Summary of Conclusions
Joint Coordination Group meeting

Date	Location
6-7 February, 2023	London

JCG members

- Peggy Hamburg, Chair
- **AVAREF** – Diadie Maiga
- **DCVMN**– Rajinder Suri
- **EMA** – Marco Cavaleri
- **FDA** – David Kaslow
- **FIND** – Bill Rodriguez (Virtual)
- **GAVI** – Derrick Sim
- **IFRC** – Petra Khoury
- **MSF** – Sidney Wong
- **UNICEF** – Andrew Owain Jones (Virtual)
- **Wellcome Trust** – Charlie Weller
- **WHO** – Ana Maria Henao-Restrepo
- **World Bank** – Mukesh Chawla

Guests

- **CEPI SAC Chair** – Manu Hanon
- **Africa CDC** – Shingai Grace Machingaidze (Virtual)
- **Global Fund** – Harley Feldbaum (Virtual)
- **Makerere University, Uganda -** Bruce Kirenga (Virtual)
- **MSF** – Francisco Viegas, Elin Dahl (Virtual)
- **PAHO** - Hector Castro, Marcelo Vila (Virtual)
- **SEARO** –Pushpa Wijesinghe (Virtual)
- **WHO** – Tania Cernuschi (Virtual)

Apologies

- **IFPMA**
- **WHO –** Rogerio Gaspar

Executive Summary

The Joint Coordination Group (JCG) met in person for the first time since the pandemic began, and there was robust and spirited participation from members and invited guests. Discussion topics included:

(1) CEPI 2.0 and the 100 Day Mission
(2) Selected highlights of the CEPI portfolio, including the Animal Model Network and Clinical; Laboratory Network expansions, Chikungunya, and Lassa
(3) Lessons learned from the Mpox and Sudan ebolavirus outbreaks
(4) Evolving organizations for pandemic preparedness and response
(5) Equitable access as a 'system attribute'

There was consensus around the framework of the 100 Day Mission, and an eagerness to further articulate the ways in which JCG member organizations and processes will need to evolve to align with this mission in both the first and second 100 days. A central lesson from members' experiences with the recent Mpox and Sudan ebolavirus outbreaks and a core tenet of the 100 Day Mission is the criticality of pre-positioning elements of a research response or "front-loading" preparedness activities.

A number of discussions touched on the changing landscape of how risk is tolerated by and shared across ecosystem partners. Many participants advocated for developing more clarity about the roles and responsibilities of the JCG partners in the evolving ecosystem and noted the linkages between this conversation and the ongoing global dialogues around the future global health architecture (including the pandemic accord).

There was consensus that partners at every part of the 'value chain' have a responsibility to prioritize and infuse equitable access into their work and that this represents a paradigm shift on par with the acceleration of timelines encapsulated by the 100 Day Mission. It is impossible to guarantee equitable access downstream if it is not part of the upstream and every step in between. Moreover, true equitable access extends beyond access to products and encompasses access to decision-making, data, clinical trial benefits, manufacturing capacity and know-how, and more.

Next steps include:

(1) JCG member organizations share their evolving plans for preparedness and response with one another across organizations. The JCG is happy to be a forum for this, if desired
(2) Use evolving structures to clarify roles and responsibilities of various members across the value chain. Consider pilot testing the draft understanding of this with one or two different types of pathogens in the UNICEF prototype pathogen chart
(3) Develop of a scenario-based exercise or suite of exercises to test some of the assumptions about roles and responsibilities.
(4) Use additional outbreaks as live fire exercises to see how to move faster to 100 days

This was Dr. Hamburg's last JCG meeting as Chair, and future meetings will be planned once a new JCG chair is in place.

ITEM 1: Welcome and introductions

ITEM 2: CEPI 2.0

CEPI CEO Richard Hatchett presented the CEPI 2.0 agenda and how it relates to the 100 Day Mission. He emphasized that this agenda cannot be accomplished by CEPI alone, but rather in partnership with JCG members, industry, and others. Key points from the presentation:

- CEPI 2.0 has three pillars. The "Prepare" pillar is about the threats that we know, including COVID-19 and coronaviruses generally. "Transform" is about how we respond to novel threats / Disease X, and the 100 Day Mission is a core feature. "Connect" is about partnerships.
- Delivering vaccines in 100 days is a break-the-glass emergency scenario for highly lethal epidemic threats, not something we would expect to do for every outbreak.
- Incrementalism will not be sufficient to achieve the 100 Day Mission. Most of the timeline for vaccine development has already been compressed and there is little room to compress it further without a full paradigm shift. That shift is to front-load preparedness activities and break down the firewall between development and intervention.
- The viral family approach is a cornerstone of CEPI 2.0 and the 100 Day Mission wherein CEPI is working to develop pre-existing prototype vaccines for representative pathogens across multiple virus families that can be rapidly adapted on proven vaccine platforms to respond to a pandemic threat (vaccine libraries).
- Dr. Hatchett used the analogy of Formula One pitstop times dropping 97% since 1950 and underscored that safety always remained a primary concern for racing, as it does for vaccine development. Similarly, the commitment and training of the pitstop team, and the trust and confidence of the driver are as important as the technology and process behind the pitstop acceleration. CEPI 2.0 and the 100 Day Mission are effectively strategies for managing risk while accelerating outbreak vaccine response.
- Dr. Hatchett also underscored CEPI's commitment to vaccine development for the core pathogens it has been working on through CEPI 1.0, noting that many of them present development and regulatory challenges that will also be present for the 100 Day Mission.

The main takeaway from the group discussion was that there is consensus around the framework of the 100 Day Mission, which CEPI has demonstrated is technically possible. Now we must collectively work to make it a reality. This includes each JCG member moving more of its activities upstream and in parallel (rather than in sequence), and being able to move more quickly in a crisis. That in turn will require new institutional mechanisms and capacities, as well as greater risk tolerance and understanding of risks. It also includes bringing along other partners, especially in the Global South and at the community level, to build trust, let countries lead, and enable equitable access. JCG members also recognized that planning for the 'second 100 days' (i.e., the period during which scale up and distribution occurs) must begin as early as possible to enable a smooth and timely transition.

ITEM 3: CEPI portfolio

Members of the CEPI team (Mel Saville, Paul Kristiansen, Katrin Ramsauer, and Tim Endy) provided a look into the current status of the CEPI portfolio, with a spotlight on the progress and next steps for select programmes previously discussed by the JCG. In particular, the session highlighted where ecosystem coordination is needed to facilitate ultimate vaccine availability and access for the two most advanced vaccine development programmes (Lassa and Chikungunya). Key points from the presentation:

- The pivot from CEPI 1.0 to 2.0 incorporates learnings from COVID-19, including a focus on greater geographic distribution and capacity building with local stakeholder engagement. CEPI's preclinical/animal model network and clinical laboratory network, for example, are in the process of expanding in terms of both capacity (i.e., number of labs) and geographic distribution.
- The CEPI 2.0 portfolio continues and expands upon the 1.0 portfolio, extending development goals from Phase 2 to licensure. CEPI has at least one candidate in clinical development targeting Lassa, Nipah, Rift Valley Fever, Chikungunya, MERS-CoV, SARS-CoV-2, and broadly protective betacoronaviruses.
- These candidates are being developed on four technology platforms: viral vector, RNA, protein-based, and live attenuated/inactivated. It is important to continue to develop

platforms validated by SARS-COV-2 and build a database of safety and immunogenicity and, in some cases, efficacy data.
- Results from ENABLE, a five-country Lassa epidemiology study, suggest that a Phase 3 trial is feasible. Experts aligned on next steps in October 2022 at a workshop in Abuja co-hosted by WHO, CEPI, and Nigeria CDC, and it is CEPI's goal to support a Phase 3 trial next Lassa season. CEPI is also working with African-based manufacturers to allow for local technology and manufacturing and, if possible, marketing authorization.
- One CEPI-funded Chikungunya candidate has completed tech transfer to a regional manufacturer and has filed for licensure. A second CEPI-funded candidate is about to go into Phase 3 efficacy studies. CEPI hopes to support additional advanced development needs through additional funding, including Phase 4 studies evaluating long-term safety, durability of immunity, and performance in special populations. CEPI and PAHO co-hosted a workshop with regional regulators in December 2022 to give visibility to all vaccines in the pipeline and the regulatory opinions, agnostic to product; the Indonesia FDA is interested in hosting a similar workshop with ASEAN countries in 2023.

Key takeaways from the discussion:
- There is low awareness of Chikungunya vaccines among endemic countries and the fact that Chikungunya is not on the WHO priority list for PQ weakens manufacturer and market interest. It is important to remember that there are many vaccines vying for priority. Better understanding of the disease burden can help drive demand, and CEPI is collaborating with Gavi and Cambridge University to conduct a global burden study that will likely be published this year.
- WHO has a TPP for Chikungunya. JCG members could not locate it online but feel it would be a valuable resource and encourage WHO to enhance accessibility.
- Accelerated licensure based on immunogenicity data is very important for the 100 Day Mission. We also need to think about what needs to happen in the second 100 days in terms of evidence generation because proof of efficacy is still critical even if an alternative regulatory pathway is taken to licensure. But are small developers best placed to individually design Phase 4 studies, or should this be done by or in collaboration with CEPI, WHO, and others to have protocols that can be put in place rapidly? Real world evidence can be randomized evidence with better quality of designs. The world also needs to invest more in animal models and serological studies to support alternative regulatory pathways to accelerate licensure. And in the second 100 days, manufacturing needs to scale up, and downstream partners need to be able to deliver vaccine and support countries in need.

ITEM 4: Lessons learned from Mpox and Sudan Ebolavirus

Ana Maria Henao-Restrepo (WHO) gave an overview of the progress of the WHO R&D Blueprint program and how the research response to outbreaks has improved as we collectively expand our knowledge and preparedness. Key points from the presentation:
- The first candidate vaccine doses arrived in Uganda in just 79 days, demonstrating that we can meet and even exceed the 100-day goal if we work together. WHO's aim is to be able to consistently launch clinical trials within one week of an outbreak of a pathogen on the Blueprint list.
- Achieving this goal requires partner commitment to several preparedness actions, including accelerating necessary development research so that products are available for testing. Dr. Henao-Restrepo outlined an approach to fast-track assessment of candidate vaccines and support pandemic prevention and control based on pre-positioned candidate prioritization, agreements, trial platforms, and financing. One key learning from the SUDV outbreak is that we need to have vaccine in vials, ready to go; previously we thought having bulk would be sufficient.
- Dr. Henao-Restrepo reported that the R&D Blueprint has published R&D roadmaps and vaccine, therapeutics, and diagnostics candidate landscapes, TPPs, trial designs, simple trial

protocols, and regulatory pathway consultations for many of the 13 pathogens it covers and Pathogen X. [Again, JCG members could not locate many of these documents online.]

Nicole Lurie (CEPI) then summarized the common themes among the Mpox and SUDV lessons learned that JCG members had reported in advance of the meeting and posed some questions to the group. These included, broadly:

- The challenges and importance of mobilizing simultaneous public health and research responses and the value of both South-South and North-South collaboration.
- The pivotal role of preparedness.
- The roles/responsibilities and timing of all parts of the "value chain" must be calibrated cohesively.
- New approaches – such as simplified regulatory pathways and viral family approaches – are evolving.
- What is the responsibility of organizations like CEPI to help developers get doses into vials and into countries as quickly as possible?
- Under what circumstances do we think about a research response with a Phase 1 vaccine? And who is responsible for a reserve of such investigational vaccines?
- Countries in the Global South want to drive things, be respected, and have responsibility. How can we be sure that happens?

The group discussion coalesced around questions of incentives, trade-offs, and roles and responsibilities – particularly regarding multi-party coordination:

- Do we need some sort of 'umbrella' organization that is accountable for coordinating and managing partners?
- How can we better work to ensure studies conducted in an outbreak are of high priority, non-duplicative, timely, and of broad geographic applicability to inform policy and regulatory decision-making? Particularly recognizing that alternative regulatory pathways are built on an expectation of appropriate post-approval studies? How can we prevent developers' financial (dis-)incentives from stymieing other researchers' efforts?
- How should the process of defining roles/responsibilities move forward?
- Who is responsible for coordinating access to vaccines across multiple countries in the second 100 days?
- How can we better incentivize companies to produce vaccines at risk, with no expectation of scale-up and marketing? How do we recalibrate our own models of support and expectations of risk-sharing as larger, traditional players increasingly leave the field and smaller biotechs and academics enter it?

Additional conclusions included:

- Reserves of clinical trial material are a critical part of preparedness and manufacturing is an important aspect of regulatory review. UNICEF would like to re-examine the legal issues around title and liability for investigational vaccine stockpiles and see how they can resolve them, potentially in collaboration with CEPI and WHO.
- To be ahead of the viruses, we need to invest in early discovery, surveillance, viral genetics, phenotyping, serology, etc.
- These JCG discussions are happening within a broader context and need to move in alignment with other discussions (such as the pandemic accord).
- We need a diversified portfolio of tools that optimize for different goals and can be applied in different situations.
- The 100 Day Mission must recognize the different political dynamics that will influence the response to pandemics vs. localized or regional epidemics, including nationalism around vaccine research and allocation, as well as company profit incentives.

ITEM 5: Summary and Close

ITEM 6: Welcome and Day 1 Recap

ITEM 7: Evolving Organisations for Pandemic Preparedness and Response (PPR)

Many organisations are revisiting their approach to pandemic preparedness and response as a result of the COVID-19 pandemic. Saul Walker (CEPI) presented some frameworks for discussion around how the JCG might facilitate alignment and coordination of these strategies in support of a cohesive, end-to-end value chain. This value chain is non-linear and not serial, and feedback loops must occur throughout the system so that downstream realities influence upstream decisions and upstream decisions impact available options downstream. UNICEF has developed a set of nine outbreak archetypes for consideration, based on stage of development and how small/local vs large/global the pathogen is likely to be.[1] Mr. Walker encouraged JCG partners to consider, for different outbreak archetypes and geographies, which organizations need to mobilize along the value chain and how they interact. He utilized the analogy of a relay race in which all the runners need to stretch, have their shoelaces tied, and be ready to make and receive hand-offs of the baton.

Mr. Walker underscored that these discussions are taking place against a broader backdrop of health systems reform and that universal health coverage and a strong primary health system are the anchors for talking about 'flexing' for outbreaks. There are also several evolving pandemic preparedness and response political architecture dialogues ongoing that the JCG's work must dock into. Mr. Walker asked how we can best develop coordination proposals further with broader consultation while putting in place agile operational arrangements to address new pandemic threats that arise in the interim.

Partners offered numerous suggestions for refining Mr. Walker's strawman mapping of partners against the value chain, including adding references to diagnostics, market shaping, and industry involvement, inter alia. CEPI will continue to work with JCG partners to improve the mapping. As part of this effort, partners suggested it would be useful to walk through what the value chain looks like for some of the CEPI priority pathogens, possibly through a tabletop exercise. Some core questions and concepts for a such an exercise to examine bubbled up through the group discussion:

- It is impossible to guarantee equitable access downstream if it is not part of the upstream and every step in between. How can partners at every part of the value chain prioritize and infuse equitable access into their work? If we do not look at all aspects of equitable access (i.e., access to doses, but also to manufacturing capacity, data, clinical trial benefits, etc.), we cannot change the paradigm. The 100 Day Mission needs to better reflect this.
- Some organizations – particularly those that are used to operating more to the left side of the value chain – are better equipped to take and manage risk than others are. We are now puling more organizations to the left, which means their risks are increasing. How can we acclimate our governance bodies to that new paradigm and better articulate the way risks are transferred along the value chain?
- What are the triggers for each of us to act in the different archetype situations? How do we, as partners along the value chain, communicate with each other and keep the system running smoothly without a designated conductor?

Mukesh Chawla (World Bank) also challenged the group to examine how each partner is revisiting their preparedness work the implications for each organization of CEPI 2.0. He noted that the financing sector is not currently set up to support essential preparedness work. Stimulating country

[1] The nine archetypes were initially designed to think through implications for UNICEF market intervention levers – and they do not replace the WHO emergencies grading system – but there was general agreement that they can be a complementary tool for other JCG partners in planning the types of responses we likely need to be prepared for in terms of medical countermeasures.

demand for preparedness funding is a key challenge, and part of the solution is tearing down the vertical vision of pandemic preparedness and instead integrating it across issues of daily political concern such as routine healthcare delivery.

ITEM 8: Toward an Equitable Access System

Equitable access was a consistent discussion point across the two days of this meeting. During this session, Kwasi Amfo (CEPI) explained CEPI's Equitable Access Framework (EAF), which is based on the principle that equitable access is a system attribute and that all actors in the global health architecture have responsibility and accountability for it. If we do not design a system to produce equity, it will not do so. CEPI welcomes greater engagement with the broader access community as it develops an implementation plan for the EAF.

Two broad discussions ensued. The first centred on the idea that regulatory readiness, including harmonization, can accelerate access. There is an ambitious agenda to be pursued, including through ICMRA, to further the progress made during COVID-19. The group discussed what CEPI's (and similar organizations like BARDA and HERA) role can and should be in looking across developers/projects and flagging systemic issues for regulators to discuss in a product-agnostic way.

The second discussion centred on the concept of equitable access and how to operationalize principles of diversity, equity, and inclusion across the end-to-end ecosystem. It was noted that achieving an effective public health response is not the same as achieving equity and the "how" is just as important as the endpoint. JCG members also felt that the term "equitable access" needs to include an aspect of timeliness.

ITEM 9: Applying our Learnings

Dr. Hatchett framed the JCG discussions from the past two days in the context of broad, global political and economic shifts such as regionalization that influence the changes that are needed and can be made in the pandemic preparedness and response ecosystem. He underscored that this transformative historical moment creates an opportunity to make a paradigm shift. He also noted that the role of the JCG has evolved with the challenges that we have faced as a community and that the JCG is an institutional roundtable.

This meeting has – encouragingly – revealed that there is an essential alignment on many critical issues across JCG partners. One of those areas of alignment is an understanding that we need to have accelerated development of medical countermeasures and they need to be equitably accessible (what CEPI has termed the "100 Day Mission.") The JCG however, is not a decision making or operational body. It is therefore up to each individual organization to now determine how it can support the 100 Day Mission, and Dr. Hatchett proposed that the JCG continue to provide a forum for collective alignment of those activities.

ITEM 10: Summary and Close

Next steps:

- JCG members should go back to their organizations and drive internal reflection on how to contribute to the '100 Day Mission.' CEPI offers it support to help expand these conversations.
    - It was recommended that CEPI convene the heads of JCG member institutions to explain the 100 Day Mission.
- JCG members are encouraged to share relevant developments within their organizations and sectors with the other JCG members so that we can continue to move in the same direction.
- We need to get more concrete about the value chain in specific scenarios and lay out, step-by-step, all of the parallel streams that need to happen and by whom. Diverse partners, including

those from regions most likely to be affected, should contribute to this action plan. A tabletop exercise or simulation could be one way stimulate this, and CEPI will develop a concept note to share with the group.
- The COVAX partners have been meeting weekly to discuss how they work together post-COVAX to address future outbreaks, epidemics and pandemics and would like to broaden this conversation to other partners and through the JCG at a future meeting.
- CEPI will continue to notify JCG partners if it is taking steps in vaccine R&D&M in response to new outbreaks, with a goal of keeping everyone informed and continuing to make progress toward 100 Days.
- CEPI will share proposed dates for future meetings after the CEPI Board approves the appointment of the new Chair in March.

CEPI and the JCG wish to thank Dr. Peggy Hamburg for her six years of service, leadership, and amity as Chair of the JCG.