufacturing capacity/capability to improve these and epidemic/pandemic vaccine preparedness/response to future outbreaks. · Support COVID-19 vaccine supply chain modelling for dose rollout projections to inform COVAX Research Development Manufacturing Investment Committee · Development and technical assessment of the innovative MedInstill filling and device technology · Harmonise the efforts and request with other players (i.e.: BMGF, PATH, GAVI, UNICEF, WHO) for COVID-19 vaccine development in line with the COVAX strategy · Contribute to the COVAX manufacturing SWAT team · Link to the COVAX delivery team
Purpose of sustainable manufacturing working group	**2020 update**
Co-Chaired by the WHO to stimulate consensus on essential assays, strive for harmonisation and increase transparency.	Work is channelled through disease specific task forces to share advice on bio-standard specifications, assays and data. Groups established for Lassa, Nipah, MERS and RVF. As for COVID-19, the MERS Task Force was initially used as an arena for discussions, before the Enabling Science SWAT team was established. Frequent coordination among Working Group members was important to coordinate standardisation efforts. Interactions with Working Group members has also been instrumental for the coordination of projects prioritised in 2020: Nipah, RVF and COVID-19

Indicator Outcome 2.3 (KPI 12)	Baseline	Target 2020	Actual 2020	Status
Percent of vaccine development partners with necessary agreements in place for vaccines to be deployed and tested during an outbreak or as preventive vaccine (as relevant)	N/A	100%	100%	***On track***

Target 2019-22
100%

Comment on progress in 2020:

All of the projects funded by CEPI involving the core portfolio or COVID-19 have as a core equitable access obligation that vaccines be deployed as necessary and appropriate. That is, deployed as part of a clinical trial during an outbreak and/or deployed as a preventive vaccine allowed by regulatory authorities.

NB: the wording of this indicator has been modified to add in the words "or as preventive vaccine (as relevant).

Indicator Outcome 2.3 (KPI 13)	Baseline	Target 2020	Actual 2020	Status
Percent of vaccine development partners with plans in place for equitable access fully consistent with CEPI's Equitable Access Policy	N/A	100%	100%	***On track***

Target 2019-22
100%

Comment on progress in 2020:

All of the projects funded by CEPI involving the "core portfolio" or COVID-19 vaccines include equitable access requirements as an element in the terms and conditions of the award agreement or as a separate equitable access agreement between CEPI and the awardee.

Indicator Outcome 3.1	Baseline	Target 2020	Actual 2020	Status
Percent of CEPI-funded vaccine development partners with plans in place for equitable access fully consistent with CEPI's Equitable Access Policy and transitioned to the COVID-19 Global Access Facility	0	100% consistent and those deemed appropriate, 100% transitioned to COVAX	90% are consistent and of those deemed appropriate, 100% transitioned to COVAX.	***On track***

Target 2019-22
100% consistent and those deemed appropriate, 100% transitioned to COVAX

Comment on progress in 2020:

CEPI's leverage, in terms of access and affordability, is generally related to the phase of development / timing of investment (degree of risk taken on board) and the amount of investment relative to other funding sources and to the company's own investment. In one particular case, the availability of other funding and market opportunity for COVID projects and a lack of alignment on more specific access provisions led to CEPI not following its original investment. CEPI's portfolio includes the AZ vaccine which was the first Advance Purchase Agreement to be signed by Gavi for the COVAX Facility. Whilst some programmes have been discontinued or fallen behind in timing for technical reasons, more programmes are expected to transition to the COVAX Facility in line with the rights of first refusal to doses found in CEPI's partnering agreements.

1.3. STRATEGIC OBJECTIVE 3: SUSTAINABILITY

Create durable and equitable solutions for outbreak response capacity

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

To ensure that CEPI's approach is sustainable, CEPI

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

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

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

1.3.1.1. Strengthened resource mobilisation efforts

CEPI's swift response to the Covid-19 pandemic, and co-convening role in COVAX, the Vaccine Pillar of ACT A, has amplified the critical and unique role CEPI is able to play in the global health ecosystem in fostering political support from new and existing investors, thereby paving the path to sustainable funding..[13]

In response to its Investment case and call for funding to develop vaccines against COVID-19 launched in March 2020[14] followed by Coronavirus Global Response pledging conferences in June later in the year, CEPI was able to expand its investment base significantly, raising close to 1.5bn including a significant portion earmarked to COVID-19, from existing and new investors[15].

To date, CEPI has secured financial support from the following thirty investors: Australia, Austria, Belgium, the Bill & Melinda Gates Foundation, Canada, Denmark, the European Commission, Ethiopia, Finland, Germany, Hungary, Iceland, Indonesia, Italy, Japan, Kuwait, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Romania, Saudi Arabia, Serbia, Singapore, Switzerland, The Republic of Korea, United Kingdom, USAID, and Wellcome[16].

In addition to securing financial support from the public sector, CEPI was also able to secure support from private sector entities as well as public contributions through the UN Foundation's COVID-19 Solidarity Response Fund.

Because CEPI's mission requires sustainable, ongoing funding to meet its foreseeable needs for financing the development of vaccines, CEPI will employ a replenishment mechanism as the main pillar of its resource mobilisation strategy in particular to mobilise resources from the public sector and to meet the target of USD 3.5bn as laid out in its new Investment case 2022-2026 strategy. Innovative financing mechanisms will also be explored to complement and diversify the replenishment approach, including leveraging International Financing Facility for Immunisation (IFFIm)[17].

As CEPI moves to its next five-year strategy, it will need financing that is:

- **Robust:** able to mobilise sufficient funds of USD 3.5bn to support CEPI's programs throughout 2022-2026
- **Diverse:** ensure funds are diverse in type (Health Security vs Overseas Development Assistance (ODA)) and source (sovereign governments, philanthropies, private sector, high-net-worth individuals)
- **Predictable:** ensure funds are available when needed for both preparedness (just-in-case) and response (just-in-time)
- **Sustainable:** the CEPI funding model should facilitate long-term, non-earmarked financing that is easy to renew.

[13] For the period 2017 – 2020, CEPI received in total USD 1,866 million, of which USD 1,459 million was received in 2020.

[14] https://cepi.net/news_cepi/2-billion-required-to-develop-a-vaccine-against-the-covid-19-virus-2/

[15] 1,487m was raised for Covid and 7,6m for Core

[16] more information on investors to CEPI in 2020 can be found in Appendix 2

[17] The International Financing Mechanism for Immunization (IFFIm) is a financing tool based on bond issuance that has been developed for GAVI – The Vaccine Alliance, but which has shown willingness to consider CEPI as an additional candidate for its financing. For more information see Annex 1.

[18] CEPI will continue to mobilise resources expanding into a whole of government approach, to diversify its funding base within investor markets and seek funding that goes beyond ODA.

1.3.1.2. Alignment of funding and scope with other organisations

Indicator Outcome 3.1 (KPI 16)	Baseline	Target 2020	Actual 2020	Status
Agreements with downstream financing partners in place for each of CEPI's priority diseases (CORE PORTFOLIO)	0	0	0	*Action required*
Target 2021 0	**Target 2022*** 3 (for 3 of these diseases Lassa, Nipah, MERS, Rift Valley Fever and Chikungunya)			
Comment on progress in 2020: The focus in 2020 was on raising funds for COVID-19 given the urgent need. Discussions began in Q1 and were then put on hold around early market assessments and market shaping activities needed to enable investment decisions on the Core Portfolio. COVAX itself provided a live fire exercise for these agreements for COVID-19 vaccines with the establishment of the COVAX Facility and Gavi advance purchase agreements. CEPI also co-chaired the COVAX Taskforce on Indemnity and Liability which finalised an approach to indemnification with manufacturers and participating countries in COVAX (both AMC92 and self-financing countries), launched a compensation mechanism for vaccine recipients in the AMC92 countries that suffer serious adverse events, and a mechanism to provide assistance to AMC92 countries that need it to ensure their domestic legal systems are consistent with the indemnification commitments and the application of the compensation mechanism. *NB: This target is likely to be reduced down to 1 for one of the priority pathogens in the future*				

Indicator Output 3.1 (KPI 17)	Baseline	Target 2020	Actual 2020	Status
$1bn raised as multi-year contributions to CEPI (CORE PORTFOLIO)	$630M	$1BN	$753M	*Action may be required*
Target 2021	**Target 2022***			
Comment on progress in 2020: Extenuating circumstances resulting in delays in core programme progress ought to be noted. In 2020, all efforts were put towards mobilising resources to meet COVID-19 vaccine development and manufacturing needs. 2020 saw a pronounced increase in the total number of sovereign, philanthropic and private sector investors joining the coalition, including several sovereign investors that made contributions to CEPI's core programme in order to be part of CEPI's governance structures. Despite gaining a number of new multi-year financial sovereign contributors to CEPI, the total funds available for the core portfolio are lower than in 2019. Noting that in 2019 we reported MUSD 778, the difference can be explained by a request from one donor to pivot funds towards Covid-19. *NB: This indicator will need review in the next report, given the amount will be rolled into the overall ask and plan for replenishment to fund the next business period from 2022-2026 (to which a budget of BUSD $3.5 is attached).*				

Indicator Output 3.1	Baseline	Target 2020	Actual 2020	Status
Resources fully mobilised to support the R&D&M COVAX investment case (COVID PORTFIOLO)	N/A	$2.1 billion funding for core R&D; $5.7 billion for manufacturing and advanced purchase agreements (mainly recoverable loans, down payments to the COVAX Facility and blended finance; not all funding will flow through CEPI)	$1,479M (rounded 1,5bn) for COVAX R&D	***On track***

Target 2021
USD 1,000,000,000

Comment on progress in 2020:

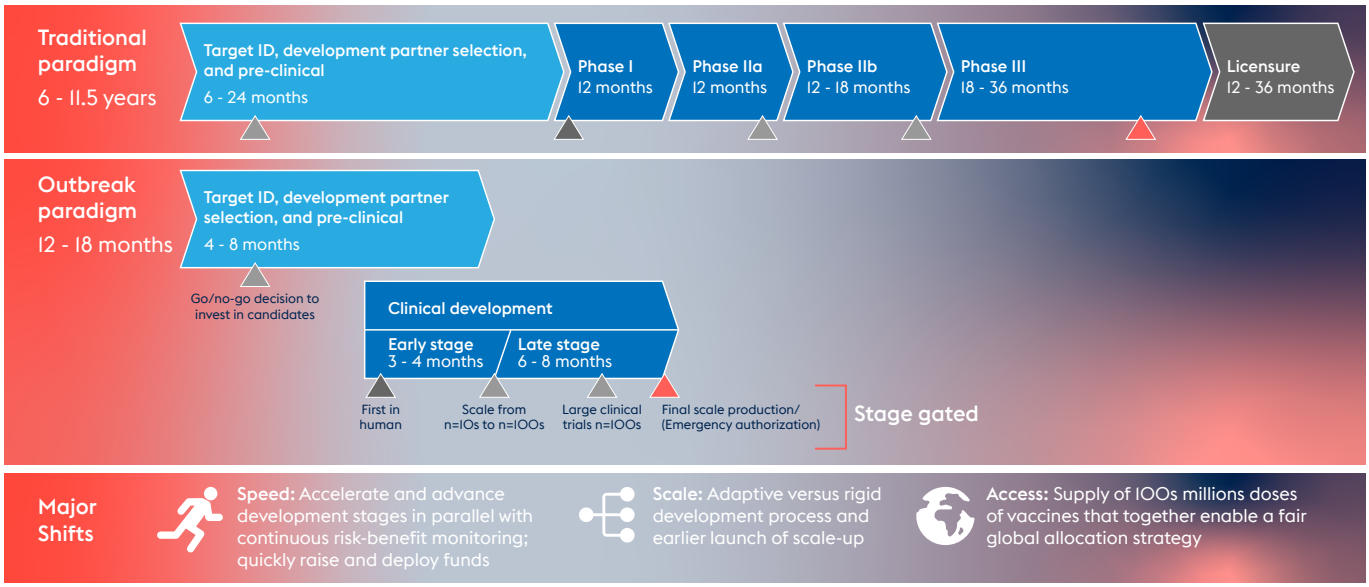
The timely launch of the investment case in early 2020 sought to raise USD2.1 over 18 months. This was followed by the Coronavirus Global Response Pledging Conferences mid-year (May and June 2020) which enabled mobilising of resources from existing as well as new investors. Following up on commitments to ensure that pledges are materialised has required extensive effort. The COVAX facility is facing a large gap in the funding needed with R&D funding also facing shortfalls.

1.3.2. Drives efficiencies to reduce costs across the end-to-end spectrum of vaccine development

CEPI is supporting projects to benefit all vaccine developers with initiatives such as its centralised laboratory network, assessment of vaccine manufacturing capacity, and primary packaging for the storage and delivery of future COVID-19 vaccines. In 2020, there are two areas that CEPI has worked on specifically in this regard; managing our portfolio (including good stewardship of the core and COVID-10 portfolios) and sustainable manufacturing.

In addition, 2020 saw a rapid reduction in the time taken to develop vaccines brought down from several years, as in the traditional paradigm, to less than a year. During COVID-19, the time from the release of the SARS-CoV-2 genetic sequence to the submission of Phase 3 clinical trial data of the first vaccine candidate for regulatory review was 314 days. In 2020, CEPI's supported an unprecedented push to develop COVID-19 vaccines at a speed and scale, while maintaining stringent safety and quality criteria, that enables the world to impact the epidemic and provide equitable access to vaccines for those who need them most.
This was achieved by pursuing three tracks in parallel: speed (developing vaccines rapidly), scale (ensuring they are developed and manufacturing capacity is created to ensure doses can be produced on a vast scale) and access (ensuring the vaccine gets to the populations who need it most), as illustrated in the figure below.

Figure 3: Traditional paradigm vs Outbreak paradigm



1.3.2.1. Managing the portfolio

During 2019 CEPI established core capabilities in R&D project management, risk management and portfolio management to actively monitor and manage the investments made in the portfolio of vaccine projects. These included i) a common portfolio management cycle for systematic project identification, selection, management and evaluation (figure 4); ii) a dedicated portfolio governance committee – the Portfolio Strategy and Management Board (PSMB) – consisting of senior members of the CEPI leadership team and internal technical and subject matter experts); iii) standardised project and portfolio management practices to drive harmonisation and comparability across the portfolio; and iv) clear and consistent management and reporting of project and portfolio information.

Figure 4: CEPI's Portfolio management cycle

These capabilities were further embedded during 2020, and further reinforced by establishing a dedicated R&D Programme Management Office to oversee aligned and disciplined execution of CEPI's vaccine projects. CEPI's approach to portfolio management was also adapted and modified during the COVID-19 pandemic response to enable higher speed and greater flexibility in decision-making relating to COVID-19 portfolio investments.

By the end of 2020 CEPI had signed over 50 partnership agreements to establish a portfolio of vaccine candidates, technology platforms and enabling science programmes with the objectives of:

- Advancing vaccines against "core" (non-COVID-19) priority pathogens through to evidence of safety and efficacy in humans and to generate ready reserves of material
- Establishing a diverse portfolio of rapid response platform technologies that can accelerate development, manufacture, and clinical evaluation of vaccines in response to outbreaks of newly emerging pathogens, designated "Disease X" by WHO.
- Rapidly advancing vaccine candidates against COVID-19 through to licensure and delivery of 2 billion doses of vaccine product for use in emergency conditions globally by the end of 2021.

Portfolio Governance Effectiveness Review

In order to ensure that the PSMB delivers its remit effectively, an effectiveness review was conducted during October / November 2020. This review assessed the extent to which the composition of the PSMB and its positioning in the broader CEPI governance architecture is relevant and appropriate to achieve the PSMB's stated objectives, and the extent to which the PSMB terms of reference are being implemented to facilitate those aims. The main focus of this review was on the full PSMB and its effectiveness in driving decisions and overseeing progress of R&D portfolio investments vis-à-vis CEPI's first five-year strategic objectives. However, a view of the "COVID-19 PSMB" was also provided and lessons that could be drawn from this for more effective PSMB operations in the future.

The review drew insights from consultations with a number of stakeholders (including PSMB members, key presenters, and selected external experts) on PSMB composition, implementation practices, results achieved to date and lessons from the COVID-19 response, as well as from a retrospective analysis of PSMB decision-making. Key findings of this review included:

- **Design:** A positive assessment of the positioning of PSMB within CEPI's governance structure, with appropriate cross-functional composition. A clearer definition of decision-making accountability between governance bodies and ensuring composition does not promote internal bias were highlighted as improvement areas.
- **Operation**: A high level of overall quality of engagement and participation in the PSMB; portfolio materials and analyses; and secretariat support to PSMB operations. Whilst PSMB guidance to project teams is seen as valuable, the review highlighted that PSMB should focus more on overall areas of strategic portfolio importance, and increase scrutiny of projects in terms of delays and budget overruns.
- **Impact:** PSMB has contributed to organisational awareness raising around portfolio considerations of risk, diversity, timelines and budget for oversight and decision-making. PSMB has so far focused on building the portfolio and as such as approved the majority of investment proposals it has reviewed; however, it is acknowledged that PSMB will need to make more difficult project trade-offs and portfolio down-selections in the future.
- **Based on the COVID-19 experience**, the terms of reference for PSMB were adapted to incorporate a mechanism to flexibly adjust operations to an outbreak situation. It is important that PSMB retains a level of flexibility to adapt CEPI's investment priorities to ensure maximum impact in the global preparedness and response ecosystem.

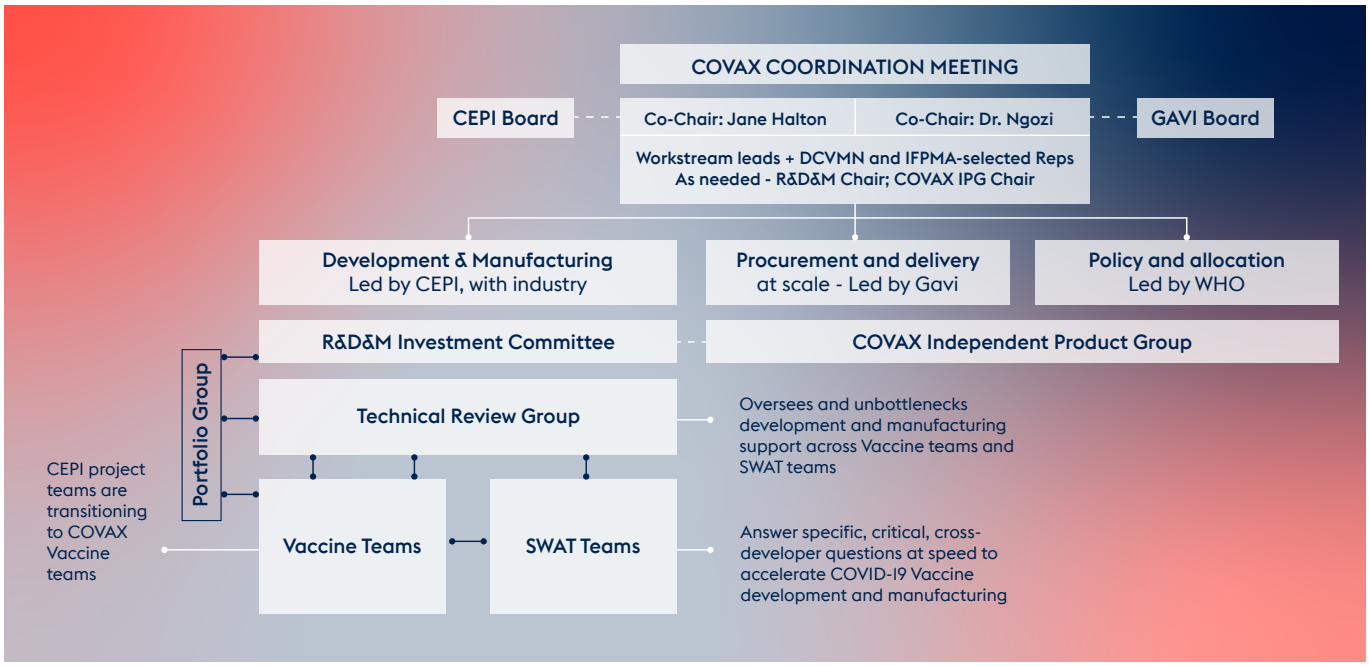
Based on these findings, a set of recommendations to improve PSMB operations have been developed and are being implemented in 2021, including:

- **Portfolio operating model:** Review and reinforce portfolio management cycle decision flow and accountabilities including processes and operations to ensure cross-functional input and the effective representation of non-technical functions.
- **Portfolio governance:** Strengthen decision-making independence and subject-matter expertise by adding external representatives to PSMB and carry out (regular) strategic portfolio reviews to support portfolio decision-making including anticipating future portfolio trade-offs.
- **Information architecture:** Maintain a decision log enabling PSMB to track past decisions and the evolution of project characteristics (e.g. delays and budget overruns) and facilitate access to relevant portfolio information for internal stakeholders.
- **Decision criteria:** Reinforce the portfolio value dimension within the portfolio management cycle and specify short- and longer-term investment priorities that will foster strategic portfolio decision-making.

COVID-19 portfolio management

For the COVID-19 portfolio, given the need to operate at speed under conditions of high uncertainty, CEPI adapted its standard portfolio management framework in the first half of 2020 to enable effective portfolio decision-making in outbreak response mode under the oversight of a dedicated "COVID-19 PSMB", which in addition to core internal PSMB members, also included representatives from the Bill & Melinda Gates Foundation and Wellcome Trust as external observers. The COVID-19 PSMB served as a temporary governance structure within CEPI. As CEPI's COVID-19 portfolio transitioned into the COVAX pillar of the ACT-Accelerator, investment decision-making for the COVID-19 portfolio moved under the responsibility of a new R&D and Manufacturing Investment Committee (RDMIC) within the COVAX structure (figure 5). The RDMIC and associated structures in CEPI came into effect in July 2020. CEPI's Portfolio management team serves as the secretariat for the RDMIC.king.

Figure 5: ACT-Accelerator / COVAX Governance



COVAX governance

The RDMIC is a multidisciplinary decision-making group, led by CEPI with industry expertise that provides portfolio strategy and investment decision recommendations to rapidly identify, develop and manufacture COVID-19 vaccines that can be deployed at scale to address global health needs. To that end, the RDMIC defines the target composition, diversity, investment allocation and risk profile of the COVID-19 R&D portfolio of vaccine candidate projects and cross-cutting enabling projects. It also provides overall oversight of project progress and serves to:

- endorse new projects;
- provide resolution of significant project issues escalated by the Technology Review Group (TRG); and
- endorse recommendations for project progression through stage gates provided by the Technical Review Group.

New project proposals coming to the RDMIC are reviewed from a scientific and technical perspective through the Technical Review Group and associated processes. The RDMIC then reviews these recommendations in the context of the broader portfolio and funds available for investment. In order to achieve the strategic COVID-19 R&D portfolio objectives, RDMIC operates to five priority principles for near-term investment of attention and funding:

- De-risking technology transfers for existing portfolio candidates, especially those likely to contribute significant doses including to LMICs .
- Ensuring investment in adjuvant capacity to optimise number of vaccine doses available from the portfolio.
- Prioritising near-term investment in funding new projects with experienced developers who can commit delivery of >100 million doses by December 2021
- Ringfencing a modest level of investment in a "Wave 2" portfolio of promising early stage technologies, as part of a longer-term strategy to deliver optimised vaccine profiles (but which will not deliver dose volumes by end 2021).
- Strive to maintain different technology platforms and geographic spread of manufacturers within the portfolio to diversify portfolio risk.

Vaccine candidates within the COVID-19 R&D portfolio are assessed for inclusion by the COVAX Facility – the global procurement mechanism of COVAX. The Facility pools the purchasing power from participant countries (including self-financing economies and the Gavi AMC economies) to secure procurement of COVID-19 vaccines from a broad portfolio of promising candidates from the COVID-19 R&D portfolio and other clinical candidates in development.

Gavi has established an Independent Product Group (IPG) to make recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility. The IPG is advisory in nature and serves to make recommendations on vaccine candidate prioritisation and portfolio balance within the overall COVAX Facility portfolio. In order to ensure effective and efficient end-to-end governance between the COVAX R&D portfolio and the COVAX Facility portfolio, activities are currently underway to define clear alignment of decision-making accountabilities, operating procedures and information flows between the RDMIC and the IPG.

As part of the ways of working to support COVID19 vaccine development CEPI established Support Work to Advance Teams (SWATs) in 2020. SWATs are groups of experts focused on resolving technical issues and challenges common across all COVID-19 vaccine development projects to promote and accelerate vaccine development. SWAT core members represent diverse stakeholders in the vaccine development ecosystem, providing expertise in enabling sciences; clinical development and operations; and manufacturing to scale. The Regulatory Advisory Group (RAG) provides guidance for regulatory science challenges and interdependencies escalated by all three SWAT disciplines. The RAG, composed of regulators representing all global regions, works to resolve and provide guidance for harmonised pathways to address regulatory science challenges, in order to accelerate vaccine development.

The objectives for all SWAT teams and the RAG are to:

- Focus on resolving common technical cross project questions and challenges at speed
- Act as an open source of information for COVAX Vaccine Teams (see definition in TRG section, above) and COVID-19 vaccine developers more broadly
- Promote harmonisation and comparability across projects, and
- Bring together different stakeholders and coordinate with other players in the ecosystem to maximise efforts.

The benefits of this organisational structure are such that CEPI envisions that the SWAT/RAG model can be used moving forward with core pathogens to address advanced development challenges, particularly in enabling sciences, regulatory approval pathways and harmonisation. Lessons learned and gaps identified in all SWATs can be leveraged for future response preparedness and the end-to-end process of responding to epidemics and pandemics with our COVAX partners.

1.3.2.2. Sustainable manufacturing and clinical trials

CEPI is working collaboratively with vaccine manufacturers to boost capacity and ensure that vaccines produced out of our investments are made available to COVAX. In 2020 CEPI engaged in a broad approach to 'scaling up' and 'scaling out' manufacturing, which includes supporting technology transfer, reserving manufacturing capacity for CEPI-funded vaccine developers, and securing supplies of materials ahead of time such as glass vials to minimise the number of bottlenecks during the production process.

For example, CEPI has partnered with bioscience facilities SK Bioscience and GC Pharma (in Korea) and Biofabri (in Spain) to reserve manufacturing capacities exclusively for CEPI-supported COVID-19 vaccine candidates. Some of the manufacturing capacity we have reserved is producing doses of the vaccines already secured and announced by COVAX (for example, SK bioscience is already producing AstraZeneca doses that COVAX has announced), as part of the collection of agreements providing a pathway to meet the 2-billion dose initiative aim, while some of the manufacturing capacity will be used to produce additional doses which will also be available to COVAX.

In June 2020, CEPI partnered with Stevanato Group, an Italian-based pharmaceutical glass producer, to secure 100 million medical-grade glass vials that could store and deliver up to 2 billion doses of COVID-19 vaccines. We have kept this partnership broad and flexible as we know that not all COVID-19 vaccine candidates may successfully make their way through the development process. So, through this approach, if vaccine programmes fail, the glass vials can be repurposed to another COVID-19 vaccine programme.

CEPI is also exploring a promising alternative to glass vials, known as the 'vaccine bag'. Similar in style to an IV drip, these devices— which have previously been used to transport and deliver sterile food products— could hold up to 200 doses of future safe and effective vaccines and could be advantageous in terms of their cost and cold-chain footprint (in comparison to glass vials, these vaccine delivery bags are lighter and smaller to store, meaning more doses can be transported at any one time). CEPI is currently seeking to engage a vaccine developer (COVID-19 or other) to run a pilot study to test how these bags could work in national immunisation campaigns.

Indicator Output 3.2 (KPI 18)	Baseline	Target 2020	Actual 2020	Status
Percent of priority actions taken to achieve efficiencies	N/A	50%		***Not applicable***
Target 2019-22 (all business plan years) 50%				
Comment on progress in 2020: Due to pivoting work to COVID-19 early last year, the intended scoping exercise to identify and prioritise actions to drive efficiencies in the end-to-end spectrum did not take place until late in the year 2020. It is therefore difficult to say whether 50% of the priority actions to achieve efficiencies have been reached. Some areas where efficiencies were achieved are outlined below, not at least including COVAX – the vaccine pillar of the Access to COVID-19 Accelerator, working to end the acute phase of the pandemic by the end of 2021 through delivering fair, equitable access to vaccines for every country that participates. *Going forward, CEPI's ambition, in the next business period is to build on the unprecedented R&D and technology gains made in 2020 to compress vaccine development timeline to 100 days.*				

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

From supporting enabling science that benefits the entire field; enabling manufacture in multiple geographies and by different manufacturers to mitigate the risk posed by single source and vaccine nationalism; to striving for ease of delivery in low-resource settings, CEPI looks at every way possible to develop vaccines in a manner that enables them to be available, affordable and accessible. For later stage vaccine candidates against Chikungunya, CEPI is supporting the development of vaccine presentation suitable for endemic countries, has undertaken matchmaking between developers and Contract Development Manufacturing Organisations (CDMO) s, funded scale-out to secondary manufacturers' sites to enable vaccine security and provided support for endemic country licensure and WHO prequalification activities.

CEPI's Chikungunya programmes also include commitments to tiered pricing frameworks that are sustainable for the manufacturer and affordable taking into account the country's income and to seeking appropriate marketing approvals in endemic countries in a reasonable period of time.

Minimising the impact of vaccine nationalism

Whilst the KPI below relates to CEPI's core portfolio CEPI has taken contingency planning for manufacturing further with its COVID portfolio and has reserved manufacturing capacity in geographically diverse locations, funded the inventory build at risk, procurement of raw materials at risk and has provided financial support to scale out manufacturing to multiple sites. Conditions for this financial support has been provided on basis of forgivable loans and on the basis that where R&D efforts fail, prior to the use of materials or capacity that those materials or capacity be fungible between CEPI projects.

Indicator Output 3.3 (KPI 19)	Baseline	Target 2020	Actual 2020	Status
Percent of vaccine Partnership Agreements in place that contain contingency plans for manufacturing (CORE PORTFOLIO)	N/A	100%	100%	*On track*

Target 2019-22 (all business plan years)
100%

Comment on progress in 2020:

All funding agreements for programmes at a sufficiently advanced stage of development contain contingency plans for manufacturing and where the CMC process is established at scale, more than 66% have implemented those plans through additional agreements to scale-out proactively and implement other contingency plans for manufacturing. See Valneva press release on scale-out to Instituto Butantan in February 2021. In all such programmes, CEPI has the right to require technology transfer in circumstances where the awardee is not performing.

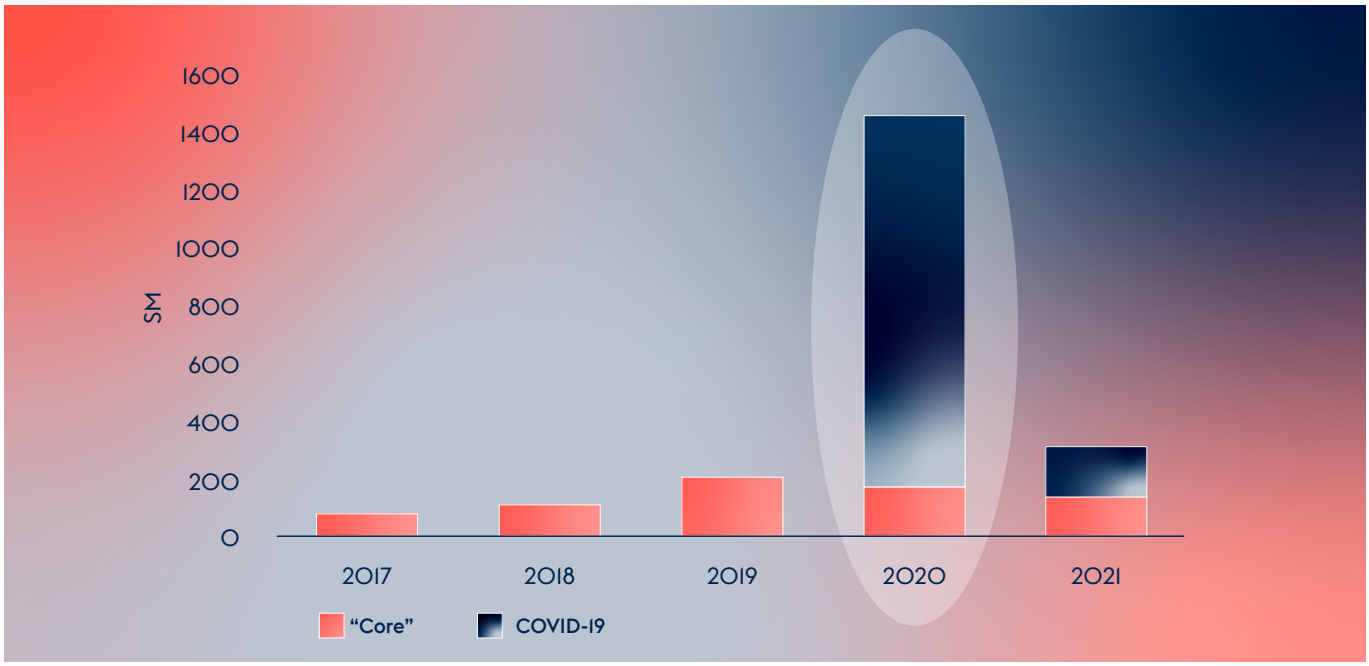
2. FINANCE

The approved budgets for 2020 were quickly outdated, and volatility and complexity in financial monitoring increased significantly compared to previous years. In 2020, CEPI received contributions close to USD$1.5 billion and disbursed $610 million to CEPI's vaccine development partners. Figures presented in this section to 2020 are presented using actual rates, while forecasted figures are presented at Budget 2021 rates. Further details on CEPI finances can be found in Appendix 2: Finance.

2.1. CONTRIBUTIONS

The support from investors is growing significantly, and by year end 2020 more than $2.2 billion had been pledged to CEPI since its launch in 2017. Out of the $2.2 billion pledged for the period 2017 – 2020, CEPI has received a total of $1.9 billion. $1.5 billion of these contribitutions was received in 2020.

Figure 6: Contributions for CEPI 1.0[19]



Out of the $1.5 billion received in 2020, $174 million was for CEPI's "core" portfolio and $1395 million for COVID-19.[20] Contributions for "core" portfolio investments were higher than budgeted by approximately $20 million, driven by several new sovereign investors contributing with "core" funding on top of COVID-19 funds.

The CEPI Board has allowed for a substantial redirection of "core" funding to COVID-19 investments. Part of these funds ($110 million) have been permanently repurposed and further funding reallocation are continuously reviewed.[21] The repurposed funds have not been spent during 2020.

CEPI receives contributions from sovereign investors, the EC and private organisation and philanthropies. Public investors represent the largest investor group and during 2020, 23 new sovereign investors joined the coalition. Overall CEPI now has pledges from more than 30 countries.

[19] This figure shows the funds received to December 2020 and the amount anticipated to be received in 2021. Out of total pledges, $55m are due to be received in CEPI's upcoming strategic period (CEPI 2.0) starting 2022.

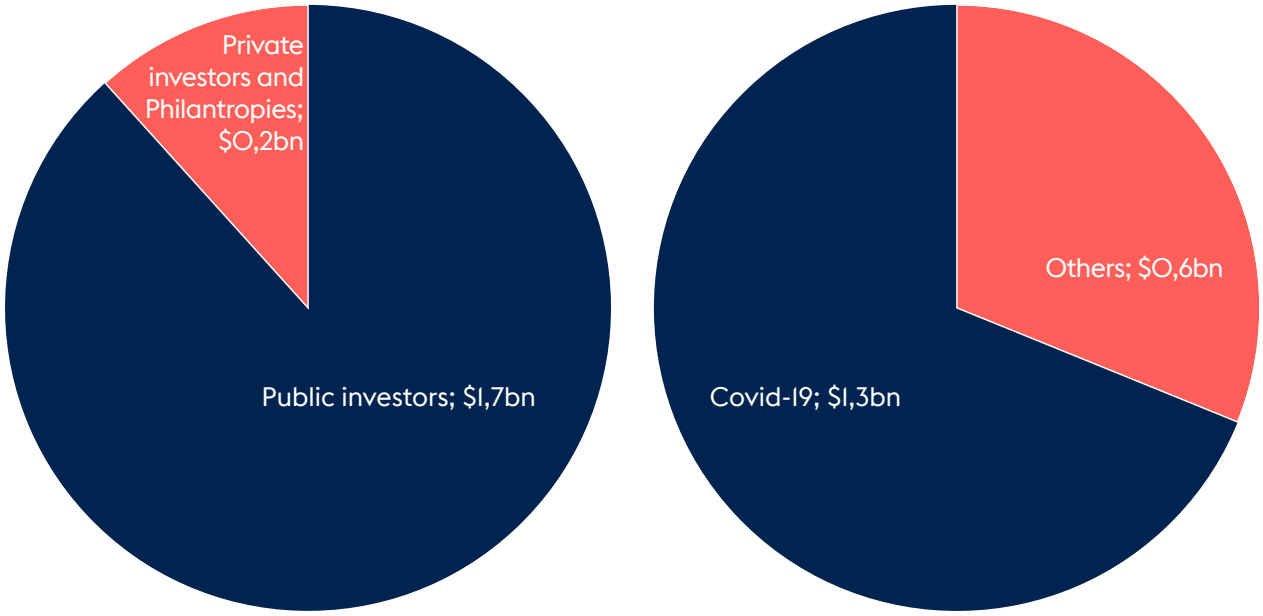
[20] "Core" refers to CEPI's pre Covid-19 investment priorities. Included in "Core" are earmarked EC funds (Horizon 2020) for Chikungunya, Rift Valley and Ebola, and funding for Ebola from Wellcome Trust and the Paul G. Family Foundation. Covid-19 funds are either earmarked through contract, or funds intended for COVID-19 investments.

[21] The repurposing of $110m in funds has been offset by equivalent reduction in future non-committed investment budgets.

The overall number of individual investors has grown from 14 by end of 2019, to 74 by the end of 2020[22]. Traditionally, most donations have been pledged to CEPI's common pool of funds, while in 2020 there has been a need for earmarked funding due to COVID-19.

Earmarked funds are pooled and spent on eligible pool of projects, whilst also considering ODA eligibility, contractual requirements, and the relative size of the donation.

Figure 7: Total contributions 2017-2020



2.2. R&D PROJECT INVESTMENTS

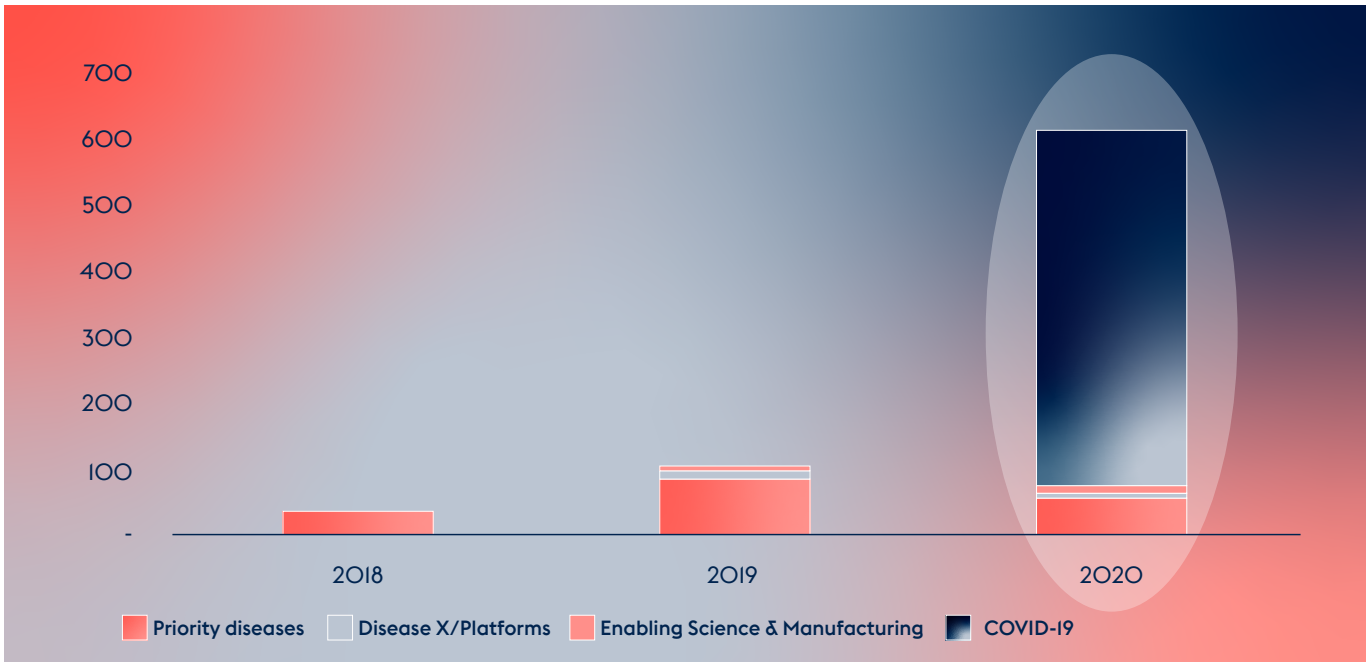
During 2020, CEPI made commitments to invest $1,2 billion in COVID-19 vaccine development. Out of this, $536 million was disbursed during 2020. Actual investments/disbursements are made in tranches, dependent on completion of pre-specified project milestones. In addition to R&D investments in CEPI's COVID-19 vaccine candidates, the amount invested in 2020 also includes reservation fees for manufacturing capacity and raw materials, and cross-cutting investments for Enabling Science and Enabling Manufacturing.[23]

The pandemic has caused significant delays to CEPI's "core" portfolio and projects, reflected in adjusted project timelines and reduced forecasts throughout the year. Out of a budget of $227 million, only $74 million was paid out during 2020. Part of this relates to the fact that CEPI did not go ahead with the planned call for Platform projects/Disease X (partly redirected to COVID-19), part of it relates to normal delays compared to project plans (administrative delays in reporting and late disbursement requests from CEPI's awardees), but a major part is a direct effect of the pandemic (eg, lock-downs, supply issues, shifting focus towards COVID-19 etc.).

[22] Including sovereign, philanthropic and private sector contributors

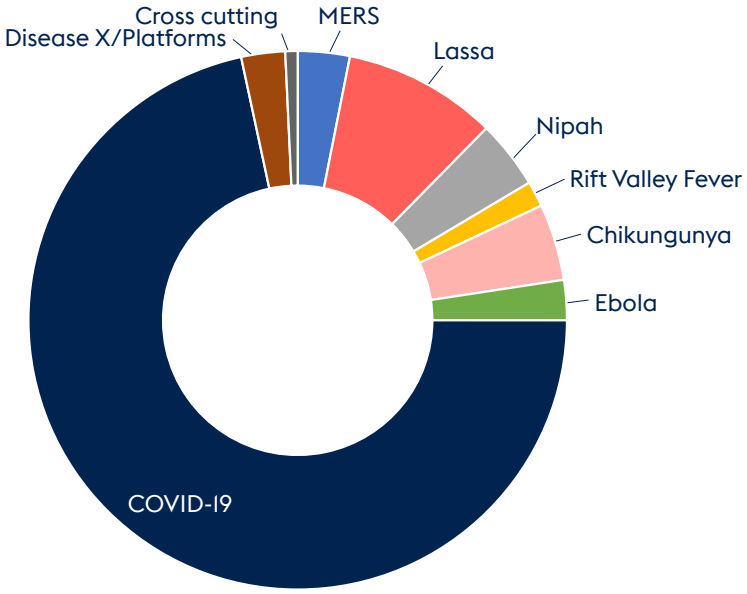
[23] Enabling Science and Enabling Manufacturing projects for COVID-19 includes Animal models, Clinical studies, Diagnostics, Epidemiology, the Centralized Lab initiative, and adjuvants.

Figure 8: R&D project investments 2018-2020



Including COVID-19, CEPI has invested a total of $749 million in R&D vaccine development since the first payment was made in Q2 2018, of which $213 million relates to CEPI's "core" portfolio. Apart from COVID-19, the largest investments have so far been in Lassa and Platform /Disease X projects.

Figure 9: R&D project investments Lifetime-To-Date (2018-2020)



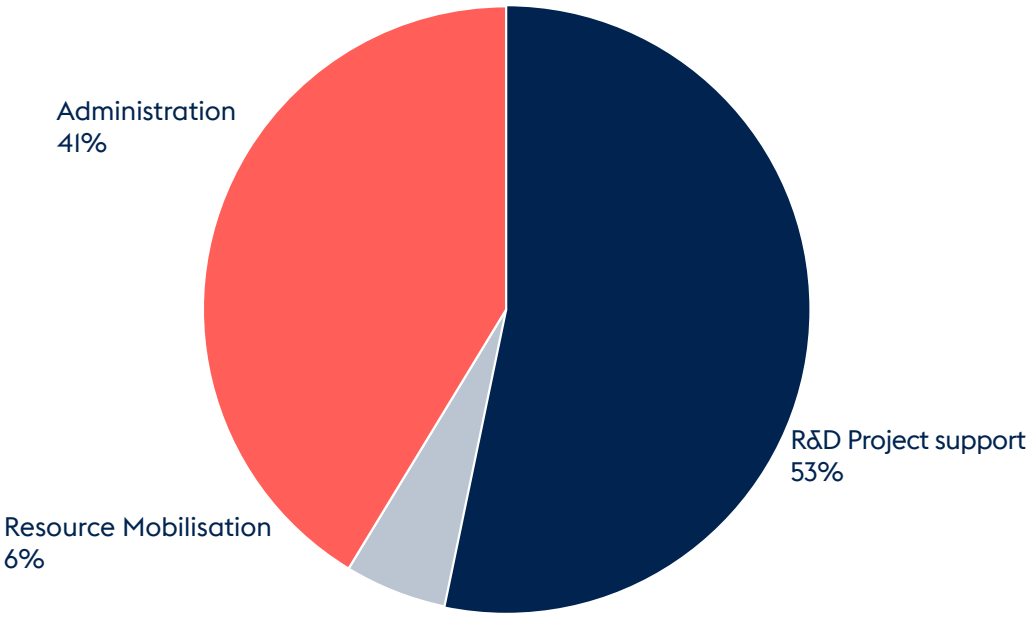
The overall approved plan for CEPI 1.0 and CEPI's "core" portfolio investments totalled to $770 million by year-end 2020 and investments will stretch into CEPI's next strategic period starting in 2022. This total figure includes attrition-adjusted current portfolio budgets, contingency, and placeholders for future investments. To date, CEPI has entered partnership agreements with a total investment value up to $725 million to support its "core" R&D portfolio (excluding contingency). Most of these investments are longer term, multi-phase investments, not all of which are expected to be committed, as these will be contingent on key milestones that candidates will have to meet as they transition between phases of development. A significant funding gap for progressing CEPI's priority pathogen portfolio has materialised and will require backfilling from future fundraising for CEPI 2.0.

2.3. OPERATING COSTS

Not only is CEPI's portfolio growing, the number of staff has also increased significantly during 2020. Operating costs amounted to $34.9 million in 2020, up by 47% from 2019 and $2.3 million above the 2020 budget. The increase was a direct effect of CEPI's response to COVID-19 and was communicated and approved by the CEPI Board early in the year.

Operating costs are depicted by activity and refers to whether an expense is channelled towards R&D project support, Resource Mobilisation[24] or Administration[25]. This provides insight into whether operating expenses are directed towards adding value to the portfolio of investments through project support, or to manage the organisation or raising funds, the last two typically labelled overhead costs. 53% of CEPI's operating costs are R&D project support.

Figure 10: Operating costs 2020 by activity ($34.9 million)



2.4. TOTAL COSTS

Looking at total costs and investments for 2020 leaves CEPI with a spend of 97.5% on its main activity, vaccine Research & Development, while 2.5% goes to overhead (Resource Mobilisation and Administration).

The indirect cost rate is 2.6%.

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

[25] Shared costs like IT, Office facilities, Finance & Operations and HR are not distributed to the different activities but are fully included under Administration. Total shared costs for 2020 were $4.9m.

2.5 PROCUREMENT

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 (lowest-level/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.

During 2020 the focus has shifted from documenting procedures and raising awareness around them in the organisation, to strengthening the procurement capability, more specific developments in the areas of: people & skills, processes, and system support.

CEPI has strengthened the team by hiring an Operations and Procurement Manager with dedicated responsibility for implementing and improving the procedures, as well as overseeing that procurements are made according to its guidance. The procurement team has now a strong focus on cross-functional collaboration and knowledge sharing, as well as on acquiring new skills, relevant to the job.

Furthermore, we have mapped procurement processes and harmonised the ways of working across CEPI locations, as well as clarified roles and responsibilities between procurement, legal, compliance and the business units. CEPI has also invested in the implementation of a contracts repository tool that will improve our controls within procurement throughout the full life cycle of the contracts. The new tool enables the procurement managers to store and track signed contracts and control that we always have valid contracts for our purchases.

During 2020, around 39 procurements were undertaken and completed in accordance with CEPI's Procurement Procedure. Table 4 below gives an overview of the different levels CEPI works with across the different procurement processes, according to estimated value.

Table 4: Overview of procurement thresholds

Type of procurement process
Lowest-level Procurement (value below NOK 100.000)/
Simple Procurement (value between NOK 100.000 – 500.000)
Full Tender (value above NOK 500.000)

3. RISK MANAGEMENT

The governing and monitoring of CEPI are carried out by the CEPI Board, the Board Audit and Risk Committee, the CEPI Leadership Team, with the support of the Governance, Risk and Compliance function (GRC). Risk management, compliance and internal audit processes are key components in assuring that proper governance and monitoring are in place and continuously improved in CEPI.

3.1. RISK MANAGEMENT

CEPI's risk management framework is designed to manage risks in order to achieve the coalition's strategic objectives. The framework provides reasonable, but not absolute, assurance for CEPI to reach its goals, through processes and activities embedded in the Secretariat and the governing bodies of the coalition. Further, the framework enables and supports effective and informed decision-making across all levels of the organisation. Risk management in CEPI means dealing with risks in a transparent, consistent and continuous manner, providing a better understanding of the nature of the risks and their likely impact, and implementing and monitoring appropriate mitigating measures.

The evolved role CEPI has taken in context of the COVID-19 pandemic, has put CEPI as one of the central actors in the global efforts to respond to the pandemic. With the amplified level of visibility, CEPI is subject to increased expectations and scrutiny. CEPI's risk management framework has been a crucial tool to handle the impact of COVID-19 risks in the organisation. Through several scenario assessment exercises did CEPI Management identify major risks to CEPI related to its work responding to the pandemic, which had to be addressed in a rapidly manner. In accordance with CEPI's risk management methodology, clear ownership for each of those risks have been assigned, mitigating measures have been defined, implemented, monitored, and updated on a regular basis. The risks and progress on implementing mitigating measures have been reported to and discussed with the CEPI's Audit and Risk Committee, as part of the regular risk management reporting.

In September 2020 the CEPI Board discussed organisational risks relevant to CEPI in its annual risk review.

In addition to manage the COVID-19 risks, CEPI has continued to further strengthen and integrate risk management in CEPI's operations as well as improving the risk management methodology.

- In 2020, risk management was an integrated part of developing the CEPI wide plan and priorities for 2021 and plans for all departments in CEPI. The purpose has been to reflect risks and mitigating measures when considering key priorities in the 2021 overall plan for CEPI, as well as for the plans at department level.
- The risk management procedure has been further developed. The updated procedure includes a description of the three main risk management processes: organisational risk management, portfolio risk management, and project risk management. The procedure has also been updated with improved descriptions of how to conduct risk management workshops, improved likelihood and consequence scales.
- The continuous tracking of portfolio and project risks informs the management- and decision-making processes.

The organisational risk register includes a "Top CEPI risks overview" – as assessed by the Leadership Team based on the feedback from each team. At the end of 2020, the following risks were CEPI's top risks:

Table 5: List of CEPI's top risks

Risk category	Risk	Impact	Probability	Risk score (gross risk)	Level of control
Strategic	Mission execution - inability to ensure equitable access	4	4	16	3
Strategic	Funding risk - CEPI not achieving its funding target	5	4	20	3
Operational	Cyber security risk	4	5	20	3
Strategic	CEPI not delivering on its core portfolio - not developing safe and effective vaccines five years after launch	5	4	30	3
Operational	Staffing capacity	5	4	20	3
Legal & Compliance	Abuse of power - fraud, misconduct, and mismanagement of funds	5	3	15	3
Program	COVID-19 outbreak portfolio size and composition risk	5	3	15	3
Operational	Lack of objective decision-making - inability to make effective portfolio entry/progression decisions	4	4	16	3

Level of control as guidance to review risk after migration

Level 1: MONITOR Keep your eye on	**Level 2: EVALUATE** Evaluate controls	**Level 3: AUDIT/ASSURANCE** Ensure that controls work	**Level 1: MITIGATE** Additional actions to mitigate risk

3.2. COMPLIANCE

CEPI continued to improve the compliance program and implemented and further developed and formalised compliance activities in 2020. This section addresses activities undertaken and developments throughout the year:

- Policy management: CEPI's current policy framework is comprehensive and covers a broad range of organisational subjects. To further strengthen the policy framework, as well as ensuring that changes in both CEPI's external and internal environment are reflected in the policies, a policy management procedure was introduced in 2020. One of the key elements is implementing a review process of all relevant policies and procedures to ensure necessary updates and that CEPI personnel receive relevant training. The policy review will be undertaken in Q1 2021 and will be an annual process going forward.
- Awardee management: In 2020, a due diligence procedure, entailing the Technical Due Diligence, Integrity Due Diligence (IDD), Governance Due Diligence and Financial Due Diligence (FDD) processes, has been developed. The procedure is codifying existing work practice. Moreover, CEPI completed a tender process for a screening and monitoring tool to further strengthen the IDD and the FDD process, including improved compliance with the US Foreign Corrupt Practices Act (FCPA), UK Bribery Act and the Norwegian Penal Code. The tool will be implemented in Q1 2021.
- Sanction compliance program: To ensure compliance with sanction regimes, in particular the US, EU, UK, and the UN regimes, as well as complying with investor requirements, CEPI started developing a sanctions compliance program. The screening and monitoring tool (mentioned under awardee management) will further strengthen CEPI's process to identify sanctioned entities and individuals.
- Business integrity training: In 2020, all staff was trained in business integrity. The training addressed topics such as code of conduct, modern slavery, corruption and bribery, gifts and hospitality, confidential information, whistleblowing, and sanction requirements.

3.3. INTERNAL AUDIT

The Internal Audit Function reports to the Leadership Team for operational purposes and to the Board Audit and Risk Committee for its oversight role. Internal audit plays a role in assisting the Leadership Team and Audit and Risk Committee in the performance and discharge of their functions and duties. In 2020, the internal audit activities continued to focus on CEPI awardee activities by carrying out seven awardee audits in total. The awardee audit activities identified relevant findings and areas of improvement to be resolved and implemented by awardee management. The recommended improvements are outlined in the form of an action plan and agreed with awardee management to facilitate continuous improvement of the awardee's management of granted funds. CEPI monitors the status of the awardee's progress on the agreed upon action plan until the action items are considered effectively implemented or resolved.

APPENDIX 1: ORGANISATIONAL UPDATE

Incident Management Team

The Incident Management Team (IMT) was formed in mid-January to manage CEPI's response to the COVID-19 epidemic that would soon evolve to a global pandemic. Most members were formerly part of the Rapid Response Steering Committee who were responsible for the preparedness planning for emergency response for CEPI's core pathogens and Disease X. Led by Nicole Lurie, the overarching goal of the IMT within CEPI was to advance development to large scale manufacture of one to three vaccines that can be used under emergency use conditions in line with a fair global allocation mechanism to help curtail the epidemic in countries that most need vaccine. To ensure alignment and integration of priority efforts towards agreed goals, 5 pillars were established to lead activities in (1) R&D operations and logistics, (2) Stakeholder Relations and Governance (3) Planning (4) Resource Mobilisation and (5) Administration and Finance. The pillars drove actions towards 6 main goals:

1. Maintain a diversified and robust portfolio
2. Support developer needs to be successful
3. Mobilise sufficient resources to deliver on our main mission
4. Protects safety and well-being of staff
5. Protect CEPI's mission and reputation
6. Capture lessons learned to inform and development of CEPI's post-pandemic strategy.

As the COVID-19 response developed into "standard business" for the organisation in 2020, the IMT morphed into the COVAX Coordination Team (CCT) without pillars, so as to move business processes back into the ordinary line-management structure.

Independent mid term review

In line with investor requirements, CEPI initiated an independent mid-term review in early 2020. Carried out by external consultants, the review captured CEPI's progress from inception in 2017 to January 2020 in addition to a review of the first six months of CEPI's response to the COVID-19 pandemic. The findings from both reviews fed into the strategy development process. Process was conducted by independent consultants MM Global Health consulting to assess CEPI's organization's design, implementation, and interim results of CEPI's operations during its first three years of business cycle. The report has two components: a review of CEPI's performance from 2017 to 2019 and a separate reflection on the first 6 months of CEPI's response to the COVID019 pandemic in 2020.

The report reflects the input of a wide range of external stakeholders and identifies areas where CEPI has done well and where there are opportunities for improvement. The Report from the review and a note on how CEPI has incorporated key MTR findings into the new strategy and how we plan to address areas for improvement in our execution plan will be uploaded on the CEPI website in Q2 2021.

APPENDIX 2: FINANCE

Contributions

Table 6: Contributions received in 2020 in USD $

$M Investors	2020
Australia	5.3
Austria	1.2
Belgium	5.4
Canada	30.3
Denmark	1.4
Ethiopia	0.1
Finland	4.3
Germany	268.4
Hungary	0.8
Indonesia	1.0
Italy	6.0
Japan	121.3
Kuwait	10.0
Lithuania	0.1
Luxembourg	0.9
Mexico	0.6
Netherlands	58.6
Norway	247.3
Romania	0.2
Saudia Arabia	140.0
Serbia	1.2
Singapore	0.8
South Korea	3.0
Switzerland	10.3
The United Kingdom	308.3
European Commission	102.3
Total Public	**1329,3**
Avast	8.0
Bill and Melinda Gates Foundation	40.0
Fidelity Charitable gift funds	1.5
Goldman Sachs Gives	1.4
Nestle	1.0
Sumitomo Mitsui Banking Cooperation	1.1
The Paul G. Allen Familiy foundation (Vulcan)	1.0
UN Foundation	10.0
Wellcome Trust	63.1
Other Private investors and Philanthropies	2.2
Total Private & Philanthropies	**128.3**
Total contributions	**1,458.6**

Table 7: Total pledges by 31.12.2020 with expected received year (in USD$)

$M Investors	2017-2021	2022-2026	Total	Percent of total
Australia	8.8	1.3	10.1	0.5 %
Austria	2.4	-	2.4	0.1 %
Belgium	6.0	-	6.0	0.3 %
Canada	80.3	-	80.3	3.6 %
Denmark	1.4	-	1.4	0.1 %
Ethiopia	0.2	0.1	0.3	0.0 %
Finland	5.6	1.2	6.8	0.3 %
Germany	367.2	-	367.2	16.5 %
Greece	1.8	-	1.8	0.1 %
Hungary	0.8	-	0.8	0.0 %
Iceland	2.0	-	2.0	0.1 %
Indonesia	1.0	-	1.0	0.0 %
Italy	12.0	-	12.0	0.5 %
Japan	221.3	-	221.3	9.9 %
Kuwait	10.0	-	10.0	0.4 %
Lithuania	0.1	-	0.1	0.0 %
Luxembourg	0.9	-	0.9	0.0 %
Malaysia	1.0	2.0	3.0	0.1 %
Mexico	0.6	-	0.6	0.0 %
Netherlands	58.6	-	58.6	2.6 %
New Zealand	10.5	0.4	10.8	0.5 %
Norway	399.3	-	399.3	17.9 %
Panama	0.0	-	0.0	0.0 %
Romania	0.2	-	0.2	0.0 %
Saudia Arabia	150.0	-	150.0	6.7 %
Serbia	1.2	-	1.2	0.1 %
Singapore	1.4	0.6	2.0	0.1 %
South Korea	6.0	3.0	9.0	0.4 %
Spain	64.4	27.6	92.0	4.1 %
Switzerland	10.3	-	10.3	0.5 %
The United Kingdom	333.9	-	333.9	15.0 %
European Commission	155.1	6.6	161.7	7.2 %
USAID	8.0	12.0	20.0	0.9 %
Total Public	**1,922.5**	**54.9**	**1,977.3**	**88.6%**
Avast	8.0	-	8.0	0.4 %
Bill and Melinda Gates Foundation	120.0	-	120.0	5.4 %
Fidelity Charitable gift funds	1.5	-	1.5	0.1 %
Goldman Sachs Gives	1.4	-	1.4	0.1 %
Nestle	1.0	-	1.0	0.0 %
Sumitomo Mitsui Banking Cooperation	1.1	-	1.1	0.1 %
The Paul G. Allen Familiy foundation (Vulcan)	3.5	-	3.5	0.2 %
UN Foundation	10.0	-	10.0	0.4 %
Wellcome Trust	105.8	0.1	105.9	4.7 %
Other Private investors and Philanthropies	2.2	-	2.2	0.1 %
Total Private & Philanthropies	**254.6**	**0,1**	**254.7**	**11.4%**
Total contributions	**2177.1**	**54.9**	**2232.0**	**100.0%**

CEPI has also received in-kind contributions in 2020. The Norwegian Institute of Public Health (NIPH) has contributed USD 0,82 million as pro-bono services to CEPI, consisting of office space and electricity. In the UK, Wellcome Trust has provided similar services, however, the amounts have not been possible to quantify.

[25] Contributions received are reported at actual rates, while budget rates for 2021 are applied for forecasted pledges.

R&D project investments

Table 8: R&D projects/investments 2020

R&D projects/investments MUSD	2020 Actual	2020 Budget	2020 Variance
Priority pathogens	56.4	147.2	-90.8
Disease X/Platforms	6.2	41.1	-34.9
Covid-19	536.3	-	536.3
Enabling Science & Manufacturing	11.5	38.4	-26.9
Total R&D projects/investments	**610.3**	**226.7**	**383.7**

R&D projects/investments MUSD	2020 Actual	2020 Budget	2020 Variance
MERS	1.6	27.8	-26.3
Lassa	21.7	65.8	-44.1
Nipah	15.3	22.6	-7.3
Rift Valley Fever	6.2	15.0	-8.9
Chikungunya	12.7	30.4	-17.6
Ebola	6.7	12.3	-5.7
Covid-19	536.3	-	536.3
Disease X/Platforms	6.2	41.7	-35.5
Cross cutting	3.7	11.1	-7.3
Total R&D projects/investments	**610.3**	**226.7**	**383.7**

Table 9: R&D projects/investments Lifetime-To-Date

R&D projects/investments MUSD	2018-2020 Actual
MERS	23.3
Lassa	69.2
Nipah	30.8
Rift Valley Fever	11.5
Chikungunya	34.4
Ebola	18.0
Covid-19	536.3
Disease X/Platforms	19.7
Cross cutting	5.5
Total R&D projects/investments	**748.7**

Table 10: Operating costs 2020

Operating costs	2017-2021	2022-2026	Total
kUSD			
Employment cost	**11,995**	**12,770**	**775**
Senior Management incl. CEO and Board remuniration	3,140	3,447	307
Policy, Strategy and Governance	919	772	-147
Advocacy and Communication	297	188	-109
Finance and Operations	899	1,050	151
Legal, Financial Awards & BD	844	899	54
Porfolio Management	211	446	235
Human Resources	438	261	-178
Research and Development	4,863	5,405	542
Investor Relations & Resource Mobilisation	384	303	-81
Consultants/Concultancy/Secondees	**18,347**	**11,305**	**-7,042**
Policy, Strategy and Governance	4,636	1,398	-3,237
Advocacy and Communication	307	191	-117
Finance and Operations	43	0	-43
Legal, Financial Awards & BD	3,374	2,942	-431
Porfolio Management	614	560	-54
Human Resources	80	0	-80
Research and Development	8,808	5,903	-2,905
Investor Relations & Resource Mobilisation	485	311	-174
Travel	**474**	**3,400**	**2,926**
Department travel expenses	467	3,152	2,685
Board, Committees, Conferences	7	248	241
Infrastructure	**2,551**	**2,216**	**-335**
Office costs & Insurance	478	487	9
Software & Licenses	323	198	-125
IT Operating costs & maintanance fees	404	414	10
IT development	1,112	875	-237
Hardware	235	242	7
Service providers/Other	**1,526**	**1,592**	**66**
Accounting fees	209	174	-35
Board, Committees, Conferences, Meetings	127	207	80
Audit fees (External & internal)	355	317	-39
Staff social	5	58	53
Miscellaneous	117	0	-117
Media & Communication	10	445	434
Recruitment expenses	702	392	-310
Discretionary fund	**0**	**1,313**	**1,313**
Total	**34,894**	**32,597**	**-2,297**

Management of Financial Risk

CEPI currently receives its donations predominately in USD, NOK, GBP and EUR, and investments are made in USD. CEPI has entered into a Trustee agreement with the World Bank where the majority of committed funds to CEPI are channelled through. Available funds are invested in the World Bank or with selected commercial banks, with the main investment goal being capital protection. To cover operational costs, CEPI is keeping cash in the donated currency for natural hedging purposes. CEPI has an established hedging facility with its current commercial bank, hence is in a position to enter into forward contracts as means of minimising currency risk caused by a mismatch between funding received and grant currencies.

In 2020, CEPI had a return on World Bank investments of $2,2 million and a positive currency effect in the accounts of $7,4 million.

Annual accounts and Board of Directors Report

CEPI's Annual accounts and Board of Directors report can be found on CEPI's website. In the annual accounts, revenue and costs are recognised in accordance with the Norwegian Accounting Act and the Provisional Norwegian Accounting Standard on Good accounting principles for Non-profit organisations and differs from the cash flow figures CEPI uses for internal and external reporting and that are presented here in the Annual Progress Report.

APPENDIX 3: HUMAN RESOURCES

Human Resources focus areas in 2020

CEPI's HR team aim to support the growth and overall development of the organisation. In 2020, efforts were focussed on recruitment, values and culture, diversity and inclusion, organisational and people development. In addition, CEPI has closely monitored the impact of the COVID-19 pandemic on the workforce with a particular focus on health and wellbeing. A flexible working concept has also been developed. Achievements over the year include:

- A concerted recruitment effort resulting in a number of new hires. Many new employees (35) were recruited and onboarded during the pandemic. The majority of the increased growth in the workforce in 2020 is a consequence of CEPI's build-up of the COVID-19 portfolio, the construct of a PMO office and the strengthening of CEPI's capabilities in manufacturing scale up, and scale out, in responding to Covid-19.
- The development of CEPI's Flexible Working concept has the potential to increase productivity and gives people the flexibility over where and when people work. CEPI's core values were articulated and defined by CEPI staff during an interactive session at the 2018 all-employee retreat. The values (Teamwork-Respect-Achievement-Integrity-Transparency) are highlighted and celebrated by senior leadership and form the basis for CEPI organisational culture. In 2020, the work on culture and values continued.
- Work on diversity and Inclusion was high up on the agenda in 2020 and was discussed in all employee meetings chaired by the CEO. The topic was also discussed at Board meetings where CEPI provided updates of the composition of the workforce, and the overall efforts in the area of diversity and inclusion. A D&I strategy and action plan was developed and discussed with the Nominations, Compensation, Diversity and Inclusion Committee (sub-committee of the Board).
- The focus on Performance Development continued and high-lighted in all employee meetings and line managers received specific training based on the key agreed leadership mechanisms for supporting the performance development:
- 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
- The Leadership team has discussed succession development for key roles

Composition of Secretariat

CEPI global HR policy and recruitment procedures highlights CEPI's commitment to promoting diversity and foster inclusion. When recruiting, CEPI carefully details skills, experience, qualifications and attributes essential for the role to make sure job profile and advertisements do not discriminate against candidates, either directly or indirectly. Deliberate and continuous efforts have been made and has contributed to develop the Secretariat into an international group of employees represented by 37 different nationalities.

Current composition of the CEPI Secretariat:

- At the end of 2020, the Secretariat had 99 permanent and fixed-term employees
- The gender balance in the CEPI Secretariat: 56% female
- The gender balance in the CEPI LT: 50% female
- The 99 Secretariat employees are from 37 different countries
- 22% of the employees originate from an LMICs
- One Leadership Team member originates from an LMIC

APPENDIX 4: CEPI BOARD SUMMARY

Board effectiveness review

In 2020, CEPI's Management continued working on implementing the recommendations of the Board effectiveness review conducted in 2019. The Board and the Executive and Investment Committee (EIC) have been kept updated on its progress; which included increased agenda review between Chair and CEO, Board-only time in meetings, improved papers and presentation format, routine invitation of external speakers, revisions to term durations, automatic review of Board membership if attendance is low, reduced management structure and appointment of a Board Effectiveness Lead and Champion. Areas planned for future focus include performance management, the Board induction process, enhancing meeting effectiveness, ensuring appropriate board competencies, evolving the use of Board members outside the meetings and investor effectiveness and engagement.

Cyber Security Advisory Group (CSAG)

A Cyber Security Advisory Group was established in December 2020, to work with CEPI's Management and support the Audit and Risk Committee's work in this area.

NCC to NCDIC

The Nomination and Compensation Committee (NCC) was renamed Nominations Compensation Diversity & Inclusion Committee (NCDIC) to reflect the expanded Terms of Reference, which gives the Committee an explicit role in overseeing diversity and inclusion activities on behalf of the Board.

Administrative items

- Following a voting process, investors elected Japan to continue as sovereign representative for another 3-year term on the Board from 1 March 2020.
- After a 2-year term, the Gates Foundation has rotated off the philanthropy Board seat and handed over to Wellcome.
- Following review by the NCC, and endorsement by the Board, the terms of Cherry Kang, Rajeev Venkayya, and Peter Piot as Board members were extended to a full 5-year term
- Articles 5.5, 6.6 and 9.25 of CEPI's Articles of Association were revised and approved in July 2020; revisions included updates to Members Meeting agenda summons, Independent Board Members and CEPI Board Chair term duration.

CEPI Board Members as of December 2020		
Organisation/Affiliation	Name	Position
Independent Members		
	Jane Halton	(Board Chair)
Africa, Centres for Disease Control and Prevention	John Nkengasong	Director
The Wellcome Trust Research Laboratory	Cherry Kang	(Board Vice-Chair) Professor
London School of Hygiene and Tropical Medicine	Peter Piot	Director
School of Public Health, Cayetano Heredia University, Lima-Peru	Patricia J. Garcia	Professor
Medicines for Malaria Venture	David Reddy	Chief Executive Officer
Nigeria, International Fund for Agricultural Development	Nadine Gbossa	Representative
Vaccine Business Unit, Takeda	Rajeev Venkayya	President
Investor Representatives		
Wellcome Trust	Jeremy Farrar	Director
Division Health Research, Federal Ministry of Education and Research, Germany	Joachim Klein	Deputy Head
National Institute of Infectious Diseases, Japan	Ichiro Kurane	Director-General
UK Department for International Development	Charlotte Watts	Chief Scientific Advisor
Non-voting Members		
Coalition for Epidemic Preparedness Innovations	Richard Hatchett	Chief Executive Officer
Wits Reproductive Health and HIV Institute	Helen Rees	(Chair SAC) Executive Director
American Association for the Advancement of Science	Peggy Hamburg	(Chair JCG) Chair of the Board
World Health Organization	Soumya Swaminathan	(WHO representative) Chief Scientist
Health, Nutrition and Population World Bank	Muhammad Ali Pate	(World Bank representative) Global Director

APPENDIX 5: MEMBERS OF THE SCIENTIFIC ADVISORY COMMITTEE

In 2020, the Scientific Advisory Committee (SAC), a key independent body within the CEPI governance structure played an essential role in supporting CEPI's COVID-19 response.

Despite the challenges caused by COVID-19, SAC met six times and provided significant support and guidance to CEPI related to the COVID-19 pandemic by offering scientific guidance on vaccine candidate investments, enabling sciences, and supporting the review of COVID-19 proposals for funding. Furthermore, SAC provided essential feedback that was considered in the development of CEPI's strategy that is CEPI 2.0.

Activities undertaken by SAC are outlined below.

Activity	Comment (Aim)	2020 Update
Virtual Meetings	The SAC meetings are critical vehicles for garnering scientific guidance from the group of experts.	SAC met six times and provided essential advice on CEPI's COVID-19 portfolio, non-COVID-19 portfolio, enabling science projects, and CEPI 2.0. Summaries of SAC meetings can be found here.
Support review of COVID-19 proposals	SAC members are invited to peer review applications received in response to calls for proposals on a volunteer basis.	Some SAC members were called upon to conduct expert peer reviews of proposals that were received for the four rounds of COVID-19 calls during 2020.
Stage Gate Review Committee (SGRC) work	SAC members are part of CEPI Stage Gate Review Committee, evaluating the progress of the CEPI vaccine portfolio and advising on next steps for the candidates	Eight SGRC meetings were conducted during 2020, where SAC members gave important input and recommendation for further development of the vaccine candidates in the CEPI portfolio.

The current SAC's term expires in March 2021. Terms of Reference for the SAC have been updated. Processes for reconstituting the SAC including renewal of some current members and selection of new members were developed in 2020. Early in 2021 CEPI had released a call for new SAC members and is in the process of reviewing applications, with the aim of achieving a broad spectrum of competencies as well as good global representation and gender balance. The new SAC is expected to be operational by April 2021.

Members of CEPI Scientific Advisory Committee (SAC) as of December 2020	
Organization / Affiliation	**Name**
Wits Reproductive Health and HIV Institute	Helen Reese (SAC Chair)
University of Texas Medical Branch	Alan D. Barrett
Institute of Human Virology	Alash'le Abimiku
Institut Pasteur	Christian Bréchot
African Center of Excellence for Genomics of Infectious Diseases	Christian Happi
United States Army Medical Research Institute of Infectious Diseases (USAMRID)	Connie Schmaljohn
Consultant	Daniel Brasseur
Ghana Food and Drug Authority	Delese Mimi Darko
Chinese Center for Disease Control and Prevention	Dong Xiaoping
Wits Reproductive Health and HIV Institute (Chair of CEPI SAC)	Helen Rees
US Center for Disease Control and Prevention	Inger Damon
James Robinson Biologics Consulting	James Robinson
London School of Hygiene & Tropical Medicine	John Edmunds
University of Maryland	Kathleeen Neuzil
Department of Global Health Policy, University of Tokyo	Kenji Shibuya
Independent Consultant	Michel De Wilde
University of Maryland	Myron Levine
US National Institutes of Health	Paula Bryant
Bill & Melinda Gates Medical Research Institute	Penny Heaton
London School of Hygiene & Tropical Medicine	Peter Smith
US Food and Drug Administration	Phil Krause
Independent Consultant (also for BMGF)	Ralf Clemens
VaxConsult	Stanley Plotkin
African Academy of Sciences	Tom Kariuki
INSERM Institut national de la santé et de la recherche médicale	Yves Lévy
Members of CEPI Scientific Advisory Committee (SAC) as of December 2020	
Takeda	Ali Alloueche
Sanofi	Jean Lang
J&J	Johan van Hoof
Wellcome Trust	Josie Golding
Pfizer	Kathrin Jansen
World Health Organization	Vaseeharan Sathiyamoorthy

APPENDIX 6: MEMBERS OF THE JOINT COORDINATION GROUP

Members of CEPI Joint Coordination Group (JCG) as of December 2020	
Organisation / Affiliation	**Name**
American Association for the Advancement of Science	Peggy Hamburg (JCG Chair)
AVAREF	Diadie Miaga
European Medicines Agency	Marco Cavaleri
US Food and Drug Administration	Gruber Marion
GAVI the Vaccine Alliance	Aurelia Nguyen
International AIDS Vaccine Initiative (IAVI)	Mark Feinberg (Advisor)
International Federation of Red Cross and Red Crescent Societies	Emanuele Capobianco
Médecins Sans Frontières	Sidney Wong
National Institute for Biological Standards and Control	Mark Page
United Nations Children's Fund	Robin Nandy
Wellcome Trust	Charlie Weller
World Health Organization	Ana Maria Restrepo
World Health Organization	Vasee Moorthy
Working Group (Regulatory)	Rogerio Gaspar
Working Group (Regulatory)	Daniel Brasseur
Working Group (Regulatory)	Murray Lumpkin