Joint Coordination Group
Meeting Summary

Date	Time	Location
Wednesday, 31 January 2024	08:30 – 12:30	London, UK

Welcome and Introductions

JCG Chair, Gagandeep Kang, opened the meeting with a reminder that the purpose of the JCG is for CEPI to hear from and discuss ideas with stakeholders in the vaccine preparedness and response ecosystem in an informal forum without needing to make decisions. CEPI benefits particularly from the perspectives of stakeholders whose expertise augments that within CEPI and, consequently, has recognized the need for greater regional and country representation in the JCG.

The meeting then proceeded to review progress in areas previously addressed by the JCG. Following the presentations and discussion, in response to participants at a prior JCG meeting, JCG attendees participated in a tabletop exercise aimed to examine aspects of the 100 Day Mission.

Progress in Regulatory Innovation

CEPI Director and Head of Global Regulatory Affairs and Quality, Adam Hacker, provided an overview of how CEPI is driving regulatory innovation in epidemic preparedness and response. He highlighted that:

- CEPI is in a unique position to gather deep insights from our network of funded partners, collaborations with industry, and extensive interactions with the WHO and regulatory authorities worldwide.
- CEPI is using those insights to map out regulatory strategies to address identified bottlenecks, especially what is needed for the 100 Day Mission, and drive both incremental and paradigm shifting innovations to accelerate vaccine development. Existing precedents in vaccine development provide a reason to believe that acceleration is possible, e.g. Chikungunya vaccine development showed that correlates of protection can be used for licensure in the absence of efficacy data; in the case of COVID-19 vaccine development immunobridging can be used for licensure and platform data can be used to support strain-change. Several CEPI initiatives for regulatory strengthening were discussed (see slides)

Key takeaways from the discussion included:

- Trust is built across regulators by working together in 'peacetime.' JCG partners should learn from existing mechanisms for work-sharing and regulatory reliance and recognition (e.g.,

WHO EUL, ACCESS consortium, Project Orbis, AVAREF, EMA OPEN) and such mechanisms and collaborations should be expanded.
- The Regulatory Advisory Group (RAG), which was created by CEPI and WHO during the COVID-19 pandemic, was highlighted as a particularly constructive mechanism.
- Members were enthusiastic about CEPI initiatives to further collaborative regulatory review and information sharing. Regulatory authorities in the regions where vaccines for potential outbreak / endemic diseases (e.g. Lassa) are being developed must be consulted from the outset so they can fully understand and evaluate the clinical research needs and support risk benefit evaluation. CEPI regulatory engagement in those regions was noted and strongly supported.
- Accelerated regulatory procedures, use of regulatory reliance and recognition, and emergency procedures should all be developed, built upon, and pressure tested in peacetime before an outbreak starts.
- WHO's work in the African region is helping countries understand regulatory hurdles to the 100 Day Mission, such as strengthening linkages between ethics committees and regulatory bodies.

Next Steps and CEPI Recommendations:
- CEPI and WHO should continue to implement initiatives that support ethics and regulatory review and the 100 Day Mission.
- CEPI and WHO should sustain the RAG.
- CEPI, with relevant developers, should ensure that regulators - in potential outbreak regions - are involved in discussions around regulatory requirements and made aware of what developers' clinical development plans to become familiar with generated data.
- Country regulatory capability should be built alongside any manufacturing capacity. Partners such as WHO, AVAREF, RVMC, and/or GAVI could likely play a role in connecting these efforts.

CEPI Networks

Nicole Lurie, CEPI Executive Director for Preparedness & Response, explained the progress CEPI has made in expanding its Centralized Laboratory, Animal Model, and Manufacturing Partner Networks – particularly bringing on new partners across the Africa, Latin America, and South Asia. She noted that these networks are available to all and not just for products that CEPI is developing. CEPI CEO Richard Hatchett added that CEPI will soon be announcing a network of controlled human infection model (CHIM) laboratories, which will also be a global resource.

Next Steps and CEPI Recommendations:
- CEPI will clarify how regional developers and regulators can make use of these networks.

Mpox

Nicole Lurie summarized CEPI's Mpox activities to date:
- CEPI has funded reagents and standards and, in 2022, convened the JCG at the request of one of its regulatory members to talk about what is needed to expand access to Mpox vaccines in certain situations.
- CEPI also started a collaboration with BioNTech to bring an Mpox vaccine candidate through Phase 2 development as an orthopox 'prototype' vaccine, as part of CEPI's viral family work.
- The epidemiology of Clade 1 has worryingly evolved in endemic countries and the CEPI Board has requested an Mpox investment proposal in March 2024 to enable equitable access to vaccines in low resource settings.

- CEPI is reviewing clinical data and the regulatory environment, working very closely with WHO and others, and requested JCG input (particularly from those in the affected region) regarding the R&D and manufacturing gaps CEPI might fill.

Key takeaways from the discussion:

- There was enthusiasm for CEPI engagement in this area, particularly to support African regulators in a regionally-led effort and to generate the additional data needed by these regulators. CEPI will discuss next steps with Africa CDC.
- Participants from the African region and regulatory agencies emphasized the importance of conducting immunobridging studies in people in endemic countries, prioritising key populations where there are evidence gaps (e.g. pediatric). It was felt ethics review boards would likely be supportive of a randomized clinical trial – if feasible –given the limited doses available.
- As part of an African-led effort, laboratory analyses should be done on the continent

Next Steps and CEPI Recommendations:

- CEPI will engage the African partners in its Centralized Laboratory and Animal Model Networks in support of immunobridging studies.
- CEPI will work with stringent and regional regulators to compile regulatory and real world evidence data on the currently licensed Mpox vaccine.
- CEPI will further engage countries regarding evidence needs and gaps.
- Gavi and CEPI will collaborate on an Mpox learning agenda.
- CEPI will update partners regarding its MPox agenda going forward, and seek continued input from, and collaboration with, affected country/regional partners.

Chikungunya

CEPI Business Development Lead, Sourabh Sobti, updated participants on the status of Chikungunya vaccine development, noting that Valneva's IXCHIQ is now the first-ever licensed Chikungunya vaccine and that CEPI secured access to approximately 200,000 doses as part of its funding agreement with Valneva. He noted that gaps remain in the evidence required for policy and financing decisions and that CEPI will imminently be announcing awards for studies to close some of these gaps. Chikungunya is part of the Gavi learning agenda and is a 'Medium Priority' for WHO prequalification; the WHO Strategic Advisory Group of Experts on Immunisation (SAGE) will discuss Chikungunya vaccines in March 2024.

Key takeaways from the discussion:

- FDA's approval of IXCHIQ was "trailblazing" and a learning opportunity because it was approved under an accelerated pathway while requiring post-authorisation data. This has implications for thinking about the 100 Day Mission.
- It is also a very good case to test collaboration: multiple regulatory authorities will require a post-approval study, so we will need collaboration and coordination across regulators and public health authorities in different countries, as well as agreement on the study design, particularly because the speed and unpredictability of Chikungunya outbreaks makes randomisation difficult.
- Defining the market and market segments well before licensure is important both for developers to weigh against the challenges of implementing post-authorisation requirements and to ensure that studies consider the needs around the anticipated market as well as around vaccine effectiveness.

- There may be a role for Gavi to fund deployment of doses for post-licensure studies through routine immunisation programmes. Gavi is looking at this under its learning agenda and in discussion with partners like CEPI and WHO.

Next Steps and CEPI Recommendations:

- CEPI, Gavi, and WHO will collaborate on a learning agenda.
- CEPI will evaluate how it can best support the collaboration of multiple regulatory and regional authorities in reviewing evidence and in considering additional studies.
- CEPI will update the JCG once it makes awards under its EUR 50 million CHIKVACCINE call for proposals (anticipated in March 2024).
- CEPI will discuss potential approaches to allocation of stockpiled doses with relevant organizations.

The XVAX Network and the Regional Vaccine Manufacturing Collaborative (RVMC)

CEPI Director of Public Partnerships, Saul Walker, discussed three examples of how CEPI is working with ecosystem partners to align and hand off responsibilities effectively: the WHO-led *interim* Medical Countermeasures Network of Networks (iMCM-Net), the XVAX Network (which docks into the iMCM-Net), and the Regional Vaccine Manufacturing Collaborative (RVMC).

Next Steps and CEPI Recommendations:

- CEPI and other partners should continuously reevaluate the roles they play in working together, particularly noting needed adjustments as the Pandemic Accord moves forward.

T24: A 100 Day Mission Tabletop Exercise

A discussion-based tabletop exercise was led by Kevin O'Prey (Palisades Group, LLC). The objectives of the exercise were to:

1. Evaluate the functional and operational steps required to implement the 100 Days Mission and carry it through to the second 100 days and beyond.
2. Discuss ways to build transparency and other confidence-building mechanisms throughout the process of vaccine development, authorization, and deployment and building trust – in one another as partners, in the regulatory process, and among communities – in implementing the 100 Days Mission.
3. Develop a shared vision and commitments to translating the vision of the 100 Days Mission into complementary operational plans.

Move 1 took place in the early days of a simulated emerging epidemic. Key takeaways from the discussion:

- Thresholds and triggers are not well-defined, but a Public Health Emergency of International Concern (PHEIC) declaration is clearly too late to mobilise a response. We need to consider other triggers, including from regional institutions, and recognise that different organisations have a different "Day 0."
- Information sharing in the early days of an outbreak is highly dependent on established relationships of trust through informal networks, which means there is often information asymmetry. However, these informal networks also provide an essential alert mechanism; any future system must recognise the value of both formal and informal networks.
- Several participants proposed that the XVAX Network serve as a formal convening forum for the vaccine element of a response.
    - Regional actors and industry must be part of this.

    - Pre-identified focal points in each organisation can connect the XVAX Network to the experts within their organisation that are appropriate to the particular outbreak context.
- Others emphasized the importance of avoiding the creation of parallel systems. There may be value in having a more targeted forum like the XVAX Network that can focus on vaccine-specific issues, but it is critical that it remain tightly connected with the overall public health response led by WHO and the affected government(s).
    - Similarly, there are systems, capacities, and triggers in place globally through the International Health Regulations (IHR) and at regional levels. The XVAX Network should complement and support these.

Move 2 took place a few weeks into the 100 Day Mission. Key takeaways from the discussion:

- Participants recommended that WHO convene regulators (of varying maturity levels) as early as possible in an outbreak, but also emphasized the importance of bilateral regulatory conversations.
- To determine a regulatory pathway, regulators need data to understand the disease, the target population, and whether any existing candidates or platforms can be leveraged. The regulatory pathway should be determined and broadly communicated as early as possible.
- To enable equitable access to vaccines, regulatory information sharing cannot be siloed according to region or institutional maturity level. Data sharing and cross regulator discussion is critical
    - Evolving conversations around access to data and samples, including through the Pandemic Accord, will have an important impact on this.
- Emergency authorisation provides flexibility and agility, but it also introduces complexities that will need to be distentangled well after the acute epidemic.
- *See also the key takeaways from the earlier discussion on Regulatory Innovations, many of which were reiiterated during this exercise.*

Move 3 took place after the first 100 Days. Key takeaways from the discussion:

- Community actors need to be involved before, during, and after an outbreak; trust cannot be built in a crisis.
- During an outbreak, global-level civil society organisations can work with local actors to prepare communities that are not yet affected. Any solutions – including vaccine rollout- must be co-created with communities. The Red Cross network is an example of a group that does this work day in and day out, and may be an important resource.
- Public communication about vaccines needs to be provided as part of a cohesive whole that addresses other public health measures. Malaria programmes provide an excellent example for how ecosystem partners can begin building trust in vaccines against CEPI's priority pathogens well in advance of product delivery.
- With emergency authorisation – especially in an accelerated, 100-Days-Mission scenario – authorities must be truthful about what is known at any given time and indicate that there will be course corrections as more information becomes available. Public health authorities, regulators, and developers must trust each other and work together to do this.
- There are certain elements of public mistrust that we can anticipate in a 100 Days Mission scenario and therefore start to mitigate them now through appropriate risk communication and by working with routine immunisation programmesto build trust in the platforms, processes, systems, and actors involved in developing a novel vaccine.
    - For example, there will be confusion around evolving evidence and resulting changes in policy recommendations, the prioritisation of different populations for vaccination, the variance in recommendations across regulators and agencies, and the occurance of side effects.
- Having a robust pharmacovigilance system in place will accelerate our understanding of safety and causal relationships post-emergency authorisation.

- Many partners are examining issues of trust and mis-/disinformation, but there is no single entity coordinating these efforts on a global scale in the context of the 100 Days Mission.

Next Steps and CEPI Recommendations:

- The XVAX Network should consider whether/how it might play a role in facilitating early, informal conversations at the onset of a potential outbreak, before the operational needs are clear and in a way that complements existing systems.
- Groups of regulatory agencies should consider whether further exercises will help with identification of additional approaches to information sharing and collaboration that will facilitate decisionmaking in a compressed time frame.
- Partners should consider whether a coordinating entity related to trust and misinformation in the context of the 100 Day Mission is needed and would be useful.
- *See also the next steps and recommendations from the earlier discussion on Regulatory Innovations.*

The Chair summarised the JCG meeting by thanking the presenters for sharing critical areas being explored and advanced by CEPI, stakeholders and partners in the evolving 100 Days Mission. She pointed out engagement with affected countries, regional and global agencies were all necessary in the context of an emergency and that the exercise had illustrated the need for continued discussion for greater clarity of roles and responsibilities. She thanked the participants for their insightful contributions and suggested future JCG meetings continue with the themes discussed here – with a broad set of representatives at the national, regional, and global levels who will be 'on the frontlines' of the next epidemic.

Dr. Lurie added that CEPI will look to conduct more exercises like this in the future.

Annex I: Attendees List

JCG Members

- Chair, Gagandeep Kang
- **AVAREF** – Chinwe Iwu-Jaja
- **DCVMN** – Rajinder Suri
- **EMA** – Marco Cavaleri
- **FDA** – David Kaslow
- **FIND** – Sergio Carmona
- **Gavi** – Derrick Sim
- **IFPMA** - Hamilton Bennett
- **IFRC** – Petra Khoury
- **UNICEF** – Hans Christiansen
- **Wellcome Trust** – Charlie Weller
- **WHO** – Ana Maria Henao Restrepo *(virtual)*
- **World Bank** – Magnus Lindelow

Guests

- **Africa CDC** – Jean-Marie Okwo Bele
- **ANVISA** – Fabricio Carneiro de Oliveira
- **NAFDAC** – Christianah Mojisola Adeyeye (*virtual*)
- **PAHO** – Andrea Vicari
- **PAHO Technical Advisory Group** – Peter Figueroa
- **Rwanda Ministry of Health** – Jean-Claude Muvunyi (*virtual*)
- **SAHPRA** – Boitumelo Semete (*virtual*)
- **Thailand Ministry of Health** – Nakorn Premsri (*virtual*)
- **UNICEF** – Tara Prasad (*virtual*)
- **WHO Prequalification** – Rogerio Gaspar

Observers

- **IPPS** – Heulwen Philpot (*virtual*)
- **WHO** - Benedict Millinchip
- **WHO** – Ioana Ghiga (*virtual*)

Apologies

- **Nigeria CDC** – Ifedayo Adetifa
- **SEARO** – Vinod Bura
- **WHO African RITAG** – Omary Sultani

CEPI

- Richard Hatchett
- Nicole Lurie
- Adam Hacker
- Saul Walker
- Sourabh Sobti
- Gwen Tobert
- Roshni Best
- Freya Hopper
- Jakob Cramer
- Samia Saad
- Martina Ochs
- Mark Lucera
- Joe Simmonds-Issler
- Shriya Prasad