

**COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS:
ESTABLISHMENT OF A FINANCIAL INTERMEDIARY FUND**

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**Development Finance Vice-Presidency
Human Development Vice-Presidency**

ABBREVIATIONS AND ACRONYMS

CEPI	Coalition for Epidemic Preparedness Innovations
EIDs	Epidemic Infectious Diseases
FIF	Financial Intermediary Fund
HIV/AIDS	Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome Program
H1N1	Subtype of Influenza “A” Virus
H5N1	Subtype of Influenza “A” Virus
H7N9	Avian Influenza Virus or Bird Flu Virus
IBRD	International Bank for Reconstruction and Development
IDA	International Development Association
IDA18	IDA18 Replenishment
MERS	Middle East Respiratory Syndrome
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
PEF	Pandemic Emergency Financing Facility
PSG	Project Steering Group
R&D	Research and Development
SAC	Scientific Advisory Committee
SARS	Sever Acute Respiratory Syndrome
WBG	World Bank Group
WHO	World Health Organization

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Coalition for Epidemic Preparedness Innovations

I. Introduction

1. The catastrophic costs of pandemics and zoonotic outbreaks with pandemic potential have a long and notorious history in human civilization, and presage an increasingly alarming future prognosis. Highly virulent infectious diseases, such as the plague, cholera, and influenza, have repeatedly swept through human societies, causing death, economic chaos, and political and social disorder. In the last century, the 1918 influenza pandemic killed approximately 50 million, and HIV/AIDS took the lives of more than 35 million. Recent outbreaks, such as severe acute respiratory syndrome (SARS), H1N1, H5N1, H7N9, Middle East Respiratory Syndrome (MERS), Ebola and Zika, have claimed thousands of lives and costs billions of dollars, both to the countries that were directly affected and to the global community that responded.

2. As the threat of pandemics grows in a globalized world where viruses move and mutate faster than ever before, so does the case for increasing the world's resilience and capacity to prepare, detect and respond to epidemic threats. Vaccines are a critical component of that response. However, the vaccine pipeline is weak for most epidemic threats, and there is an urgent and pressing need for a system that will advance vaccine candidates as far as possible before epidemics emerge, and then run efficacy trials immediately when they do. The Coalition for Epidemic Preparedness Innovations (CEPI) was created to address the financing gap for development of vaccines for Epidemic Infectious Diseases (EIDs).

3. CEPI was officially launched in Davos in January 2017 as a global mechanism to explore and develop new ways to stimulate, finance and co-ordinate vaccine development against priority public health threats, in alignment with the WHO R&D Blueprint for action to prevent epidemics¹. CEPI is a partnership of public, private, philanthropic and civil organizations, and was established as an independent legal entity in the form of an international non-profit association organized under Norwegian Law. CEPI is governed by its own institutional bodies, including a Board and a Secretariat. CEPI expects to receive financial contributions from donors of up to US\$1 billion.

4. The CEPI Board has invited the Bank to serve as CEPI's Trustee, given the Bank's extensive experience with the provision of trusteeship services, internationally recognized sound financial systems, and an exemplary record of providing fiduciary oversight as a custodian of donor resources.

5. To respond to the CEPI Board's invitation, it is proposed that the Bank establish a Financial Intermediary Fund (FIF). FIFs are innovative arrangements that typically leverage a variety of public and private resources in support of international initiatives, enabling the international community to provide a direct and coordinated response to global priorities. The Bank, as Trustee, will draw on its financial platform and extensive experience with the provision of such services

¹ The R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis. WHO Member States welcomed the development of the Blueprint at the World Health Assembly in May 2016.

for other FIFs. The Bank is expected to provide the standard set of trustee services, which include contributions management, investment management, cash transfers, and accounting and financial reporting.

6. By engaging as Trustee, the Bank can play a critical role in facilitating an early and effective start to CEPI, and signaling support to an important international initiative focused on a preeminent global public good. To allow the Bank to engage with contributors and enable CEPI to start the provision of financial support to vaccine manufacturers already in 2017, expeditious operationalization of the proposed FIF would be necessary.

7. The mission of CEPI is fully aligned with the Bank's twin goals of ending poverty and promoting shared prosperity. Epidemics affect everybody, but disproportionately burden low income households and negatively impact the poorest members of the society. The Bank is committed to strengthening global health security, building strong and resilient health systems, and helping countries be better prepared for disease outbreaks. Vaccine development is critical to this goal. By partnering with CEPI, the Bank will twin the financing for development of vaccines with several ongoing initiatives to potentially leverage vaccine development and deployment to higher levels of effectiveness and impact.

8. The rest of this paper is organized as follows. Section II provides the strategic context and rationale for the Bank's engagement as Trustee. Section III presents the proposed Trustee engagement. Section IV outlines risks identified along with mitigation measures. Section V includes the proposed recommendation.

II. Strategic Context and Rationale for Bank Engagement

A. Strategic Context

9. The 2014-2015 Ebola outbreak in West Africa, as well as other recent epidemics and pandemics, including SARS, H1N1 flu, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Lassa, highlight significant gaps in the world's ability to prepare and respond to infections of epidemic potential, and a particularly urgent need for a new approach to stimulating, coordinating and financing the development of vaccines. Stakeholders from international organizations, governments, industry, public and philanthropic R&D funders, academia and civil society organizations agreed to explore new ways to drive vaccine innovation for priority public health threats. This led to the creation of CEPI.

10. CEPI was officially launched at the 2017 World Economic Forum Annual Meeting in Davos, with the objective of taking an end-to-end approach to vaccine development, with an initial focus on two priorities:

- Moving new vaccines through late preclinical studies to proof-of-concept and safety in humans before epidemics begin; and
- Supporting vaccine platforms that can be rapidly deployed against known and unknown pathogens.

11. This global initiative will develop vaccines for MERS, Lassa fever, and Nipah in the first round. These three vaccines were selected from WHO's list of the top eight emerging pathogens likely to cause severe outbreaks in the near future (published in December 2015), and for which few or no medical countermeasures exist.² The other five pathogens are Crimean Congo hemorrhagic fever, Ebola virus disease and Marburg, SARS coronavirus disease, and Rift Valley fever.³ These diseases provide the basis of WHO's Blueprint for R&D preparedness to help control potential future outbreaks. Subsequent selections of vaccines would prioritize pathogens likely to affect IDA countries.

12. IDA countries would benefit disproportionately more from vaccines targeted for development by CEPI. MERS is a viral respiratory disease caused by a novel coronavirus (MERS-CoV) that was first identified in Saudi Arabia in 2012, but since then has spread to several countries, including Yemen. Although the majority of human cases of MERS have been attributed to human-to-human infections in health care settings, scientific evidence suggests that camels are a major reservoir host for MERS-CoV and an animal source of MERS infection in humans.⁴ Lassa fever is known to be endemic in Benin (where it was diagnosed for the first time in November 2014), Ghana (diagnosed for the first time in October 2011), Guinea, Liberia, Mali (diagnosed for the first time in February 2009), Sierra Leone, and Nigeria, but probably exists in other West African countries as well.⁵ Nipah virus infection is an emerging disease endemic in Southeast Asia, and human cases have been reported regularly in Bangladesh and in neighboring regions of northern India.⁶ Likewise, Crimean Congo hemorrhagic fever, Ebola, and Rift Valley are also endemic to low-income IDA countries in Africa and Asia.

13. The ability of CEPI to catalyze the development of new vaccines against disease outbreaks capable of assuming epidemic proportions hinges on the ability of vaccine developers to conduct clinical trials in affected countries to test vaccine safety during Phase III of its development and on the ability of countries that would need the vaccines most to procure, regulate and use the vaccines so developed. In hosting the FIF for development of vaccines and ensuring that they are advanced past the Phase II stage of clinical development, the Bank will twin the efforts of CEPI with its own ongoing initiatives to strengthen country level preparedness. The Bank's suite of emergency responses and lending instruments strategically complement vaccine development and deployment objectives, and provides opportunities for robust, sustainable and effective action at all levels of development, deployment and response.

14. The opportunity of accelerating vaccine development against pathogens with pandemic potential is recognized as a critical part of pandemic risk management. Under IDA18, the Bank is committed to support at least 25 countries in developing and implementing pandemic preparedness plans. CEPI's financial support for specific actions to improve regulatory capacity in low-income countries and develop the core capabilities for conducting clinical trials at country level, including

² See, for instance, <http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en/>

³ Other diseases with epidemic potential - such as HIV/AIDS, Tuberculosis, Malaria, Avian influenza and Dengue - were not included in the list because there are major disease control and research networks for these infections, and an existing pipeline for improved interventions.

⁴ <http://www.who.int/mediacentre/factsheets/mers-cov/en/>

⁵ <http://www.who.int/mediacentre/factsheets/fs179/en/>

⁶ <http://www.cfsph.iastate.edu/Factsheets/pdfs/nipah.pdf>

training of staff, establishing a strong laboratory infrastructure, and strengthening the national regulatory authority could complement support provided through IDA as well as the Pandemic Emergency Financing Facility (PEF). Development of vaccines under CEPI could help to ensure that low-income countries have the critical capacity to rapidly and effectively accelerate access to life saving vaccines.

15. More specifically, the Bank and CEPI have established a task force on Strengthening Country Capacity for Vaccines Research and Development. This task force will consider ways of scaling up investments in vaccine R&D as an essential element in strengthening pandemic preparedness and strengthening capacity in low-income countries for late-phase clinical trials. Recommendations of this task force will in provide guidance to countries and development partners on how to direct their resources and efforts to develop and sustain vaccine R&D capacity so that when countries experience infectious disease outbreaks, they are ready to carry out clinical trials and make investigational vaccines available to their populations.

B. Context for the Bank’s engagement as Trustee

16. With over US\$600m in pledges (see Table 1), CEPI is working hard to initiate its work in 2017. By engaging as Trustee, the Bank can play a critical role in facilitating an early and effective start to CEPI, and signaling support to an important international initiative focused on a preeminent global public good. The Bank has extensive experience with the provision of trusteeship services to other FIFs, internationally recognized sound financial systems and an exemplary record of providing fiduciary oversight as a custodian of donor resources.

Table 1: Current Pledges and Indicative Contribution Payment Schedule*
(in US\$ millions)

Contributor	2017	2018	2019	2020	2021	2022	2023	2024	2025	TOTAL
Australia	2									2
Belgium	1									1
Bill&Melinda Gates Foundation	20	20	20	20	20					100
Canada	3									3
Germany	12	24	24	24	24					106
Japan	25	25	25	25	25					125
Norway	13	19	19	30	46	19	19	19	19	203
Wellcome Trust	20	20	20	20	20					100
TOTAL	95	108	108	119	134	19	19	19	19	639

*US\$ equivalent amounts calculated using the August 23, 2017 exchange rates

17. The CEPI Board would like to leverage the Bank’s expertise and fiduciary excellence as a provider of financial services and has invited the Bank to act as its Trustee to manage the inflows and outflows of funds. CEPI has already initiated its first call for proposals. Decisions on the allocations of funds are expected to take place by the end of September 2017 and the transfer of funds to implementers is expected by the end of 2017. In addition, many of contributing countries need to pay their 2017 contribution installments by the end of this calendar year. It is, therefore, important for the Bank to respond as expeditiously as possible to CEPI’s request.

18. Management's evaluation of whether to engage in this initiative was guided by the *Directive, Procedures and Guidelines* on the establishment of FIFs.⁷ It should be noted that, consistent with the "Cascade" approach, the Bank team asked the CEPI Secretariat to explore the interest of commercial banks/other private sector players to provide trusteeship services. CEPI had discussions with several commercial banks, including Citibank and DNB, but no commercial bank was willing to provide the type of trusteeship services that CEPI is requesting from the Bank.

III. The Proposed Trustee Engagement

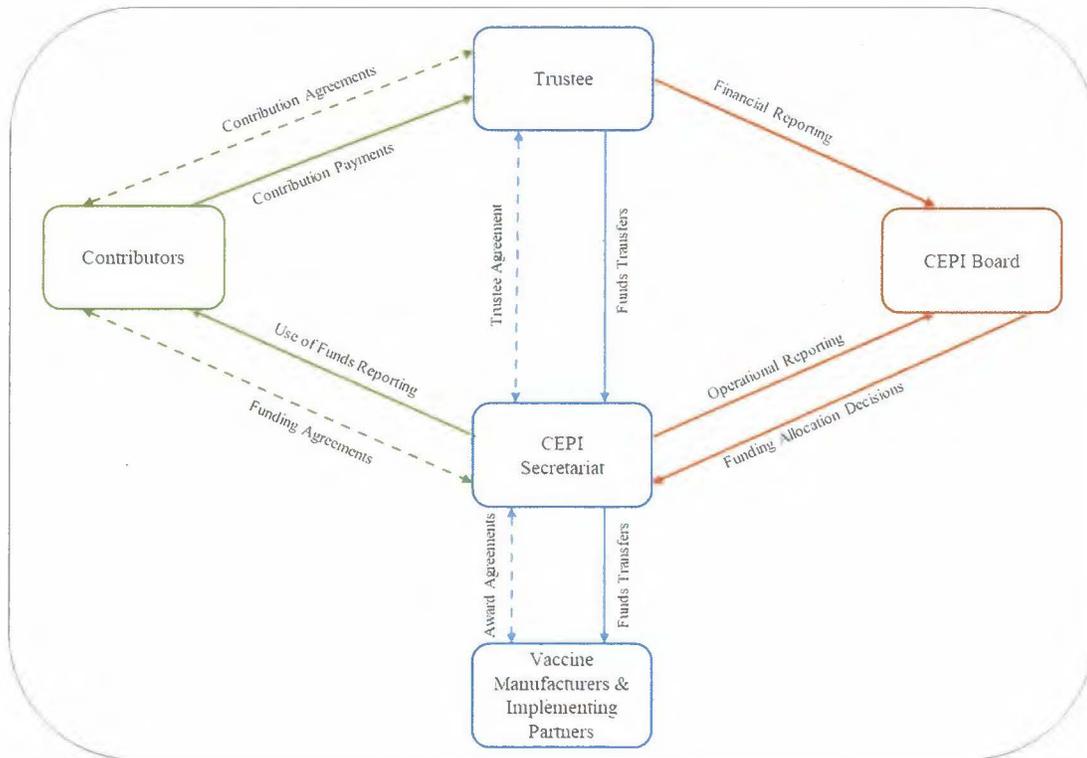
19. To respond to the CEPI Board's request to the bank for trusteeship services, it is proposed that the Bank establish a FIF to support CEPI. FIFs are innovative arrangements that typically leverage a variety of public and private resources in support of international initiatives, enabling the international community to provide a direct and coordinated response to global priorities. The Bank currently serves as trustee for 29 FIFs.

20. Unlike for most other initiatives supported by FIFs, for the CEPI initiative, the Bank will serve as Trustee to a legally independent organization that has already been established with its own governance and operating arrangements. CEPI is a legal entity established in the form of an international non-profit association under Norwegian Law. In its start-up phase, CEPI's governance structure includes an interim Board, interim Secretariat, Scientific Advisory Committee and a Joint Coordination Group. A permanent governance structure is expected to be finalized later this year (see Annex 1 for a more detailed description of CEPI's expected governance and operational arrangements). The Bank did not have a role in shaping CEPI's governance and operational arrangements.

21. Figure 1 summarizes the structure of the proposed FIF.

⁷ <https://hubs.worldbank.org/news/Pages/NewsArchiveContent.aspx?Type=KioskWB&ItemID=6354>.

Figure 1. Operating Flowchart of the Proposed Trustee Engagement with CEPI



22. The Bank, as Trustee, will enter into contribution agreements directly with FIF contributors and will have contractual obligations only with CEPI for the transfer of funds. CEPI will further transfer funds to vaccine manufacturers and implementing partners in accordance with CEPI Board’s approvals and pursuant to agreements between CEPI and such vaccine manufactures and implementing partners. The Bank will report to the CEPI Board on the financial results of the trust fund’s activities through regular Trustee reports for CEPI Board that will be available to all CEPI stakeholders, including contributors.

23. The scope of the Trustee service will be designed to provide flexibility and make clear the relationships between the involved parties as well as to enable CEPI to gradually build its own portfolio and treasury management functions. The Bank is expected to provide the standard set of trustee services, which include contributions management, investment management, cash transfers and accounting and financial reporting (see Box 1). The Bank does not envisage providing any customized services such as frontloading, i.e., raising funds on capital markets against future contributions to CEPI.

Box 1. Trustee Services

The following describes the set of trustee services expected to be provided by the Bank to CEPI:

- **Contributions management:** facilitating financial contributions to the trust fund based on signed legal agreements between the trustee and contributors; executing FX conversions of contribution receipts as required.
- **Investment management:** investing funds as part of the commingled investment pool for all trust funds and FIFs administered by the Bank; allocating investment income to the trust fund.
- **Cash transfers:** transferring cash to CEPI in accordance with the trustee agreement between the Bank, as trustee, and CEPI.
- **Accounting and financial reporting:** Maintaining appropriate accounting records, including on receipts and transfers; providing regular financial reports to CEPI and contributors and annual auditing of the trust fund's activities as part of the Bank's single audit process.

24. Under none of the above arrangements would the Bank, as Trustee, have any responsibility or accountability for the use of the funds after they have been transferred by the Bank to CEPI. The Bank will not be involved in any action seeking to enforce the return of any misused funds. This will be specified in the Trustee agreement between the Bank and CEPI and between the Bank and contributors.

25. As for other FIFs, as Trustee, the Bank will require a seat on CEPI's Board as an Observer.

26. The FIF will operate on a full cost recovery basis in accordance with FIF customized fee arrangements. Costs in the first year of operation would include reimbursement of the Bank's start-up costs.

IV. Risks and Mitigation Measures

27. Key risks to be assessed in a FIF-supported partnership are: *reputational, strategic, stakeholder, and financial.*

- **Reputational risks:**
 - The risk associated with the Bank's role in a FIF that supports a separate legal entity that is in its start-up phase and in which the Bank has no role in shaping CEPI's permanent governance, funding and operational arrangements, will be mitigated by agreeing only to carry out limited trusteeship responsibilities in the legal arrangements with CEPI and contributors, by making this clear in all relevant legal documents, and by ensuring that the Bank's limited trustee role is clearly communicated.
 - The risk that insufficient funds are contributed to render the FIF effective will be mitigated by an 'effectiveness condition', i.e., that no fund transfers may be made from the FIF until contributions amounting to at least US\$100 million have been confirmed by way of signed contribution agreements with the Trustee.

- **Strategic risk** that activities financed by CEPI may not be aligned with the Bank’s strategy and priorities or may duplicate other Bank financing would be mitigated through the Bank’s requirement to participate as an Observer on CEPI’s Board, active engagement with CEPI Secretariat, time-bound and subject to review engagement as Trustee, coordination at country level to ensure synergy across CEPI, PEF and IDA support, as well as through clear communication that the Bank has a trustee-only role and no responsibility over the allocation of CEPI funds.
- **Stakeholder risk** that the Bank would accept contributions from unknown sources or enter into legal obligations for the transfer of funds with entities that do not have adequate operational capacity will be mitigated by receiving funds from well-established contributors to WBG trust funds, the establishment of legal obligations only towards CEPI, which will be responsible for the transfer of funds to vaccine manufacturers and implementing partners, and the establishment of legal agreements that clearly define the roles and responsibilities of parties.
- **Financial risk** that the Bank, as Trustee, might be exposed to interest rate or foreign exchange risk or might incur substantial investment losses will be mitigated by (i) the use of grant (or non-reimbursable capital) contributions to the FIF; (ii) ensuring that there is a match between the currency in which contributions are kept in the trust fund and the currency of cash transfers to CEPI; and (iii) investing the trust fund liquidity as part of the commingled investment portfolio for all trust funds administered by the Bank. Contributor non-payment risk will be mitigated by ensuring that the transfer of funds from the trust fund to CEPI are based only on cash received from contributors.
- **Exit strategy:** Best practice for Bank engagement in FIFs requires consideration of a process for periodic review and possible exit from the engagement⁸. Experience with other FIFs has confirmed that hard triggers for the Bank’s exit from engagement in FIFs are not always desirable, nor feasible to implement in practice. Instead, the Bank’s engagement as trustee should be time-bound and subject to review. This requirement will be included in the FIF establishment documents.

Given that the contributions are expected to be received over the next eight years, the FIF will have an “end-contribution date” of December 31, 2025. The Trustee may receive contribution payments from contributors up to this date. Cash transfers to CEPI for approved projects may be required beyond the end-contribution date. The last date by which such transfers can be made to CEPI will be December 31, 2027 (the “end-disbursement” date). Following the end-disbursement date, the Trustee will take the necessary actions for winding down its affairs in an expeditious manner, including returning any remaining resources in the FIF trust fund to the contributors. The end-contribution date and the end-disbursement date can each be extended following review and approval by Management.

⁸ *Management Framework for World Bank Partnership programs and Financial Intermediary Funds: Strategic Engagement, Oversight and Management.* SecM2013-0286. June 14, 2013

The Bank's Trustee engagement will be reviewed by Management three years after the date of establishment of the FIF, and again, in the lead-up to the end-disbursement date, to determine the justification for the Bank's continued engagement in this initiative and make any adjustments, as required. Such reviews will take into account, *inter alia*: (i) CEPI's relevance for the Bank and the alignment of CEPI's goals with the Bank's goals and strategy in the health sector; (ii) CEPI's complementarity with the support provided through IDA and PEF; and (iii) the continued justification/need for CEPI to engage the Bank's trustee services in light of CEPI's own financial management capacity, which CEPI seeks to develop over time.

Legal agreements will also include termination clauses permitting the termination by the Bank with six months' notice. While it is not expected that termination provision would be triggered, this provides an additional level of protection for the Bank.

V. Recommendation

28. Executive Directors are hereby requested to approve Management's proposed approach, as described herein, for the establishment of a Financial Intermediary Fund at the Bank to support CEPI by acting as its Trustee.

Annex 1. Description of CEPI

A. Purpose

CEPI aims to rationalize and accelerate research and development responses to new outbreaks by coordinating resources of industry, governments, philanthropic organizations and NGOs, prioritizing development goals, and facilitating the advanced development of vaccines for Epidemic Infectious Diseases (EIDs). It will tackle the barriers to epidemic vaccine development, advancing safe, effective, and affordable vaccines to contain outbreaks at the earliest possible stage.

B. Governance and Operations

CEPI is a legal entity established in the form of an international non-profit association organized under Norwegian Law. In its start-up phase, CEPI's governance structure includes an interim Board, interim Secretariat, Scientific Advisory Committee and a Joint Coordination Group. A permanent governance structure is expected to be finalized in Fall 2017. Acting on guidance provided by CEPI Board, the CEPI Secretariat initiated a thorough review of the CEPI governance model, as CEPI transitions into operating phase. The proposal presented by CEPI Secretariat to its Board included the following governance arrangements:

- **CEPI Board**, comprised of 12 members plus 5 observers, with one observer seat potentially reserved for CEPI's fundholder (trustee).
- **Four Board Subcommittees**, for Audit & Risk; Compensation & Nomination; Resource Mobilization; and Executive & Investment.
- **Investors (Contributors) Council**, to ensure targeted involvement and bona fide influence for contributors.
- **Joint Coordination Group**, to focus on identifying challenges that could impact delivery of vaccines in CEPI's portfolio, and developing plans for response.
- **Scientific Advisory Committee**, to advise CEPI on scientific matters, including recommendations as on diseases and projects to be prioritized.
- **Task Forces**, time-bound constituted on as-needed basis to augment capacity and capability of the Secretariat.

C. Eligibility and Oversight Modalities

CEPI will disburse funds to research institutions, academics, biotech firms and the pharmaceutical industry more broadly. Eligibility criteria could include, inter alia:

- **Applicant competency, experience and track record:** This includes, technical competency/expertise, access to infrastructure and facilities (in-house or through contract manufacturing partnerships), and clinical/regulatory capabilities (in-house or through consortium of partners).
- **Technical feasibility:** This includes soundness of the theoretical concept/scientific rationale of the proposed vaccine candidate; availability/completeness/quality/validity of

the integrated product development plan from research through clinical development; current development status/technical readiness of the proposed vaccine R&D candidate; soundness of the clinical development approach through phase II, regulatory and prequalification pathways, and strategy for obtaining emergency use approval.

- **Manufacturing scalability and speed:** This includes soundness/scientific rationale of manufacturing processes/technologies supporting the candidate vaccine; current status/availability of manufacturing; time to produce/release sufficient quantities of vaccine for emergency use in a response to a disease outbreak; suitability of manufacturing processes/technologies for large scale production and delivery in an emergency.

Proposals, including whether applicants meet the eligibility criteria, will be reviewed by expert external reviewers. External reviewers will be carefully selected, checked for conflicts of interest and will sign confidentiality agreements. All proposals will be approved by the CEPI Board. Funding will generally be for three years and for no more than five years and must reflect the proposed activities and agreed conditions of the award decision made by the CEPI Board. CEPI reserves the right to terminate agreements per mutually agreed “go/no-go” decision criteria, which are reviewed by the SAC.

CEPI award agreements note that for each CEPI-funded project, CEPI will provide oversight through its participation to a Project Steering Group (“PSG”) which will have responsibility for managing projects, assessing the progress towards the achievement of project milestones, performance against objectives and reviewing financial reports. The PSG is a monitoring and advisory group that will include representatives from CEPI, the awardee organization as well as independent members. The structure and composition of the PSG will reflect the proportion of funding from CEPI, including CEPI taking greater oversight for dedicated programs. The awardees will provide written reports to CEPI at least quarterly during the award period, and will provide regular reports to CEPI after the completion of the award in order to allow CEPI to determine the impact of its funding and evaluate progress, performance and key issues.