



Minutes of Board meeting #19

Date & Time

Closed Board Sessions - Voting Members only

Sunday 18th September 2022 – 13.00-17.00

Tuesday 20th September 2022 – 15:45 – 17:00

Board meeting – Sessions 1 & 2

Monday 19th September 2022 – 10.00 – 17.00

Tuesday 20th September 2022 – 09.00 – 15.30

Location

Mulia Hotel, Bali

Board members

- Jane Halton, Chair of the Board
- Cherry Kang, Christian Medical College Vellore, Vice-Chair of the Board
- Lucia Rizka Andalucia, Ministry of Health
- Cyrus Ardalan, OakNorth Bank
- Githinj Gitahi, Amref Health Africa
- Nisia Trindade Lima, Oswaldo Cruz Foundation
- Veronika von Messling, Federal Ministry of Education and Research
- Anita Zaidi, Bill and Melinda Gates Foundation

Online

- Ichiro Kurane, Japan
- Samba Sow, Center for Vaccine Development
- Rajeev Venkayya, Aerium Bio

Non-voting members

- Peggy Hamburg, JCG Chair
- Emmanuel Hanon, SAC Chair
- Richard Hatchett, CEO CEPI

Online

- Mukesh Chawla, World Bank (delegate for Juan Pablo Uribe)

Invited Attendees

- Yasuhira Shiozaki, CEPI Goodwill Ambassador

Apologies

- David Reddy, Medicines for Malaria Venture
- Soumya Swaminathan, World Health Organization (non voting Board member)

Observers

Investors council

In person

- Austria: Vanessa Wood
- Canada: Michael Torunian
- Ethiopia: Afework Kassu Gizaw
- Gates Foundation: Hannah Cameron
- Germany: Torsten Geißler
- Norway: Daniel Hirsch
- Republic of Korea: Danbi Kim
- USAID: Tracey Goldstein
- Wellcome Trust: Charlie Weller

Online

- Austria: Norbert Feldhofer
- Finland: Outi Kuivasniemi
- Indonesia: Roy Heraman
- Korea: Yeonsoo Suh

Management

In person

- Anand Ekambaram
- Mads Høgholen
- Frederik Kristensen
- Fernando Pons
- Samia Saad
- Melanie Saville
- Joseph Simmonds-Issler
- Monina Viernaza
- Claire Willman

Online

- Nicole Lurie (Item 4)
- Magnus Holme (Item 7)
- Emma Wheatley (Item 5)

Opening

- Jane Halton opened the meeting, noting herself and Richard Hatchett held highly productive meetings in Jakarta with Indonesian government representatives. Jane noted that Indonesia is chairing the G20, will chair ASEAN, and has been an extremely strong advocate of global health. This was the first CEPI Board meeting in the Southern Hemisphere and the Board was delighted to be in Indonesia, noting that the pandemic had hit Bali hard.
- Kunta Wibawa, Secretary General from Indonesia's Ministry of Health, welcomed the Board to Indonesia. Kunta noted main areas of focus under Indonesia's G20 presidency include strengthening the global health architecture; medical countermeasures, R&D&M collaboration and innovation; the 100 days mission; equitable access to vaccines, therapeutics and diagnostics. CEPI fits squarely within this agenda.
- Charlie Weller made opening remarks on behalf of the Investors Council (IC), noting:
 - investors were particularly interested in the agenda item on strategic partnerships,
 - the IC had been working on its Terms of Reference, and will bring these to the Board in December
- Richard expressed appreciation to the Indonesian government for meetings in Jakarta and hosting the meeting in Bali. Richard noted the Board meeting was occurring in a dynamic ecosystem, with recent developments including the establishment of the Financial Intermediary Fund (FIF), replenishments for other institutions, and a recharting of national regional and global relationships; all in a turbulent world.
- Richard Hatchett and Jane Halton introduced new Board and Management members attending in person for the first time, as well as introducing Anand Ekambaram, the new CEPI Executive Director Manufacturing & Supply Chain.
- No new conflicts were declared. Signature of the minutes was delegated to Jane Halton and Cherry Kang.

Item 1: Evaluation: Joe Simmonds-Issler presented a recap of the process highlighting the evaluation looked at CEPI's first five years, both in terms of the plans as originally set out and the activities undertaken in context of COVID-19. It was a mixed methods review, structured around the OECD DAC criteria of relevance, coherence, efficiency, effectiveness, sustainability and impact; and considered lessons learned for CEPI 2.0. An external evaluation committee provided independent review of the methodology and work of the evaluators, and the report was shared with the Board and Investors in August. Joe summarised the findings, and actions Management had developed in response – covering CEPI's scope, equitable access, LMIC engagement and partnership, MNC engagement and partnership, effectiveness, and organisational efficiency. Key points in discussion

- It was noted five years is a short period of time, and yet the environment around CEPI has changed extensively in its first five years of operation, and as such CEPI's adaptation to those changes and ability to have impact has to be understood in full context.
- It is important to reflect on CEPI's role and decisions in the context in which they occurred. CEPI ended up playing a role far beyond the scope of CEPI 1.0, accelerated product development beyond expectations and original objectives, and played a catalytic and driving role in the creation of COVAX.
- The Board felt a nuanced view of the COVID-19 activities was deserved, noting:
 - CEPI's COVID-19 investments were made in a specific context, and the size of the portfolio and CEPI's risk appetite was foundational to COVAX's success.
 - CEPI controlled only some levers
 - CEPI's COVID-19 investments may have significant wider benefits in relation to the development of more well-characterized vaccine platforms

- CEPI invested early and significantly in Oxford/AZ's vaccine which saved millions of lives
- It was noted that CEPI management has in fact started working on many of the recommendations of the report.
- There should be prioritized and actionable items that are regularly reported on to the Board. There are also areas that are important to be taken forward as part of ongoing discussions, including around partnerships, LMIC engagement, manufacturing and quality, and regional capacity
- Before jumping too quickly into actions, it will be important to reflect on what CEPI is and how the world has changed. CEPI is a mission driven organisation, but what that mission entails has evolved, as has our influence beyond our core work
- KPIs are important for some areas and less appropriate for others

Resolution:

- *Management will revise the Management Response and return to the EIC for sign off before publishing*
- *The EIC/Board will sign off TORs and process around future evaluations*

Item 2: Fundraising: Samia Saad gave an overview of CEPI's current funding status and prospects:

- Since foundation, CEPI has raised USD 3.9 billion, of which USD 1.6 billion is pledged for CEPI 2.0
- Board and investor advocacy plays a critical role in supporting CEPI's fundraising
- A significant amount of the funds raised have been from a few contributors, but CEPI is working concerted to bring in a broader group of investors
- Areas of focus in the mid to long term include co-funding partnerships, innovative financing, foundations, High Net Worth Individuals, embedding CEPI in annual government budgets, embedding CEPI in the developing pandemic preparedness and response architecture, and a broader funding base
- CEPI is invited to provide technical advice in forums such as the newly established FIF which brings credibility and can support resource mobilization

Key points in discussion:

- Innovative financing includes different components: using IFFIm to frontload pledges, impact financing for projects, blended financing, and many other areas. Certain programmes may lend themselves more effectively to innovative financing, but this may take time to come to fruition
- CEPI's core way of working is through unrestricted funding, with decisions around WHAT it funds based on best science
- CEPI needs to carefully think through its value proposition to LMICs. CEPI has developed an MOU with the African Union, operationalized through the Africa CDC, but should look to have this endorsed by the African Union Heads of State
- There is significant investment in national and regional manufacturing. CEPI's focus on innovations and distributed manufacturing supports access, and offers a good basis for partnership
- The physics community has been successful in aligning and persuading governments to buy into their work in a collective way rather than in competition. While there are differences, there may be lessons for CEPI to learn. The importance of having a clear and compelling narrative to those beyond the scientific community was noted.

Item 3- Ecosystem: Frederik Kristensen presented on CEPI's role in the external ecosystem for epidemic and pandemic preparedness and response, highlighting:

- Since the last Board meeting CEPI has been approved as an implementing entity of the FIF, has actively engaged on COVAX's future, has strengthened regional engagements including with HERA, PAVM, and PAHO, and has strengthened internal capacity and capabilities on policy
- CEPI's high level policy goals are: Ensure a continued focus on R&D & Manufacturing innovations in the new global health architecture; enabling equitable access; supporting geo-diversified

R&D&M; securing end to end financing for vaccine R&D&M; and global readiness for new products resulting from CEPI's portfolio (particularly including in the regulatory space). All of these can and should be seen in context of the 100 Days Mission

- There are a number of initiatives happening in the ecosystem in parallel, and CEPI has mapped which it leads, contributes to, and follows

Key points in discussion:

- There was support for the high level goals, but the Board noted the primary goal should be engaging proactively in shaping the evolving Global Health architecture to facilitate CEPI goals.
- As well as the system, CEPI should have a clear view of its critical relationships
- The FIF's future role, and process to further define it, was discussed in detail. It was noted that CEPI's role as an implementing partner is important, that CEPI should remain closely engaged around the future importance of R&D, and to influence the future direction. It is critical the FIF can evolve and have the needed flexibility and risk appetite to pivot and serve as a financial aggregator in an outbreak, and be able to support CEPI's core activities. The lack of readily available surge financing was one of the critical lessons from the response to Covid-19.
- Appreciation of CEPI having achieved status as Implementing Partner in the new PPR FIF, and support for CEPI's continued engagements in the FIF, while recognizing that funding for R&D&M will not likely be an initial priority. CEPI should advocate for regulatory strengthening as part of preparedness under the FIF, and consider working with countries in developing proposals
- It was noted that there are two architectures which are intimately connected – one for business as usual, and one in a pandemic. The financing needed for the two is different.

Peggy Hamburg and Richard Hatchett provided an update on thinking around evolving the JCG, noting:

- The evolution of the JCG should be seen in context of the evolution of the ecosystem
- The JCG is viewed positively by members for sharing information, and some of the relationships formed through the JCG supported the development of and relationships within COVAX
- The JCG has been an effective mechanism to notify and prepare downstream and implementing partners of products coming down the pipeline. CEPI held meetings in Nigeria on Lassa, and Singapore on Nipah; but some think more can be done on regional and LMIC engagement.

Key points in discussion

- Coming out of the pandemic CEPI has an opportunity to be a more assertive voice for product development in the ecosystem. The JCG is a CEPI platform that can be used to focus on developing new vaccines in epidemic/pandemic threats.
- Support was given for systematic as opposed to ad hoc engagement with industry.
- There is an ongoing and important issue to prepare public and policy makers for next generation vaccines and products, noting vaccine hesitancy and misinformation.
- The scope needs to be further defined. There may be potential to help define the agenda across countries and platforms and partners

Resolution: Revised JCG TORs will return to the Board for approval. Due: December 2022

Item 4: R&D&M: Melanie Saville presented a proposed prioritization for CEPI's R&D&M activities to initiate at this point based on the funds CEPI has raised and hopes to raise, the financial runway CEPI has, and towards achieving CEPI's strategic objectives. Melanie noted:

- The prioritization was put together according to principles of CEPI's unique role, CEPI's stage-gated approach to funding, the need to have contracts exceeding the budget given attrition, the benefits of long term partnerships for the 100 Days Mission, the need for enablers to support projects, and the importance of manufacturing networks
- The prioritization looked at all CEPI's work, and took a programme approach including products, platforms, manufacturing, enablers and partnerships; as well as considering co-funding.

- Manu Hanon shared that the SAC had:
 - reviewed CEPI's coronavirus activities and proposed strengthening focus on broadly protective coronavirus vaccines, and also exploring intra nasal vaccines, and human challenge infection models.
 - Explored platforms for rapid response and advised where improvements should be made
- CEPI does not have a rapid response budget, but is frequently asked to provide technical or financial assistance during outbreaks.
- CEPI has leveraged USD 300 million in co-funding. CEPI is actively exploring where and who it could partner with and co-fund activity with, but apart from HERA and SCARDA, would imagine the range to be relatively low in the short term
- Manu Hanon noted that in November a deep-dive portfolio review would be conducted.

Key points in discussion

- The Board thanked Management for responding fulsomely to feedback given in previous meetings, and expressed general alignment with the proposal
- It was proposed that CEPI should have a small budget set aside for emerging outbreaks. This could be managed according to a simple strategic framework for decision making. Such a view could prioritise responding to diseases within viral families CEPI is working on, or acting in contexts which are affected by diseases CEPI is working on.
- The interconnections between the priority pathogen, viral family, and platform work are important
- Very active portfolio management is critically important. CEPI is reviewing prioritization within programmes, and such portfolio management is actively conducted through the VRDMC and PSMB (which includes the two SAC co-chairs). Quality of implementation of decisions is critical.
- The increasing understanding of the plasticity of SARS-CoV-2 was noted with regards to the broadly protective coronavirus vaccine work. It was noted that there are some areas in basic science and immunology that will be critical to the success of partners that CEPI funds, and while CEPI is not into basic research, it is important these questions are addressed. It was noted NIAID is funding much of this work, and CEPI and NIAID are co-chairing a group on the broadly protective coronavirus vaccine effort. CEPI is well placed to drive towards a correlate of protection
- It was recommended SCARDA and CEPI formalise their collaboration. Ensuring good partnership and trust is critical
- For future portfolio and R&D&M overviews, it would be helpful to frame the landscape CEPI is operating in, noting others will have priorities which are consistent with CEPI's objectives and an awareness of this should inform how and where CEPI acts

Day 2

Item 4 R&D&M priorities continued re. Messenger RNA:

Melanie presented CEPI's plans for the mRNA platform, and noted upcoming potential investments:

- mRNA is critical for the 100 Days Mission, but also is important for other work CEPI is conducting including the virus vaccine libraries, for helping develop priority pathogen vaccines, and for developing prototype vaccines for vaccine preventable diseases to sustain the mRNA technology outside of outbreaks
- mRNA is part of CEPI's desire for rapid, sustainable, diverse, equitable manufacturing. CEPI is keen to support improving the platform for LMIC use, and has other calls which support this
- CEPI is keen to have expanded validated mRNA technology to offer the chance of enforcing equitable access commitments for LMICs.
- The proposed approach would include stage gated funding and significant developer co-funding. It would include funding a prototype candidate, and developing a vaccine for an exemplar pathogen
- Critical issues being reviewed as part of what will come forward in any proposal are IP and freedom to operate, as well as potential for commercial value

Emmanuel Hanon provided a brief scientific overview, noting:

- mRNA has been revolutionary. It has advantages of speed between preclinical and clinical, and speed of establishing commercial scale manufacturing. It is the choice for fast response when relevant
- CEPI's strategy to invest in libraries and prototype vaccines is appropriate and will support equitable access.
- The limitations include the uncertainty around persistence of immunity, broadness of protection, reactivity, costs and the transportation and storage challenges.

Key points in discussion

- A number of members expressed broad support for the plans.
- The IP in mRNA is uniquely challenging, and will require CEPI to be creative to ensure equitable access in its partnerships
- The incentive structure in this space will be challenging but it is essential to find a way to partner, and to build on success
- Whether to work on exemplar diseases was discussed. On the one hand it was noted that this raised mandate questions, on the other it was noted that this would support the company's development of necessary expertise, would support development of vaccines on families that CEPI is working on, and may help answer questions about durability. In addition it is essential for any partner producing outbreak vaccine to have a routine product to maintain ongoing manufacturing
- CEPI should be thoughtful about how much to invest in this space
- Ensuring LMIC access in an outbreak is essential. Indonesia may be interested in discussing with CEPI its activities and relevance to a G20 initiative
- Proposals coming forward for decision need to clearly articulate the proposal in context of the portfolio of vaccine platforms, and on the equitable access arrangements.

Resolution: The Board endorsed delegating decision on investments to the EIC. Management were asked at the point of proposal to set out how the investments fit in the mRNA landscape, and how the activities fit with CEPI's platform strategy.

Manufacturing: Richard Hatchett gave a brief presentation on CEPI's effort to establish a set of preferred partners for manufacturing to support CEPI's vaccine portfolio; to secure LMIC vaccine production where outbreaks are likely to occur; and contribute to a global manufacturing network for improved epidemic and pandemic response. CEPI issued a call, and received 63 expressions of interest, which were assessed through technical, access and partner lenses; and at this stage have been reduced to 7 facilities who CEPI will look to form agreements with and return with final recommendations to the Board. It was noted that the intention was not to build new facilities, but due diligence may identify areas needed to be strengthened.

Resolution: The Board noted the update and expressed strong support for the direction of travel.

Item 5 – Strategic partnerships

Richard noted CEPI's standard way of operating has been through calls for proposals, which reflects the importance of innovation and competition. Richard noted that over time CEPI is a mission driven organization, and that focusing on the mission can require or encourage thinking about alternative ways to achieve the mission as effectively as possible. With this in mind Management have begun to put together a framework to consider if there are circumstances where CEPI would look to directly partner with an organization, and the rationale and rubric for doing that. Richard noted that technical impact, equitable access, partner potential, and public and policy impact would be key considerations. Strategic partners could help fill a target need, bring a sustainable business model, offer scale, support achieving equitable access, and contribute to system equity; while CEPI can offer a unique connecting role, an

emphasis on innovation, matchmaking, visibility in them contributing to the wider 100 Day Mission, and towards system equity. CEPI has begun to consider an approach that would include screening, a heatmap, and a deeper dive assessment. **Resolution: Management will come back to the Board with an evolved framework, selection process, and high level view of how strategic partners may fit into the wider context of CEPI's objectives. Due: March 2023**

Item 6 – Organisation: Fernando Pons gave a brief overview of CEPI's operational and organizational priorities, emphasizing three areas: customer focus and organizational agility; staff wellbeing and engagement; and organizational growth and consolidation. He noted:

- An integrated review of systems and processes is being conducted to ensure efficiency and effectiveness; and this will include a voice of customer exercise to understand views of partners
- The importance of diversity and inclusion being considered in a top down and bottom-up way
- That growth and consolidation are critical, and CEPI is reviewing talent and salary bands in context of a highly competitive job market

Key points in discussion:

- The competition for talent was underscored, noting the creation of like-focused groups such as TLS, HERA, SCARDA, as well as high inflation.
- The importance of focusing on culture, brand, job security and development are critical
- That the Board could annually have a cultural review

Resolution: The Board noted the update. It was agreed to share the staff survey annually with the Board.

Item 7 – Risk: Magnus Holme gave an update on the work since the April Board meeting to review CEPI's risk management framework. Deloitte has been engaged to support the review, and has provided an assessment of strengths, areas to improve, and recommendations which have been discussed with the ARC Chair and Board Chair in detail. Cyrus Ardan noted the work by Deloitte and by Magnus and team has been of very high quality, but CEPI is at an early stage in the journey. Systems, data, and cultural aspects will be key as CEPI progresses. The target in 18 months is for a comprehensive approach, covering all areas, which will have a dashboard that can help the board by indicating risk tolerance, appetite limits, and be actionable. A timely, and frequent, Board update will be important. Jane Halton noted that the trajectory CEPI is on is usual, and now is the time to evolve. Risk appetite needs to be clearly understood and expressed, and the Board needs to have oversight and triggers. Key points in discussion:

- CEPI's consideration of third parties should extend to partners such as Gavi, WHO
- Innovation implies risk, and so there is a need for a tailored approach
- CMC is a risk for CEPI
- There is significant financial risk in the global context

Resolution: The Board were positive to the work done and direction of travel, and noted the update.

Item 8 – Finance: Mads Høgholen presented on CEPI's current financial status, CEPI's anticipated spend in 2022, and CEPI's draft budget for 2023. Mads provided an overview of pledges and contributions, investments, and operational expenditure, in the current year and according to the plans for 2023. Mads showed the trajectory and implications of the R&D&M plans across the five year period. Mads noted foreign exchange volatility and that CEPI's end of year salary process was ongoing and would be key considerations when the budget comes back to the Board in December for approval.

Resolutions:

- The Board noted the status of the 2022 budget
- The Board noted the draft 2023 budget

- The Board agreed that the EIC would discuss whether the 2023 budget should include a small budget line for rapid response

Item 9 – Committee read outs

- **NCDIC** (report given before Item 7) Rajeev Venkayya noted the NCDIC met on 19 September and discussed CEPI’s approach to anti-racism and diversity and inclusion matters. This was prompted by the recent external report at Wellcome and Wellcome’s self-characterisation as institutionally racist. Management provided an overview of CEPI’s activities, and the NCDIC gave feedback and asked for a fuller update as Management proceed. Richard noted that CEPI wanted to be proactive rather than reactive
- **EIC:** Jane Halton noted the EIC had met 4 times since the previous Board meeting, and thanked members for their diligence and flexibility. She noted items covered had included specific projects, the Modern Slavery statement, mRNA, procurement and others
- **EAC:** Cherry Kang noted that following the April Board meeting, the EAC had been engaging on the principles and framework around equitable access and the framework would come to the Board in December. Cherry noted that it is important to underscore what CEPI can and cannot control in terms of equitable access. A discussion was held around short term premiums for distributed manufacturing towards longer term increased regional security and greater equity.
- **ARC:** Cyrus Ardalan noted that the ARC had discussed the finances, focusing on risks including inflation, exchange rate, and cash flows. The ARC proposed to put in place a traffic light system around the budget, to alert the board if and as the finances require a review of the programme. The ARC asked Management to provide benchmarks of operating costs and a target position for CEPI. Richard noted that the combination of foreign exchange volatility and inflation may lead to a greater variability in the numbers coming to the Board in December and ahead
- **JCG:** Peggy Hamburg noted the JCG had met once since the last Board and discussed the current ecosystem, and focused specifically on Monkeypox.
- **SAC:** Emmanuel Hanon noted many key points from the two SAC meetings since June had been discussed in the Board meeting, and highlighted that one SAC meeting focused on Monkeypox, and another on the COVID portfolio, and what was needed to increase the chance of success towards the 100 days mission through reviewing different platforms.

Resolutions:

- The committee updates were noted
- Management were requested to return to the Board, through the NCDIC on diversity and inclusion related matters, once some progress had been made. **Due: March 2023**

Item 10 – Items to note:

- The Board noted the Agreements since last meeting, Portfolio update, and Actions papers
- The Board discussed future meeting date and locations. **Resolutions:** Management to circulate revised calendar invites for 2023 and 2024 meetings

The meeting adjourned.