



# Summary of Minutes of Board meeting #21

## In person – Washington DC

9 March 2023 - 11.00 - 17.00 (EST)/ 10 March 2023 - 09.00-15.00 (EST)

### Board members

#### In Person

- Jane Halton, Chair of the Board
- Cherry Kang, Christian Medical College Vellore, Vice-Chair of the Board
- Anita Zaidi, Bill and Melinda Gates Foundation
- Veronika von Messling, Federal Ministry of Education and Research
- David Reddy, Medicines for Malaria Venture
- Rajeev Venkayya, Aerium Bio
- Cyrus Ardalan, OakNorth Bank
- Dr L. Rizka Andalucia, Ministry of Health of the Republic of Indonesia

#### Online

- Ichiro Kurane (Day one: 11.00-11.50)
- Dr Yasuhiro Suzuki (Day one: 11.00 -12 .15, day two: 09.00-09.45)
- Githinji Gitahi (Day one in full)
- Samba Sow (Day one in full, day two: 09.00-13.40)

### Non-voting Members

#### In Person

- Richard Hatchett, *CEO CEPI*
- Emmanuel Hanon (SAC Chair)
- Juan Pablo Uribe, World Bank (Day one: 11.00-12.30)

#### Online

- Dr Michael Ryan, WHO (Day one: 11.00-16.40; Day Two in full)

### Invited Attendees

- Atul Gawande: Assistant Administrator for Global Health, USAID (Opening, Item 1)

#### Online

- Tommy Romskaug: Ernst & Young Auditor (Item 7)

### Observers

#### Investors council

#### In Person

- Wellcome Trust: Charlotte Weller
- Finland: Outi Kuivasniemi
- Korea: Eunkyung Shin
- Japan: Tetsuya Itani
- Switzerland: Florian Dolder
- USAID: Tracey Goldstein
- Mexico: Ambassador Ulises Canchola
- Austria: Norbert Feldhofer
- BMGF: Hannah Cameron
- Italy: Eugenia Palagi
- Canada: Michael Torunian
- Indonesia: Dwi Puspasari
- Malaysia - Mohd Nor Azman Hassan (Day two only)

#### Online

- Ethiopia: Afework Kassu Gizaw
- Germany: Torsten Geißler
- New Zealand: Isaac Holliss (Day one only)
- Norway: Daniel Hirsch
- Australia: Dr Stephanie Williams (Day two only)

### Management

- Mads Høgholen
- Frederik Kristensen
- Joseph Simmonds-Issler
- Melanie Saville
- Luc Debruyne
- Rachel Grant
- Magnus Holme (Items 4, 5, 6)
- Fernando Pons
- Anand Ekambaram
- Nicole Lurie
- Samia Saad
- Sally Girgis-Hjoberg (Day two)
- Monina Vierneza

#### Online

- Emma Wheatley (Item 3 and 4)
- Astrid Helgeland (Item 5 and 6)

## Opening

- Jane Halton opened the meeting, thanking the US Government for hosting CEPI
- Atul Gawande provided opening remarks, highlighting the critical importance of global health security, the US's partnership with CEPI, the 100 Days Mission, the 200 Days Mission, and other priorities for the USAID.
- Adjustments to Board membership were noted:
  - Ichiro Kurane made departing remarks after 6 years on the Board, and the Chair thanked him for significant contributions to CEPI
  - Dr Suzuki was welcomed as a new investor Board member
  - Mike Ryan had been appointed as the new WHO representative on the CEPI Board
  - Following recommendation from the NCDIC:
    - Soumya Swaminathan was appointed to the Board for an initial 2-year term, filling the seat vacated by Nisia Lima. Her appointment is effective March 13
    - Cherry Kang was appointed chair of the JCG, replacing Peggy Hamburg, effective immediately.
- The previous minutes were endorsed, and signature delegated to Jane and Cherry
- No new conflicts were declared
- Charlie Weller provided a summary from the Investors Council:
  - 3 learning sessions were held with investors and CEPI Management on topics of interest: 100 days, regulatory, and equitable access. These were very well attended and received
  - In the IC meeting, investors:
    - acknowledged CEPI needs to develop creative solutions to partnering for impact and discussed mechanisms for partnership beyond CFPs. Investors would expect to see good process, criteria, and frameworks for such decision making
    - asked for an overview of CEPI's portfolio to be added to CEPI's website, to help investors with positioning CEPI and sharing progress
    - asked if CEPI should reconsider the level of programming it initiates based on different funding scenarios
    - were positive to the manufacturing strategy, and expressed particular interest in how CEPI will support the development of human capital
    - asked for tools to help advocate on CEPI's role on equitable access

## Item 1 – CEO update/strategy day playback Richard Hatchett made brief opening remarks:

- The CEO and Chair had a series of highly positive meetings with US Government and partners
- That CEPI's positioning in the emerging architecture among a growing number of peer organizations (such as SCARDA, HERA, BARDA) is an area of critical focus. CEPI needs to focus on how partners collaborate; but also engage in wider processes including G7 and G20
- There has been a series of recent outbreaks that CEPI has been part of the response for. All are critical to tackle, but are also viewed as opportunities to develop and hone capabilities and relationships towards the future achievement of the 100 Days Mission

- The challenge of H5N1. Richard noted that all recognize that the world's ability to respond to an influenza pandemic is weaker than it was for a coronavirus, with fixed and comparative limitations of manufacturing, delays on delivering egg-based vaccines
- Efforts are underway to pick up the pace of CEPI's spend rate to advance high quality and impactful programmes in support of CEPI's objectives.

Jane Halton made opening remarks, summarizing the in-person Board strategy day:

- This was a hugely valuable opportunity for the Board to take a step back and look at reframing CEPI's ambition in a future-focused way. The Board looked at where CEPI sits, its strengths, and where it needs to be disciplined. It discussed the mission and noted that waiting for the new architecture to be concluded before taking action is not the right path, and CEPI is part of action now, including in responding to outbreaks like Sudan, Marburg. CEPI is setting aside a small response fund with proper governance.
- We now have 6 years' experience and can conceive of CEPI's role in a more nuanced, sophisticated way. This helps consider when CEPI should intervene, but also when CEPI is more in a supporting or advocacy role.
- There is a clear difference between epidemics and pandemics, and it is critical to be ready for both. The 100 Days Mission is not achievable without preparedness, which is where most of CEPI's work sits. Preparedness enables response. The 100 Days Mission has an immediate selling point to politicians, but requires a deeper level of understanding to both be a programme of work and to be achievable with partners.
- CEPI has a very significant role as a custodian of products and supporting the R&D pipeline
- The Board has asked Management to look at the pathogens it works on and particularly H5N1. Early on there were reasons for not considering flu, but we have learnt many things and should reassess
- CEPI's role is a necessary component but not sufficient to ensure equitable access
- Cyrus Ardalan had previewed early thinking on innovative financing.
- The Board discussed principles and potential strategic partnerships; including the approach, the importance of not partnering exclusively; but also the benefits of leveraging unique or particularly broad capabilities.
- The Board has been very focused that CEPI as an organization reflects the world. CEPI has concentrated in certain locations, and the Board discussed whether that should change. The Board does not see the need to be somewhere for the sake of it and suggested there would need to be a very clear purpose and rationale for expanding. That noted, there are certain geographies which are key to CEPI.

In discussion:

- It was noted a major focus area was CEPI regulatory strategy. CEPI needs to help define clear regulatory pathways for all its priority pathogens
- The EID vaccine R&D ecosystem is the envy of others – this is in large part thanks to CEPI
- It is very important for CEPI to now define its role and not let others define it
- Strategic partnerships are critical for CEPI to deliver on its mission. These partnerships will not be exclusive and will only be a small proportion of CEPI's funding. Where CEPI sees a rapid-fire way to outcomes, it will not shy away from pursuing them – but the Board will need to be fully signed up before any will be endorsed.

### ***Resolutions***

- Management to conduct a landscape analysis on H5N1 and revert to the EIC on the findings and if there are any gaps or high-value activities for CEPI. *Due: Q2 2023*
- Management to present on CEPI's regulatory approach to the Board. *Due: June 2023*
- Management to define a process to review the pathogen list. *Due: H2 2023*

**Item 2 – Portfolio:** Melanie Saville gave a presentation on CEPI's portfolio, noting recent portfolio progressions in Lassa, Nipah, and Chikungunya; as well as COVID-19 candidates achieving licensure. In addition, Melanie noted progress in partnerships on mRNA innovations, investments in enablers, progress on the University of Queensland platform, and progress on manufacturing, laboratory, and animal networks. Mads Høgholen presented on CEPI's spending in 2022, noting that the anticipated costs at the start of the year were reassessed as the year progressed and describing the key drivers which include project delays and drift, attrition and a decline in the need for COVID-19 funding.

Key comments:

- Early portfolios are hard to assess for attrition. As you move forward, there is more of a historic set of numbers that can be used
- CEPI needs to consider attrition relative to its specific pipeline, in terms of working in LMICs, with new partners, with due diligence and capacity issues. It may be CEPI needs to over programme by 40%
- CEPI should explore having projects ready to go/invest in, if more funding becomes available
- CEPI will need to be flexible. CEPI should establish rolling calls e.g., with regular review. Melanie then provided detailed overviews of CEPI's work and strategy for Lassa, for Chikungunya, and for Nipah.
- Melanie noted that the SAC would provide input to a number of calls for proposals in its next meeting on 25 April and summarized planned calls/funding planned in 2023 and values attached to these. Key comments:
- The Board highlighted the work on Lassa as a major contribution of CEPI to the world. For the Lassa programme to succeed, CMC and partnerships are critical. Management noted that there is significant clinical trial site capacity strengthening work underway already.
- A discussion was held on the need for appropriate market authorization holders as well as manufacturing strategy
- The need for partnership with other organizations, and them taking on products CEPI supports, is critical.

**Resolutions:**

- **The Board noted the update.**
- **Management will review establishing a more open, rolling approach to calls. *In place H2 2023***
- **Management will continue to report on spend through 2023. *Ongoing***
- **Management will review with the SAC its adjuvant strategy to support its portfolio. *H1 2023***

**Item 3 – Manufacturing:** Anand Ekambaram presented the draft strategy, highlighting:

- The strategy is built around delivering the CEPI 2.0 strategy and 100 Days Mission and achieving equitable access. It is contextualized by and responds to external drivers including the inherent complexity of vaccines, the lack of geodiversity, and a fragmented and not always sustainable ecosystem
- The strategy includes a focus on embedding manufacturability in early product development; developing geodiversity, human capital and partnerships in the DCVM community; addressing

sustainability issues and focusing on cost effectiveness; and acting as a matchmaker to connect and integrate developers and manufacturers

- There are issues to address in the next stage of the strategy, including human capital, ensuring CEPI's processes are designed with the CEPI 2.0 mentality; and ensuring the right knowledge management is in place
- Current areas of activity include funding manufacturing innovations; developing and partnering for the manufacturing network; developing and ensuring CMC support; and supporting outbreak response as needed
- The connection and importance of the value chain(s) for product development, site readiness, sustainability, and market uptake

***Key comments in discussion:***

- CEPI playing a stronger role in manufacturing is critical for the success of CEPI 2.0. CEPI has developed a CMC framework and is looking at ensuring that there are integrated plans with developers that include the manufacturing focus. It is extremely important to consider how products fit to manufacturing platforms.
- It is important to articulate CEPI's role in manufacturing very clearly
- Manufacturing is often considered late in a process. Clinical development can fail if CMC is not considered early on.
- There are a number of areas which are critical to success:
  - Technology transfer, site readiness, expertise, and process development where partners have not commercialized a product before.
  - Ensuring the right standards, GMP, training capabilities/expertise for CMC. Gates training programmes have been established and CEPI might leverage.
  - Different outbreaks require very different level of responses, so scale is a central consideration. The manufacturing network has partners who bring different strengths, which can include speed, scale, technical expertise in certain areas
  - Given that consistent manufacturing is the bedrock of supply, CEPI should consider manufacturing platform development as a goal in itself
- CEPI's approach
  - Needs to be sustainable, with the right partners, able to deliver both epidemic and pandemic response
  - CEPI is putting pandemic response plans within partner contracts, with a focus on changeover procedures, considering what stockpile is needed, what working capital is needed for such a stockpile
  - CEPI plays a role but does not own ensuring there is an overall ecosystem/ market uptake, and needs to manage expectations carefully
  - Requires commitments from other actors/governments to those CEPI invests in
  - Should be clear with regards to the platforms CEPI prioritises
- There is not a large amount of idle manufacturing capacity globally
  - It is critical that CEPI and partners have access
  - Building new capacity is a monumental task. CEPI will instead partner and strengthen what exists.

- There needs to be surge capacity without compromising core vaccination
- Sovereigns are reviewing the capacity in the system and their access to it. It is important to view the market in totality, and see how CEPI operates within the context, and can also advocate or lobby for a systems approach
- Discussing specific diseases and manufacturing needs (e.g., Lassa) brings issues to life
- The financing model, and what CEPI's role in financial sustainability is or is not, is important.
  - New manufacturers will have to invest heavily before they can optimize COGs. CEPI and other funders also need to give Global South entities space to become competitive; and there may need to be subsidizing within the system to support new partners developing. CEPI should have an advocacy role
  - It is critical to understand Gavi's purchasing strategy within Africa (and products/countries supported by CEPI) and be aligned with the prioritization.
  - There is decreasing funding available for capacity already.
  - Flu offers a specific model where there is high capacity, and a commercial model
- The Board noted that MSC strategy had listed Lassa as an area to test operationalizing the concepts noted in the paper. Board suggested considering Chikungunya in addition.

**Resolution: The Board noted the update, and asked Management to evolve the strategy based on the feedback. The importance of understanding the wider landscape, and how CEPI fits into that and its advocacy role, were stressed for the next iteration. *June 2023***

**Item 4. Equitable Access Communications:** Emma Wheatley gave an overview of the Equitable Access Framework the Board endorsed in December. Cherry Kang, Chair of the EAC, noted the importance of clear communications. Rachel Grant highlighted:

- Access is a polarized and polarizing space, but the intent of CEPI's communications approach is to create space for CEPI to operate within this environment.
- CEPI's strategic communications objectives are:
  - Ensuring stakeholders understand how CEPI is defining equitable access.
  - Ensuring stakeholders understand what CEPI is doing to achieve equitable access, both directly and indirectly
  - Ensuring stakeholders understand the limits of CEPI's remit and leverage, and the role others have to play in achieving system-wide change
- It is critical that this is not seen as the launch of a new policy, rather a reflection of CEPI's positioning and approach built on CEPI's learning to date

Key points in discussion:

- CEPI does not control achieving access – but where it has the space to act it will. Its communications and advocacy work are part of this
- Partner engagement will be tailored. CEPI will do this in a way that the different parts add up to a clear and coherent picture
- Partners from the Global South are increasingly central to CEPI's portfolio – this should be highlighted
- There are set views on some of these topics, but CEPI should continue to work to inform and frame the issues based on the knowledge it has. By creating space, CEPI will allow potential partners to come closer to CEPI's position and to engage.



- It was noted that the issue is not a zero-sum game, and CEPI having an approach based on its learning to date was praised by the Board
- It is important to be proactive in communications as well as responsive. You cannot win all communications battles, but consistency of messaging is vital. CEPI's voices should reflect the world.
- Sovereign investors will benefit from being able to use and share the arguments that will be part of the communications work

**Resolution:** The Board noted the update and endorsed the approach

**Item 5 – Risk** Magnus Holme gave a presentation, highlighting:

- The project will ensure CEPI's risk framework, tolerance, thresholds and controls, are fit for CEPI 2.0. This will reflect that CEPI's core business is R&D and innovation; and have an approach that is clear, simple, actionable, and understood within CEPI. The work is being developed with the ARC, an internal steering committee, and external support.
- The progress of the work, specifically on risk appetite, methodology, and hierarchy. Magnus gave an overview of templates for reporting to the Board and a risk dashboard. This will cover aggregated reporting on top risks, and which risks need attention
- Risk appetite statements for top risks will be developed, as will reports. The risk appetite approach will be embedded at the portfolio level, and for project decisions. Management and the ARC will meet in May, and new reports will come to the June Board.

**Key points in discussion:**

- The Board commended the team for the work conducted, noting it as real progress.
- The increased presence of risk analysis in investment documents for the EIC was noted
- CEPI should think broadly about the risks it may face
- There will be an important behavioural and cultural component to implementation
- Vaccine development can be all or nothing. This means defining risks in a thoughtful way is important.
- There will be different risk appetites for different elements of work. Technical is often higher, whereas operational is much lower
- Cybersecurity was covered. This has been a constant focus for CEPI, including with a cyber security subgroup of the ARC. The cost vs benefit of insurance was discussed and CEPI's current position was noted as appropriate.

**Resolution:** *The Board endorsed the direction of travel. Management to return to the Board as the work progress. Due: June or September 2023*

**Item 6 – organization, and agility** Astrid Helgeland presented on the CEPI organization, highlighting CEPI grew from 155 to 212 staff in 2022. The staff originates from 51 countries. The percentage of female staff, and staff from LMICs, has consistently grown since 2018, however there is a greater percentage of female staff at the most junior levels. Astrid noted CEPI is actively working to evolve its culture, with a number of ongoing and new initiatives. Fernando Pons presented on CEPI's focus on operational agility, highlighting:

- Agility as the ability to react quickly to changing circumstances, both external or internal, and to change promptly in order to adapt to those changes in order to achieve strategic objectives faster and better.
- Agility will enable speed, effective processes, alignment across initiatives, and further improve and develop enduring relationships with key partners

- Agility operates at strategic, tactical, and delivery levels
- Management has conducted a customer and partner research exercise, gathering qualitative and quantitative data, and conducting interviews with key stakeholders. The findings are positive but indicate clear areas of improvement, with an initial focus on Stage Gate Reviews; Project Reporting; and the Call for Proposal process
- Management is also conducting an internal exercise of process, systems and controls mapping the most relevant customer facing processes to make both continuous process improvement as well as transformative change.
- Management will return with specific deliverables as the project progresses

#### **In discussion**

- The risk framework and organizational agility are and must be interconnected – with controls mapped into systems and process maps
- Having specificity of objectives and progress on agility will be important
- Inclusion is critical as well as diversity. People being heard is key.
- CEPI's trend lines year on year are positive
- Specific questions were asked on
  - Parental leave policies across locations
  - Seeing the staff survey once published
  - CEPI's turnover rates and if there are any burnout issues
- Management noted:
  - The staff survey would be concluded soon
  - CEPI is considering a talent retention scheme
  - The idea of alumni network is being considered
  - For any new areas of focus, Management considers if new staff are needed, or contractors are better placed to conduct the work
- All organisations want to be lean, but CEPI needs to have some inbuilt capacity to be able to respond.
- The Board would like to see how many people are in each department, which are the focus areas of recruitment, and where CEPI expects to be at the end of 2023
- CEPI's structures and ways of working in 2.0 need to be fit for purpose

#### **Resolutions**

- **Management to share the staff survey results, and a more detailed overview of the size of the organization. *Due: Q2/Q3 2023***
- **Management to provide updates on the operational agility work as it progresses. *Ongoing***

#### **Item 7 – Finance and Accounts**

Mads Høgholen presented the 2022 Board of Directors Report and Annual Accounts. He noted that, as before, the way CEPI presents the budgets and cash-flow are different compared to the normal format for the Board, and have to be in line with the Norwegian Accounting act and the associated bookkeeping rules. Mads explained how revenue is calculated and the impact of requirements from investor contracts and demonstrated this with examples. Mads also provided a reconciliation of the Annual Accounts and the



standard Board cash overviews. Cyrus Ardalan noted the ARC had met with the auditor and was comfortable with their findings. Tommy Romskaug presented the findings of the external audit, noting:

- The auditor was not aware of any material unadjusted differences, or misstatements, and therefore intended to issue an unqualified auditor's report
- The top area of risk focused on in the audit was awardee costs, and the second areas of focus was investor contributions
- The audit noted that a material part of recognized costs (27%) is cost accruals based on awardee estimates and not approved costs; however, this is a large decrease from 2021 (75%)

The Board and auditor held a closed discussion

### **Resolution: The Board approved the BoD report and the annual accounts**

#### Item 8 – Committee read outs

- NCDIC
  - Recent work has focused on the nominations approved by the Board.
  - The NCDIC received the DEI and HR report before the Board discussion
  - The NCDIC is actively working on bringing forward an extra candidate to replace the seat that will be vacated by Cherry. The executive search consultancy has developed an “outside-in” competency matrix. This will be circulated to the Board, who will be asked for input on their own areas of expertise. This will inform the subsequent recommendation. It will also be shared with the IC in future
- EAC: Met in February to discuss the EA communications plan
- ARC: Has focused on supporting the risk management work, the finance and external audit, and also met with and discussed plans on CEPI's internal audit. In addition, the ARC has had Dr Suzuki join the committee, and it looking to bring in an independent member of the ARC with a strong accounting/audit background
- EIC: Has met monthly, and covered topics including the Pandemic Fund, nominations, specific partnership proposals. In addition, the EIC received a view of 2023/2024 evaluations, and agreed for a lighter touch Board effectiveness review in H2 2023, and that this should include the SAC; and to discuss the 2024 MTR in coming months
- SAC: In April, the manufacturing strategy, as well as upcoming CFPs, will be covered
- JCG: Met in person February 6 and 7 for the first meeting since the start of the pandemic. The group had a slightly expanded membership. The discussion was very positive, and all organizations reflected on what was needed to achieve the 100 DM and deliver countermeasures in an accelerated fashion – specifically considering what each organization would need to do. The JCG also discussed lessons from Mpox and Sudan

#### Items to note and closing The Board:

- Noted the agreements paper, and actions since last meeting paper
- Asked for the actions paper to be updated with the Actions from the March 2023 Board and circulated

Jane Halton

- Noted future Board dates and potential locations
- Thanked the US for hosting the Board meeting
- Thanked Peggy Hamburg for her service to CEPI

- Thanked Cherry Kang for her leadership of the EAC and as Vice Chair of the Board