

CEPI

Public Summary

Board meeting #12

Video/Teleconference

11.30-14.30 CEST, 2-4 December 2020

Board members

- Jane Halton, Chair of the Board
- Cherry Kang, Christian Medical College Vellore, Vice-Chair of the Board
- Jeremy Farrar, Wellcome Trust (day 3 up to 14:08 CEST)
- Patricia J. Garcia, School of Public Health, Cayetano Heredia University, Lima-Peru
- Joachim Klein, Federal Ministry of Education and Research, Germany
- Ichiro Kurane, Ministry of Health Labour and Welfare, Japan
- David Reddy, Medicines for Malaria Venture
- Peter Piot, London School of Hygiene & Tropical Medicine
- Rajeev Venkayya, Takeda (day 1 up to 13:00 CEST & from 13:25 CEST)
- Charlotte Watts, UK Department for International Development (day 1 & day 2 until 14:00 CEST)

Non-voting members

- Richard Hatchett, CEO CEPI
- Peggy Hamburg, JCG Chair
- Helen Rees, SAC Chair (up to 13:30 CEST on day 3)
- Soumya Swaminathan, World Health Organization
- Muhammad Pate, World Bank (day 2)
- Mukesh Chawla (delegate for Muhammad Pate, day 1 & 3)

Apologies

- Nadine Gbossa, International Fund for Agricultural Development

Observers

Investors council

- Australia: Kari Pahlman
- Austria: Norbert Feldhofer (day 1)
- BMGF: Anita Zaidi (delegate for Jeremy Farrar, day 1 & 2)
- Canada: Jennifer Lai
- Ethiopia: Abebe Genetu (day 1 & 2)
- Finland: Outi Kuivasniemi
- Germany: Ulrike Busshoff (day 2); Laura de la Cruz (day 1 & 3)
- Italy: Leonardo Bencini (day 1)
- Japan: Kazuho Taguchi; Takayuki Okubo (day 1 & 2)
- Korea: One Seo
- Mexico: Ambassador Ulises Canchola
- New Zealand: Peter Bartlett
- Norway: Tom Hunstad (day 1 & 2)
- UK: Jennifer Stuart (delegate for Charlotte Watts, day 2 from 14:00 CEST & day 3)
- US: Tracey Goldstein
- Wellcome Trust: Charlie Weller

Management

- Frederik Kristensen
- Mads Høgholen
- Joseph Simmonds-Issler
- Richard Wilder
- Zesanatt Pequeno
- Astrid Helgeland (closed session)
- Luc Debruyne (consultant) (items 2 & 3)
- Rachel Grant (items 2, 3 & closed session)
- Magnus Holme (items 2, 5, 6 & closed session)
- Nicole Lurie (item 2 & 3)
- Samia Saad (item 2, 3, 4 & 5)
- Melanie Saville (item 2, 3, 4, 6 & closed session)

- *John Nkengasong, Africa CDC*

Guests

Chris Viehbach, RDMIC Chair (day 1, item 2)
Christoph Benn, Global Health Security (GHD) (day 2, item 3)

Opening

Jane Halton opened the meeting. Several new conflicts were declared.

Charlie Weller (Investors Council Chair) noted that the Investors (now numbering 22) met 30 November 2020:

- The sovereign investor seat is due for renewal in March 2021.
- In discussing CEPI's strategy, investors appreciated the increased granularity, and noted that the ambition level was high, but expectations post-COVID-19 will also be high.
- Investing in a broad range of pathogens goes beyond reach of individual governments.
- CEPI might prioritise where in 2.0 it will act, according to funding.
- Investors support the idea of developing a post-pandemic consensus, but encouraged CEPI to be clear what role it would play here, and how to maintain focus on R&D.
- Investors greatly appreciated the comprehensive approach to LMIC engagement.
- Investors are very engaged on the replenishment approach, endorsing it in principle, and look forward to a whole of government approach to funding including workshops between Management and Investors. Investors are willing to support advocacy and asked to be closely involved in the asks and the investment case development.
- Investors asked for clarity on how requests related to CEPI replenishment and any additional requests for funding to support R&D investments under COVAX will be coordinated and if and where there will be synergies.

Richard Hatchett gave a CEO update, reflecting on a year where the global scientific community has come together. CEPI has played a critical role in the response, moving quickly to accelerate COVID-19 vaccine development, helping to establish COVAX, Access to COVID-19 Tools Accelerator (ACT), and through establishing COVAX giving the world an opportunity to pursue a collective approach. Progress is beginning to become tangible, as the world assembles the tools needed to end the acute phase of the pandemic, with the UK's temporary authorisation of the Pfizer vaccine coming only 326 days since the viral sequence was released. Richard noted that CEPI has been willing to take significant risks and has seen its role expand accordingly. This new role will likely be strengthened and in practice institutionalised as the ecosystem evolves dynamically. CEPI has reflected extensively on this experience in developing its next five-year strategy, and it is time to seize the opportunity to build a more prepared world for the future.

Resolutions:

- The Board delegated signing minutes for the September meeting to Jane Halton and Cherry Kang.
- Board members asked to update their recorded declarations of interests.

COVID-19

Richard Hatchett opened the session, noting the remarkable validation of the Messenger RNA (mRNA) vaccine technology but pointing out that a full and broad set of vaccines will be essential to achieve the scale and diversity the world needs. He noted COVAX is in implementation mode, working to make vaccine available globally as quickly as possible, with the COVAX Facility looking to conclude deals, but a substantial funding shortfall remained. CEPI continues to build the portfolio, towards which it will soon make its initial investments in 'Wave 2' vaccines, and to assume risk on behalf of COVAX and the world. The focused effort to respond to the COVID-19 pandemic has transformed CEPI and fundamentally reshaped its approach to CEPI 2.0.

Portfolio: Melanie Saville gave an overview of the status of progress in the global vaccine portfolio, noting that 11 candidates were now in phase 2/3, and that all but one of the candidates supported by the COVAX R&D portfolio have progressed into clinical trials.¹ CEPI had identified mRNA as a key platform for rapid response and the results from Moderna and Pfizer have confirmed this, demonstrating strongly positive efficacy data in record time.

Chris Viehbacher, Chair of the COVAX R&D and Manufacturing Investment Committee, provided an overview of the portfolio composition and status, highlighting that CEPI moved quickly and pushed the field forward. The Research Development and Manufacturing Investment Committee (RDMIC) has identified five priority areas for attention and funding: de-risking technology transfer for existing portfolio candidates; ensuring investment in adjuvant to optimise dose numbers; prioritising near term investments that secure MUS\$100 doses or more in 2021; modestly investing in second generation COVID-19 vaccines; and ensuring diversity of platforms and geography., Chris noted that the RDMIC and IPG are working closely together to ensure information exchange and coordination of effort.

Finances: Mads Høgholen presented on CEPI's finances in terms of COVID-19, noting pledges made to CEPI total BUS\$1.4, with BUS\$1.3 secured; that CEPI has signed contracts with a value of BUS\$1.2, with BUS\$1.1 committed; that by mid-November, BUS\$0.5 has been paid to partners, with an additional BUS\$0.7 of further investments approved; and finally, based on signed contracts only, CEPI has positive cash balance through 2021, but if all approved but as yet unsigned investments materialise, without action or injection of funds, CEPI would run out of cash by Q2 2021.

In discussion:

- CEPI are supporting development of a correlate of protection (CoP) as an alternative for the need for field efficacy trials. The first step was a workshop on CoP. CEPI's centralised lab testing effort will help with the development and ultimately the evaluation of correlates of protection through the development of standardised assays.
- Moderna received early and critical funds from CEPI. These should be seen to have been part of the success story.
- CEPI has and will continue to push partners to achieve fair and sustainable pricing.
- The anticipated funding shortfall, if all current projects continue and anticipated new projects materialise, presents a risk to CEPI that must be carefully monitored. CEPI Management is closely monitoring the situation and feels that carefully calibrated risk taking is appropriate, given that one cannot regain lost time.

Resolution: The Board noted the update.

Strategy

Richard Hatchett introduced a discussion on CEPI's next 5-year strategy from 2022 through 2026, reflecting on what CEPI's role should be as the world emerges from the pandemic and how CEPI will go about raising funds. Reducing future epidemic and pandemic risk will require coordinated global effort and CEPI has been reflecting on where it can contribute most effectively and how to foster the development of a post pandemic consensus, building on lessons learned from the COVID-19 response. Richard provided a high-level overview of CEPI's draft strategy. As the world emerges from the COVID-19 pandemic, there will be a unique opportunity to build on the rapid progress of vaccine platforms, emerging institutional arrangements (e.g., COVAX, Access to COVID-19 Tools Accelerator (ACT-A), saliency of the threat, window of political opportunity, and anticipated national and regional investments in manufacturing to improve global preparedness while leaving no one behind).

¹ Since the Board meeting, the UQ/CSL program has been terminated due to the production of an anti-clamp immune response in participants in the Phase 1 clinical trial, leading vaccinated participants to return false-positive results on a number of widely used HIV diagnostic tests.

- CEPI is articulating two “moonshot” targets for the longer term:
 - Reducing the time from the publication of viral sequence to the availability of clinical data for deciding emergency use to 100 days.
 - Systematically eliminating the risk of future coronavirus pandemics (building on CEPI’s work on MERS and COVID-19).
- The attainment of these targets will need global coordination of research agendas.
- CEPI proposes modifying its vision and mission statements to reflect acknowledgement of pandemic risks and the extension of remit to include monoclonal antibodies and other vaccine-like technologies.
 - **Vision:** A world in which epidemics and pandemics are no longer a threat to humanity.
 - **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.
- CEPI’s proposed strategic objectives for 2022-2026 are to:
 - **Prepare** for known epidemic and pandemic threats (including COVID-19 and the pathogens CEPI is already working on through vaccines or monoclonals).
 - **Transform** the response to the next novel threat (drawing on platform technologies and the prototype pathogen approach to systematically work towards eliminating the risk of future coronavirus pandemics and innovating to ensure cheaper, faster and more distributed manufacturing).
 - **Connect** to drive the development of a post pandemic consensus and drive the design of a more robust and effective global preparedness and response architecture (by developing rapid response outbreak protocols, coordinating a scalable on-demand manufacturing network, and enhancing global collaboration with initiatives such as the Vaccines Manufacturing and innovation Centre (VMIC), the EU Health Emergency Preparedness and Response Authority (HERA), the proposed Serum Institute of India (SII) joint venture for biodefence, and other national and regional entities and capabilities).

Key comments:

- Strong support for the level of ambition, noting that now is the first time the world can credibly articulate the goal of taking the threats of epidemics and pandemics off the table. Completing work on vaccines and biological countermeasures for Lassa, Nipah, MERS and the other priority pathogens should also be central to the plan.
 - CEPI should aspire to develop capabilities and sustainable capacity for multiple platforms and evaluate how reliable each is and what roles each may play.
 - A different pandemic, caused by a more virulent pathogen, could have had a far greater impact than COVID-19.
 - The 100-day target will be a rallying cry but will require that the right preconditions are in place.
 - Equity and access must remain at CEPI’s core. As one Board member put it, scarcity is the enemy of equity –and increasing supply should be a key strategy for CEPI to achieve its equity goals.
- Multiple Board members emphasised the importance of distributed manufacturing and helping to develop regional approaches to offset any tendency toward vaccine nationalism.
 - It may be possible in the future to support the development and manufacturing of mRNA vaccines in LMICs and Upper Middle-Income Countries (UMICs), which would enable regional manufacturing of products to meet local needs and thereby extend global capacity.
- CEPI clearly has a role in developing antibodies and antivirals but should leverage other partners, leading in some areas, collaborating in others.

Day 2

Strategy part 2

Frederik Kristensen provided a more detailed summary of the proposed strategy, highlighting:

- The strategy builds on CEPI 1.0 (2017–2022), lessons learned from the COVID-19 response, and the board’s deliberations through the year.
- The main components of each of the three strategic objectives and a proposed approach to a more detailed partnership strategy.
- A dedicated approach to LMIC engagement was presented, with a number of potential areas to focus on, including: strengthening clinical trial networks; funding manufacturing innovations and developing partnerships to coordinate capacity; engaging priority regional and country organisations; improving opportunities for LMIC talent within the Coalition; including LMIC experts in projects relevant to them; increasing CEPI’s presence in LMICs; improving LMIC representation in the CEPI organisation.
- The next steps will be to focus on operationalisation, including updating or adapting governance bodies such as the SAC, JCG, and IC, and CEPI’s Theory of Change and results framework; developing an implementation and staffing plan; aligning country and partner resources; and remaining attuned to wider shifts in the landscape.

Comments:

- The Board were supportive of the strategy and CEPI’s expanded ambition, thanking and complimenting the team for completing its work while also responding to COVID-19.
- CEPI should apply what we have learned from responding to novel threats to reduce development times for its core portfolio. Inefficiencies that slow progress can be addressed prospectively, through regulatory planning, shared capacities, and innovative clinical trial designs.
- The Board expressed great enthusiasm for the mRNA vaccines, which represent a revolution in vaccinology. The shift from biology to chemistry which the mRNA approaches embody will facilitate technology transfer and simplify manufacturing and could represent a leapfrogging opportunity for LMICs.
- The Strategy’s proposed level of coordination with national and regional partners, including other organizations, will require a significant commitment of human resources and having sufficient internal capacity will be critical if CEPI is to succeed.
- The Board was pleased with the elevation of focus on engagement with LMICs but there was also broad concurrence that CEPI needed to extend its resource mobilisation efforts and should not overly rely on ODA sources.
 - Clarifying what activities will be funded by ODA resources will likely be essential.
 - CEPI should consider conducting intentional listening sessions with LMIC partners to promote co-creation of partnerships and can piggyback on efforts LMICs are leading.
 - CEPI should consider explicitly calling out its desire to partner with DCVMs.
- CEPI should explore additional innovative financing approaches, particularly where the funding of manufacturing is concerned, and should map the forms of capital (sovereign, MDB, private sector) available to address different requirements.
 - During the COVID-19 response, no public sector entity was responsible for funding scale up of manufacturing. Sovereigns funded such work, but only for their own needs. MDBs were reluctant to provide at-risk funding. Such activities are out of scope for Gavi. CEPI was under-resourced and had also previously viewed such activities as out of remit.
- CEPI has an important role in regulatory science and policy for vaccines and related biologics and should support provisional approval for candidates taken beyond ready reserves for clinical trials.
- Building a sustainable approach to programmes, portfolios and coordination will be critical.

Resolutions:

- The Board approved the vision, mission, strategic objectives, and level of ambition.
- CEO to follow up with Board members for one on one discussions regarding specific topics.

Investment Case and Replenishment

Samia Saad and Christoph Benn presented an overview of the Investment Case and Replenishment Strategy, highlighting:

- The key messages for the investment case will be:
 - To appeal to self-interest as well as leaving no one behind.
 - To seize the opportunity to transform global preparedness and response. COVID-19 investments have accelerated vaccine technologies by 10 years.
 - To clearly explain CEPI's role and position in the post-COVID ecosystem and in establishing a consensus about how to reduce future pandemic risk.
 - To promote a world in which epidemics and pandemics are no longer a threat to humanity by reducing vaccine response time to 100 days and mitigating or eliminating the threat posed by whole virus families, including coronaviruses.
- The replenishment strategy will focus on:
 - Securing funding through a whole-of-government approach to secure financing that is robust, diverse (in terms of funding source), predictable (available when needed and with response funding), and sustainable (long term and easily renewed).
 - Securing around 90% from public sources and remainder from philanthropic and private sector replenishment.
 - Include three complementary models:
 - A bespoke replenishment model as the main mechanism – with an investment case, replenishment campaign, two conferences (one hosted by a G7/G20 champion), and with a carefully selected set of key global fora and events to build towards a final pledging conference (late 2021).
 - Better leverage of the existing International Financing Facility for Immunisation (IFFIm) with vaccine bonds issued against long term donor pledges (ODA and non ODA) which makes most multi-annual funds available immediately.
 - A Global Public Investment (GPI) model for financing public goods, with CEPI potentially as a pathfinder model as a medium-term approach that includes a public-private insurance mechanism/fund.

Comments:

- Now is the time to act and seize the moment. The world never wants to live through another catastrophic pandemic like COVID-19, but CEPI is still comparatively hidden to a large part of the world and a lot will depend on how COVAX performs.
- The Investment Case needs to be differentiated so that the benefit for LICs and MICs of participating is clear. CEPI should think about identifying champions from LICs and MICs and hosting regional events during the replenishment campaign.
- Economic self-interest must be part of CEPI's narrative and framing. This is an opportunity to spend billions to save trillions.
- CEPI could set out what the 100-day target can mean in terms of economic benefits, but also in terms of equitable access.

Resolutions:

- The Board noted the planned approach to the investment case and replenishment strategy.
- The Board agreed to actively participate in for CEPI's replenishment campaign with support from Management.
- The Executive will share the final Investment Case with the Board and Investors before publishing.

Day 3

Budget

Mads Høgholen presented on CEPI's finances, highlighting:

- 2020 was an exceptional financial year. The Board had been updated frequently.
- MUSD110 (Tranche 1) has permanently been reallocated from core to COVID-19 activities.
- MUSD20 has been granted from Gates Foundation for second generation COVID-19 vaccines.
- 2020 operating costs will be MUSD2.1 higher than budget, primarily due to work on COVID-19/COVAX.
- Based on current plans, if CEPI awards funding to all approved projects, it would run out of funds by mid-2021. That noted, CEPI is confident that through attrition, delays to projects, stage gates, ability to not award additional funding, potential repayment of COVID-19 investments provided as forgivable loans to support manufacturing at risk, as well as the prospect of raising additional funding, the projected funding shortfalls are in face manageable.
- Proposed 2021 operating costs reflect a 24% increase over 2020 forecast, primarily due to increases in staffing, especially in the Vaccine R&D and Resource Mobilisation teams.
- Benchmarking suggests that the proposed 2021 CEPI organisation is well placed in terms of operating expenditure and overheads when viewed alongside comparable organisations.

Key points in discussion:

- There is a limit on how far you can reduce overheads before it is counterproductive, and CEPI should avoid being in a race to the bottom – and needs to focus on being sustainable.
- Considering attrition and if CEPI receives repayments from the forgivable loans, the cash balance will stay positive throughout 2021.
- CEPI has a hedging strategy and reports regularly to the Audit & Risk committee on its currency risk exposure, and has funds largely in a blend of dollars, NOK, Euro, and Pounds. There is natural hedging for operational costs, but as of yet CEPI has not exercised active hedging due to the very dynamic timelines for donation commitments and receipt.

Resolutions:

- The Board noted the 2020 forecast update.
- The Board approved to the 2021 budget.
- The Board noted the 5-year financial plan update.

Board Effectiveness

Richard Hatchett presented an update on the Board Effectiveness initiative, noting:

- Changes include increased agenda review between Chair and CEO, with more 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.
- Charlie Weller, Chair of the CEPI Investors Council, noted that with an increased number of investors, a working group was established to reflect on ways of working for the IC, and how to engage with the Board. Key thoughts include the importance for the IC of Investor Board seats, a desire for enhanced engagement with the Coalition (including replenishment and LMIC engagement), and how to engage with the Board.
- The IC Chair and Board Chair are discussing using the Members meeting more extensively, and Jane Halton noted a willingness for an annual Chair and Investor meeting.
- Richard noted the proposal to identify Board Champions for specific areas of work, to support, mentor and provide a sounding board for members of the executive.

Jeremy Farrar, Board Effectiveness Champion, presented responses and reflections, highlighting:

- A key judgment of a Board is how well it navigates a complex time, being stretched beyond what is predicted. CEPI has done this well in 2020, and the changes made have enabled this.
- CEPI's mandate and profile are much higher now as a result of the pandemic and we should be considering what CEPI's role should be in 5-10 years and working toward that. Many more people feel part of CEPI than before. CEPI should perhaps consider open/stakeholder meetings.
- The Board is obviously not a scientific advisory group and CEPI needs to make sure that as it grows it doesn't end up with an overly complicated Board structure, as other organisations sometimes have.

Key points in discussion:

- The Board has moved from a more technical to a more strategic level.
- CEPI has been able to balance risk in a careful, thought through fashion – with sound decision making but an absence of unnecessary bureaucratisation. It is critical to keep agility.
- Board members should contribute to the work of CEPI where they can but should only be enlisted where they can add value. The need for champions should be demand driven, and expectations of champions should be further elaborated.
- An informal consultation group on engagement with LMICs may be useful.
- Closed sessions are extremely valuable, but must remain above operational issues, when Management are not included in discussions.

Resolutions:

- The Board Charter was approved.
- Jeremy Farrar to reach out to Board members and committees, to listen to perspectives, and come back to the Board with thoughts on how CEPI needs to evolve beyond 2021. **Due: March 2021 Board.**

Renewals: Rajeev Venkayya noted that there were several Board members, and governance group chair terms, up for renewal, and the Nominations, Compensation, Diversity, and Inclusion Committee (NCDIC) is responsible for nominations. The committee will meet in December, and feedback will be sought from Board members, with the plan to give a recommendation back to the Board on nominations/renewals early 2021 or at the start of the March meeting.

Resolution: The Board endorsed the proposed process.

Committee read outs

- Ichiro Kurane presented on the ARC meeting on 19 November, where the current top risks to CEPI was reviewed, and the committee also discussed finance and agreed to review proposed 2021 internal audit candidates in writing.
- Cherry Kang noted the EAC met on 19 October and provided detailed advice and comment on an ongoing negotiation. A paper regarding CEPI's approach to achieving equitable access in COVID-19 efforts will be published.
- Jane Halton noted that the expanded Executive & Investment Committee (EIC) had met extensively over the course of the year, mainly to provide oversight of COVID-19 and COVAX activities. She thanked Rajeev Venkayya and Jeremy Farrar for participating as advisors.
- Melanie Saville outlined a proposal to refresh the SAC membership, following expiry of term membership, and to better reflect the work of CEPI in the next period. Members will be invited to apply, and new areas of focus will include manufacturing and geographical diversity. The process will be openly advertised, and there will be an approach to ensure staggered membership. Helen Rees noted the SAC has been extremely supportive, and we might consider whether SAC terms parallel those of Board members.
 - In discussion it was suggested CEPI Management reflect on what has been learned from the RDMIC and the expertise they bring, and how that model and learning may contribute to future CEPI needs.

Resolutions:

- The committee updates were noted.
- Appointment of SAC members was delegated to the EIC. **Due:** before the March 2021 Board.

Items to note**Resolutions:**

- The Board noted the Core (non-COVID-19) portfolio update.
- The Board noted the updates and status of actions from previous meetings.
- The Board noted the forward look.
- The Board noted the risk register.

Closed Board session

Voting members of the Board held a closed discussion:

Cyber: The Board was briefed on recent cybersecurity activities and updated on the threat landscape.

Resolution: The Board noted the update.

Portfolio: The Board was briefed on a programme-related issue.

NCDIC: Rajeev Venkayya provided a verbal update from the NCDIC meeting that was held on November 9. The two topics covered were proposed 2021 compensation, and Diversity and Inclusion.