EQUITABLE ACCESS REVIEW OF

CEPI's Chikungunya Partnership Agreements

O'NEILL INSTITUTE
GEORGETOWN LAW

CENTER FOR TRANSFORMATIONAL
HEALTH LAW

Equitable Access Review of CEPI's Chikungunya Partnership Agreements

This Equitable Access Review (hereafter the Review) of CEPI's Chikungunya vaccine development agreements was commissioned by CEPI in 2024 as an external review of how equitable access has been incorporated into CEPI's partnerships and planning leading to the licensure of the first Chikungunya vaccine by the US FDA in 2023 and other candidates now in late stage development. This Review aims to evaluate and generate lessons learned on how CEPI performed against its commitment to equitable access, and how these learnings may contribute to further enhance CEPI's agreements and activities moving forward. The Center for Transformational Health Law (CTHL) at the O'Neill Institute for National and Global Law at Georgetown University, was selected to undertake the Review. This section presents the key findings from the Review, which are examined in detail in this report.

KEY FINDINGS

The licensure of the first Chikungunya vaccine demonstrates the critical role of CEPI's mission in the global health architecture to enable equitable access. It is possible, although far from certain, that a private "travelers' market" (and the incentives high-income governments offer for certain medical breakthroughs) for one or more Chikungunya vaccines, or high demand from endemic and low-middle-income countries (e.g. Brazil and India), would alone provide sufficient incentive for private sector investment adequate to achieve licensure by a national regulatory authority and subsequent WHO prequalification. It is also possible, although far from certain, that a public sector investment driven largely by defense or military interests would produce such a vaccine. It is likely, without investments by CEPI or a similarly oriented organization, that neither of these motivations would mobilize sufficient resources to achieve a safe and efficacious vaccine against the Chikungunya virus specifically targeted to be accessible to those in endemic regions.

The licensure of a CEPI-supported vaccine is good evidence that it played a direct role in bringing to market a medical intervention that will address the significant morbidity and disability resulting from Chikungunya virus infection, play a key role in outbreak or epidemic response, and support public health agencies in endemic countries as well as the relatively small private market for out-of-pocket purchase in countries like India. Furthermore, CEPI's investments in technology transfer and data generation in endemic countries may be instrumental in ensuring long-term, sustainable access to Chikungunya vaccines where they are needed most.

CEPI's internal processes effectively mapped leading Chikungunya candidates, established pathways toward licensure and WHO prequalification, and developed tailored terms for partners' diverse vaccine platforms and regulatory strategies. The structure and direction of CEPI's calls for the development of human vaccines against Chikungunya viruses effectively steered investment incentives to lead candidates from Phase II through Phase III clinical trials, facilitated formation of technology transfer agreements with geodiverse manufacturers, and secured CEPI's rights to direct use in emergency circumstances and ultimately supported vaccination strategies in regions in LMICs affected by the virus – an area that is expanding.

CEPI Board's Equitable Access Committee (EAC) responded nimbly and flexibly to novel contracting issues and advised with principle-based guidance, although it should meet more frequently and predictably. When novel contractual and benefit-sharing possibilities – for example, a rolling safety stock of CHIKV vaccine - arose over the course of Chikungunya development agreement negotiations, the Equitable Access Committee guided CEPI based on principles of transparency and that the conclusions reached could be applied to other or future CEPI partners. All internal interviewees agreed that turnover at the EAC had affected its ability to meet regularly and predictably. Looking ahead, strengthening the EAC's continuity and increasing its frequency of engagement could further enhance its role in shaping CEPI's equitable access strategy, fostering more consistent oversight, and ensuring that CEPI's commitments to fair distribution and benefit-sharing continue to evolve in alignment with emerging global health challenges.

CEPI's terms for rolling safety stock and benefit-sharing were well-aligned with its Equitable Access Policy and Framework. Rolling safety stock requirements, stake in revenues from high-income markets, and partner obligations with respect to priority review voucher awards represented contractual innovations that aligned well with CEPI's broader equitable access commitment and framework. A priority review voucher (PRV) is an award from the U.S. Food and Drug Administration (FDA) that speeds up the review of a future drug application. It is awarded for developing treatments targeting diseases that commercial developers might otherwise neglect and can be sold or transferred.

As CEPI's work expands across the global vaccine supply chain, it may need to develop more extensive policies for downstream technology transfer and consider additional internal guidance as its role in shaping market dynamics evolves. While CEPI itself does not play a procurement role for the vaccines it supports, its influence extends to how its funding partners establish manufacturing and commercialization arrangements. The successful development of partnerships where CEPI is not a signatory to the agreements raises new questions about CEPI's role and interests. As those partners apply for licensure, interact with Gavi, UNICEF, and WHO, and other global suppliers, and increase their role in the commercialization of vaccines to low- and middle-income countries, CEPI may wish to further develop policies and guidance for terms it may or should influence in downstream agreements. This guidance may direct CEPI's efforts at enabling equitable access and transparency where it is not a party or observer for downstream partnerships.

CEPI's Chikungunya vaccine development agreements have provided an opportunity to review its rights to clinical trial data generated through funded projects. Vaccine development agreements with selected candidates were made within different contexts, including varying vaccine platforms, regulatory approaches, and stages in the development process. Differing data-sharing requirements became apparent as the candidates advanced

toward Phase II and Phase III trials and licensure. This variation may support the need for a more tailored approach to securing rights to clinical trial and pre-clinical trial data, including those predating the agreements' effective dates.

Based on reviews of 4 agreements – 3 under CfP3i and 1 under CfP3iii - and interviews with CEPI representatives, specific agreement provisions are recommended. In this Review, the Calls for Proposals (CfP) under CEPI's Chikungunya vaccine development initiative are categorized into CfP3i and CfP3iii, each with distinct objectives. Both CfP3i and CfP3iii were co-funded by the European Union. CfP3i focuses on advancing vaccine candidates through Phase III clinical trials, regulatory approvals, and WHO prequalification, while ensuring robust clinical data generation, including studies in endemic LMIC regions. It also emphasizes manufacturing readiness and engagement with global and local regulatory authorities to facilitate vaccine accessibility in endemic areas.

CfP3iii primarily aims to facilitate technology transfer to geo-diversified manufacturers, while also supporting long-term clinical and effectiveness studies, including those assessing antibody persistence and expanding indications for adolescent and pediatric populations. The key distinction between the two is that CfP3i prioritizes vaccine development and regulatory progress, whereas CfP3iii is designed to enhance manufacturing capacity and long-term accessibility through technology transfer, in addition to providing late-stage funding to assess long-term safety, durability of protection and a measurement of vaccine effectiveness.

> One agreement appears to retain injunctive remedies for the vaccine developer in the situation where CEPI exercises the Public Health License while all agreements give CEPI the right to seek injunctive relief against the developer in parallel to dispute resolution by arbitration. Given the importance of dispute resolution for CEPI's interests, especially equitable access interests and the Public Health License, CEPI may wish to consider reserving injunctive remedies for itself, in other words only CEPI would be entitled to injunctive relief for priority interests like data sharing and the Public Health License.
>
> Definitions of "emergency" and "outbreak" differed between the agreements. Two agreements define "outbreak" with respect to only WHO or national government declarations, while one agreement specifies declarations made by "one or more public health agencies" which may convey implicit or ambiguous alternatives. In all agreements, CEPI *does* specify its rights to direct use for an increased outbreak preparation need. Across agreements, references to "outbreak" are consistently paired with mentions of an "increased outbreak preparation need," which CEPI determines at its discretion after consulting with experts, reducing the materiality of differences in definition of "emergency" and "outbreak."
>
> Provisions specific to access by healthcare workers featured in only one agreement and that provision is advised to be included more broadly going forward.

CEPI's Equitable Access Policy and Framework should be integrated into CfP3i governance. While CEPI's Equitable Access Policy and Framework are reflected in standard contractual terms, there can be a better sustained governance mechanism whereby the CEPI Board's Equitable Access Committee is apprised of developments over the course of project progress or a specific voice for equitable access is included at the JMAG. One of the agreements reviewed established an Equitable Access Group, integrating to some extent the Equitable Access Lead into the JMAG, and creating an Equitable Access Plan to better

communicate EA terms appearing across development agreements. It is advised that these features be more detailed and particularly with respect to the latter, that the additional benchmarks be integrated into the plan through the quarterly reports.

CEPI should consider developing internal criteria for when the Secretariat should refer questions to the CEPI Board's Equitable Access Committee. In the interest of transparency and replicability, CEPI may wish to consider development of internal criteria that may guide project leads, counsel, and other CEPI staff for when matters arising during negotiations or project execution should be weighed by the Equitable Access Committee and advice issued. Such criteria may include questions of novelty, cost, and divergence from CEPI's standard policies.

CEPI should consider developing asset and rights repositories. As CEPI progresses through 2.0 and with the evolving emphasis on transparency in its EA principles, it is advisable for CEPI to develop a comprehensive repository of its assets, including rights to require use of stockpiles during outbreaks and intellectual property access rights. This initiative would enhance transparency, accountability, and equitable access to the 'public goods' CEPI manages. As one of the interviewees suggested, such asset repositories would make it easier to scrutinize its use and ensure equitability.

CEPI should consider engaging in discussions on a safety stockpile management framework. Access to CEPI's rights to direct the use of safety stockpiles may attract equity and transparency concerns. CEPI should consider engaging with international partners such as Gavi, PAHO, UNICEF and WHO on developing a global stockpile framework that ensures equitable and timely access.

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BACKGROUND

This Equitable Access Review (hereafter the Review) of CEPI's Chikungunya vaccine development agreements was commissioned by CEPI in 2024 as an external review of how equitable access has been incorporated into CEPI's partnerships and planning leading to the licensure of the first Chikungunya vaccine by the US FDA in 2023 and other candidates now in late stage development. This Review aims to evaluate and generate lessons learned on how CEPI performed against its commitment to equitable access, and how these learnings may contribute to further enhance CEPI's agreements and activities moving forward.

Chikungunya or Chikungunya virus infection (hereinafter CHIKV) is an arboviral disease primarily transmitted to humans through the bite of an infected mosquito, mainly *Aedes aegypti* and *Aedes albopictus*. CHIKV primarily affects tropical and subtropical countries, leading to its identification as a priority pathogen by CEPI and the World Health Organization (WHO). Infected individuals typically experience fever and joint pain, which may last for years and cause disability and significant decrease in quality of life.

The mortality rate for CHIKV is roughly 1 in 1,000, and pediatric populations and those over 65 who contract CHIKV are at heightened risk of long-term complications and mortality. Immunodeficient populations are susceptible to liver failure, brain swelling, and seizures; infants are at higher risk of developing sight limitations, retinal lesions, acute disseminated encephalomyelitis and Guillain-Barré syndrome.

In accordance with the proposal as initially accepted, the primary audience for this Review is CEPI's Board. These findings may also be of interest to other constituencies, namely the CEPI Scientific Advisory Committee, which plays an advisory role, and the CEPI Board's Equitable Access Committee, which oversees CEPI's approach to enabling equitable access. Key audiences may also include global health organizations such as the WHO and GAVI, policymakers in ministries of health, pharmaceutical and biotech companies (manufacturers and developers), academic institutions, and advocacy groups focused on equitable access to vaccines. Additionally, funding bodies and community health organizations would benefit from the insights, ensuring that the findings contribute to broader discussions on global health equity, pandemic preparedness, and access to life-saving interventions. This review is also aimed at enhancing transparency, fostering collaboration, and driving impactful change.

The Center for Transformational Health Law (CTHL), housed at the O'Neill Institute for National and Global Law at Georgetown University, was selected to undertake the Review. The work of the Center for Transformational Health Law focuses on examining legal and health policy responses to the COVID-19 pandemic, advancing evidence-based public health law, and supporting more equitable systems for improved health around the world. Its experts are current and former practitioners in the law of biomedical innovation, scholars of public health preparedness law and regulation, and experts in the law of technology transfer.

The Review began in May 2024, and focused on evaluating the implementation of CEPI's Equitable Access Policy in Chikungunya vaccine agreements, the advances made towards CEPI's commitment to enabling equitable access to vaccines through its funding and ensuring "vaccines are first made available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay."

The Review also included focus on CEPI's commitment to ensure open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development. The Review was conducted using a mixed methodology and included a review of literature available in the public domain, CEPI reports and publications, non-public documents made available by CEPI for the Review, and interviews with key decision-makers, partners, and civil society organizational representatives.

CEPI's 5 Year Strategy:
Understanding Priorities for CEPI 2.0

CEPI's 2022-2026 Strategy presents CEPI's direction and ambitions for the period, based on its mission and vision to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. The COVID-19 pandemic underscored the need for a holistic, global approach to preparedness and response, of which the principle of equitable access remains core.

CEPI aims to reduce the impact of epidemics and pandemics by building on the successes of the world's response to SARS-CoV-2. To this end, CEPI seeks to ensure a swift response to outbreaks through the rapid development of vaccines and related countermeasures; make every effort to enable globally fair and equitable access to vaccines and targeted biologic countermeasures; and in the mid-to-long-term, ensure that appropriate vaccines and promising biological countermeasures are available to meet the needs of all populations.

CEPI has devised three strategic objectives for CEPI 2.0 to achieve its strategic aspiration to develop a safe and effective vaccine in 100 days from the moment a pathogen is sequenced and/or the need for a vaccine is recognized to initial availability for use.

> ***Prepare*** for *known* epidemic and pandemic threats by building on COVID-19 achievements. CEPI aims to develop vaccines and promising biological countermeasures against the most prominent known threats, leveraging market forces where possible and making critical, catalytic investments where they are insufficient.
>
> ***Transform*** the response to the *next novel threat* by harnessing innovations in technology and systems to significantly reduce the global vulnerability to threats of novel pathogen outbreaks.
>
> ***Connect*** to enhance and expand global collaboration by connecting emerging infectious disease (EID) stakeholders to enable rapid countermeasure development, effective response and equitable access for those in need.

In order to transform the response to the next novel threat, including enhanced effort toward equitable access, CEPI aims to leverage priority pathogens to develop and characterise vaccine platforms enabling rapid development of vaccines or monoclonal antibodies. CEPI also endeavours to create libraries of vaccine candidates for virus families to demonstrate proof of concept for viruses with a high probability of inducing outbreaks.

CEPI's 2022-2026 Strategy emphasises partnerships, focused on engagement with low-income and middle-income countries (LMICs) in the activities funded, convened, and implemented by CEPI. Focused strategic collaborations are aimed at connecting resources and capacities related to emerging infectious diseases across regions and countries of all income characteristics with global industry partners, academic institutions, and other public/private organizations.

CEPI's Equitable Access Policy and Framework

CEPI's approach to equitable access has evolved over the course of its Chikungunya vaccine investments, including a major revision to its Equitable Access Policy in 2018 (all agreements were finalized under CEPI's revised policy), the adoption of an Equitable Access Framework, and the impact of its work during the COVID-19 pandemic. This Review evaluates CEPI's Chikungunya vaccine investments against the standards in place when those agreements were made, while also considering how subsequent agreements and policy changes align with the framework adopted during those updates. Equitable access to epidemic vaccines in the context of an outbreak has been defined by CEPI. CEPI's Equitable Access Policy seeks to facilitate equitable access to epidemic vaccines in three fundamental ways:

- Funding the development of vaccines and maintaining investigational stockpiles, to be used free of charge when an outbreak occurs;
- Coordinating with others in the global health community to enable licensure of vaccines funded by CEPI, including by securing resources for pivotal clinical trials and;
- Collaborating with others in the global health community to ensure the procurement, allocation, deployment and administration of licensed vaccines to protect global health, at a price that does not limit equitable access and is sustainable to the manufacturer.

CEPI will also ensure open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development.

CEPI's Equitable Access Framework articulates CEPI's approach to realizing the objectives of its Equitable Access Policy. This Review will similarly interpret CEPI's Equitable Access Policy through the Equitable Access Framework. At the time its first tranche of Chikungunya agreements were adopted, CEPI's approach to equitable access was comprised of the following five principles:

Access to Vaccine Products and Platforms

The CEPI Equitable Access Policy recognizes that equitable access principles must be implemented throughout all stages of vaccine development, manufacture, and deployment.

CEPI funding agreements reflect this need both through the flexibility built into elements of the funding agreements, and the diversity of funding agreements. CEPI's Cfp3i agreements specifically call for investigational reserve availability after Phase II, stockpile after licensure, and ultimately access premised upon costs of inputs and price.

Project Continuity

An essential component of CEPI's equitable access commitment is its role in coordinating with others in the global health community to enable licensure of vaccines supported by CEPI. For Chikungunya vaccines, the awardees agreed in the funding agreements to nominate a back-up 'trusted collaborator' in case they are unavailable or cannot meet capacity requirements. These run parallel to a Public Health License exercisable by CEPI under specified conditions which permits use of project data and enabling technology to develop, manufacture, and market a vaccine for use in preparation for or response to an outbreak including under conditions where preparation for an outbreak is deemed necessary.

CEPI's Chikungunya vaccine funding agreements also require technology transfer provisions to sub-awardees in low- and middle-income countries to build infrastructure and personnel experience. By facilitating local manufacturing capacity, these technology transfers enhance regional production capabilities, ensuring that vaccines are not only developed but also readily available where they are most needed, expanding vaccine access in endemic regions. Consistently with CEPI's Equitable Access Framework which was adopted subsequent to the first tranche of the CHIKV agreements, these provisions address manufacturing and stockpiling of investigational products for epidemic diseases and, in the event of a pandemic, to support scale up and scale out of vaccine production.

Sharing of Commercial Returns

The awardees committed to make any final vaccine product developed with CEPI funding and manufactured after scale-up available to those who need it at a price which is sustainable for the manufacturer and consistent with CEPI's Equitable Access Policy. The mechanisms for determining and sharing commercial returns are designed to ensure CEPI captures the full value generated by its funding. This allows CEPI to reinvest in projects that advance its equitable access approach.

Data Sharing

CEPI's Equitable Access Policy includes that it will "ensure open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development." In its Chikungunya vaccine development agreements, the broad template specifies the sharing of project data "relevant to topics of interest to the research community, such as disease-specific assays, animal models, correlates of protection or diagnostics and epidemic preparedness mechanisms" with more specific requirements including (i) publishing details of clinical studies before subject recruitment, (ii) submitting clinical data and results for publication within 12 months after study completion, (iii) subject to confidentiality, enabling CEPI, through a neutral third party laboratory to access data and samples for the comparison of equivalent vaccine candidates within CEPI's portfolio, (iv) making a copy of the final manuscript of all research publications freely available upon acceptance for publication

or immediately after publication, (v) sharing project data, as agreed, with other awardees under the CfP3i Programme relevant to issues such as disease-specific assays, animal models or diagnostic and epidemic preparedness mechanisms including stockpiling, and (vi) sharing project materials with CEPI's independent third party assessor to enable the comparison of vaccine candidates in the funded disease areas.

Monitoring Implementation of Equitable Access

CEPI manages both the scientific progress of the projects it supports and how its equitable access requirements are implemented in practice. CEPI requires partners to regularly report on what they have done to date or to look ahead as to what they will do to meet vaccine stockpiling and other equitable access requirements.

CEPI's CfP3i and CfP3iii Programmes

The Chikungunya vaccine development agreements were negotiated with awardees pursuant to CEPI's CfP3i call for proposals for the development of human vaccines against Chikungunya (CHIKV) disease and CfP3iii call for late-stage clinical development and equitable access of Chikungunya vaccines in endemic countries. These calls for proposals built on CEPI's prior investments in Lassa fever, MERS-CoV, and Nipah vaccine candidates and versatile vaccine platforms, and were informed by a thorough review of the R&D pipeline of emerging infectious diseases (EID) vaccines.

In September 2018, CEPI's Scientific Advisory Committee (SAC) advised that CEPI should invest in human vaccine development against Rift Valley fever virus and Chikungunya virus (CHIKV). Through CfP3i, CEPI aimed to support the rapid progression of the most advanced clinical CHIKV vaccine candidates through mid-stage and late-stage clinical development, and to support activities enabling Phase III clinical trials, including identification of correlates of protection and their validation to facilitate future regulatory approval. CfP3i also prioritized local manufacturing partnerships and technology transfer.

Through CfP3iii, CEPI is funding studies to assess the long-term safety, durability of protection and a measurement of vaccine effectiveness in CHIKV endemic countries for advanced and/or licensed CHIKV vaccine candidates. This Review analyses four Funding Agreements, as detailed in the methodology below, with three partners reached to carry out the project under CEPI's CfP3i and CfP3iii Programmes.

METHODOLOGY

Literature Review

Secondary Literature

Methodologically, this Review is based upon a structured literature search using PubMed, Excerpta Medica dataBASE (EMBASE), and using the following predefined keywords: Chikungunya and "funded in whole or in part by CEPI and EU Horizon 2020"; Chikungunya AND vaccine; Chikungunya AND antibod!; CEPI AND equitable access; vaccine AND CEPI AND [name of partner]. These key words were also used for grey literature searches. Annexed to the Review is a bibliography that may be used as a resource for CEPI personnel, Board, Equitable Access Committee, and partners. From that review, the research team developed a stakeholder map for the CEPI agreements. This map built on our existing contacts, the literature review and the use of the 'snowball'* technique to identify additional literature relevant to the Review analysis.

Securities Filings

The O'Neill Team also reviewed securities reports, updates, and notifications filed by partners for which such filings were required by the U.S. Securities and Exchange Commission (SEC).

Document Review

Governance documents

In addition to agreements and interviews facilitated by CEPI, the Center for Transformational Health Law (CTHL) Team undertook an extensive review of CEPI's publicly available governance and strategy documents, including the CEPI 2.0 Program Document. The CTHL Team reviewed Board meeting summaries for the period March 2019 to September 2023, the minutes from the Board's Equitable Access Committee from November 2019 to February 2024, the Board's Audit and Risk Committee minutes from November 2020 to November 2021, and the Board's Executive and Investment Committee minutes from November 2019 to August 2021.

The CTHL Team reviewed the current Equitable Access Policy, the original Equitable Access Policy approved by the Board on 20 February 2017, and the analysis of relevant changes surveyed by CEPI leadership in Vaccine.† The Equitable Access Framework (published May 2023) and O'Neill Institute's Equitable Access Review of CEPI's COVID-19 Vaccine

* Relevant study sources or references or citations are identified within those sources to find additional relevant literature

† Vaccine 38 (2020) 2144-2148]

Development Agreements (2022) were also included. Documents specific to CHIKV were reviewed: CEPI Call for Proposals (CfP3i): Human vaccine development against Rift Valley fever and Chikungunya disease; the Call for Proposals (CfP-3iii) CHIKVACCINE late-stage clinical development and equitable access of Chikungunya vaccines in endemic countries Chikungunya Vaccine: Assessment of LMIC Perspective 2023; the **Overview of CEPI's "CfP3i" Call for RVF and CHIK Vaccine Proposals** and the summary document dated March 20, 2019 - the **Advancing Equitable Access to Epidemic Vaccines through CEPI's Vaccine and Platform Development Agreements** were also reviewed.

> *Other governance documents reviewed included:*
>
> Business Plan 2019-2022 and preliminary business plan of 2017-2021.
>
> Joint Coordination Group (JCG) Meeting Summaries from 2018 to 2023.
>
> Summary of CEPI Scientific Advisory Committee (SAC) meetings held from June 2018 to November 2023.
>
> Board of Directors Report, Annual Accounts and Auditors' Reports from 2017 to 2023.

Vaccine Development, Manufacturing, Supply, and Clinical Trial Readiness Agreements

For the purpose of this review, the CTHL Team was provided access to 4 funding agreements with three CEPI partners, as well as one amendment to one of the agreements.

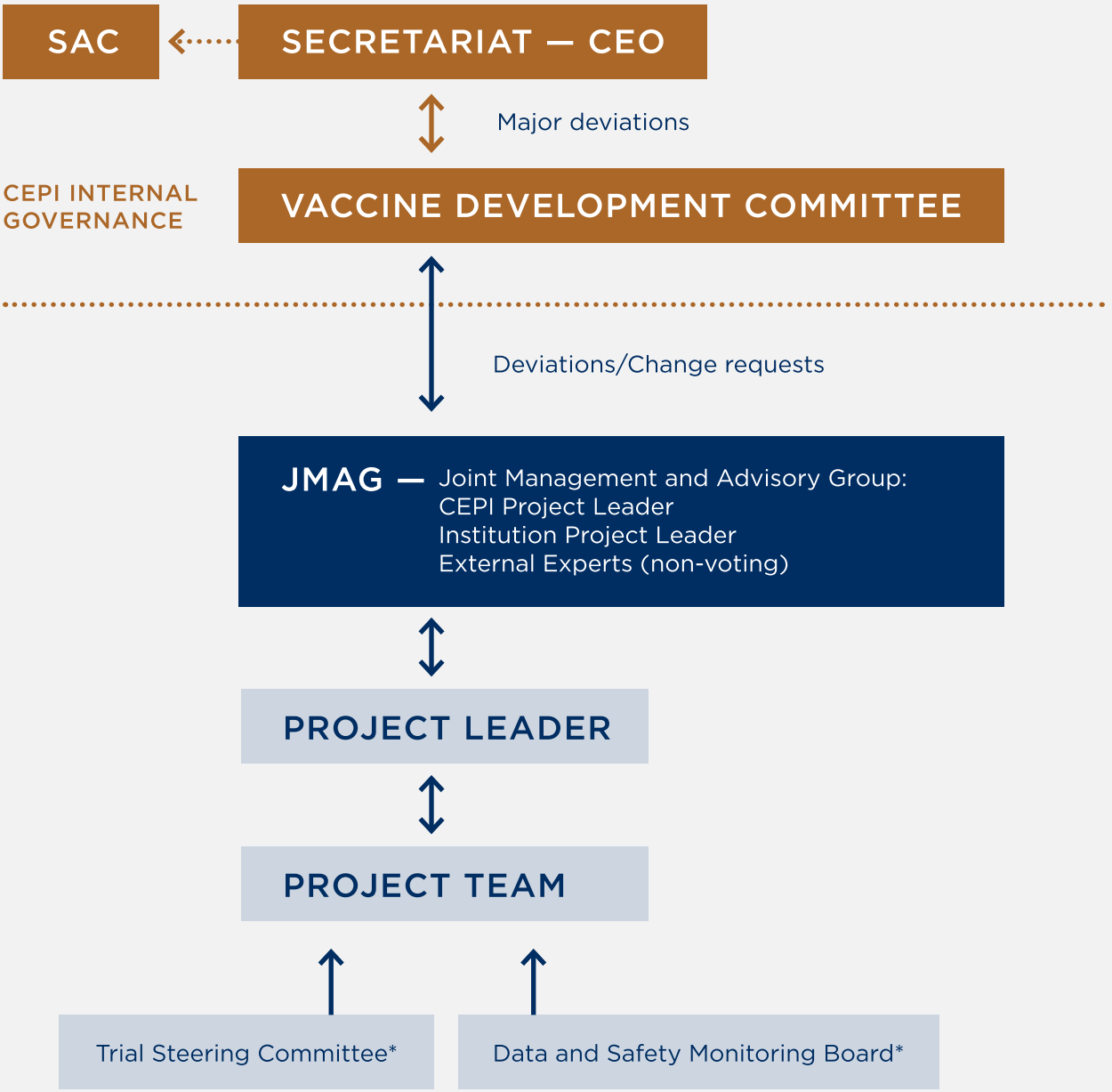
The CHIKV agreements entered under CfP3i seeks to accomplish one or more of the following major objectives: (i) initiation of the licensure enabling Phase 3 program including recruitment of adequate number of subjects from endemic LMIC countries; (ii) CMC readiness: CTM release for the pivotal Phase 3 trial; (iii) agreement on alternative vaccine licensing strategy by EMA, FDA and endemic regulators; (iv) development of Outbreak/Efficacy Protocols for endemic countries; (v) dialogue with the WHO Prequalification Office to establish pathway for WHO PQ; (vi) engagement of LMIC Manufacturers; (vii) evaluation of a correlate of protection by passive transfer studies in animal models; and (viii) evaluation of vaccine safety in a pre- and post-natal development animal model.

The CHIKV agreement entered under CfP3iii seeks to accomplish one or more of the following major objectives: (i) complete or completed Phase III clinical testing in a primary target population and additional studies in an endemic region; (ii) study plans including specific sites for conducting phase IV studies of 3-year duration or more in an endemic country to assess long-term safety, durability of protection; (iii) study plans, phase II or III, on expanding the indication of the vaccine into the pregnant population, pediatric and immunosuppressed populations; (iv) clinical development phase appropriate GMP manufacture and release of CTM for proposed studies; (v) technology transfer of a commercial process to a geo diversified manufacturing organization can be supported or established via a supply agreement; (vi) pursue licensure for the candidate via established stringent and/or local regulatory authorities with a focus on regulatory approval that will ensure use in the Global South i.e. endemic CHIKV areas; (vii) plans for regulatory interactions, including those with a view to ultimate vaccine licensure and/or emergency use with a national regulatory agency and regulators in endemic countries; (viii) plans for maintaining a rolling stock of vaccine (Pre- and Post-licensure) which could be deployed in an emergency.

Table of Reviewed Agreements

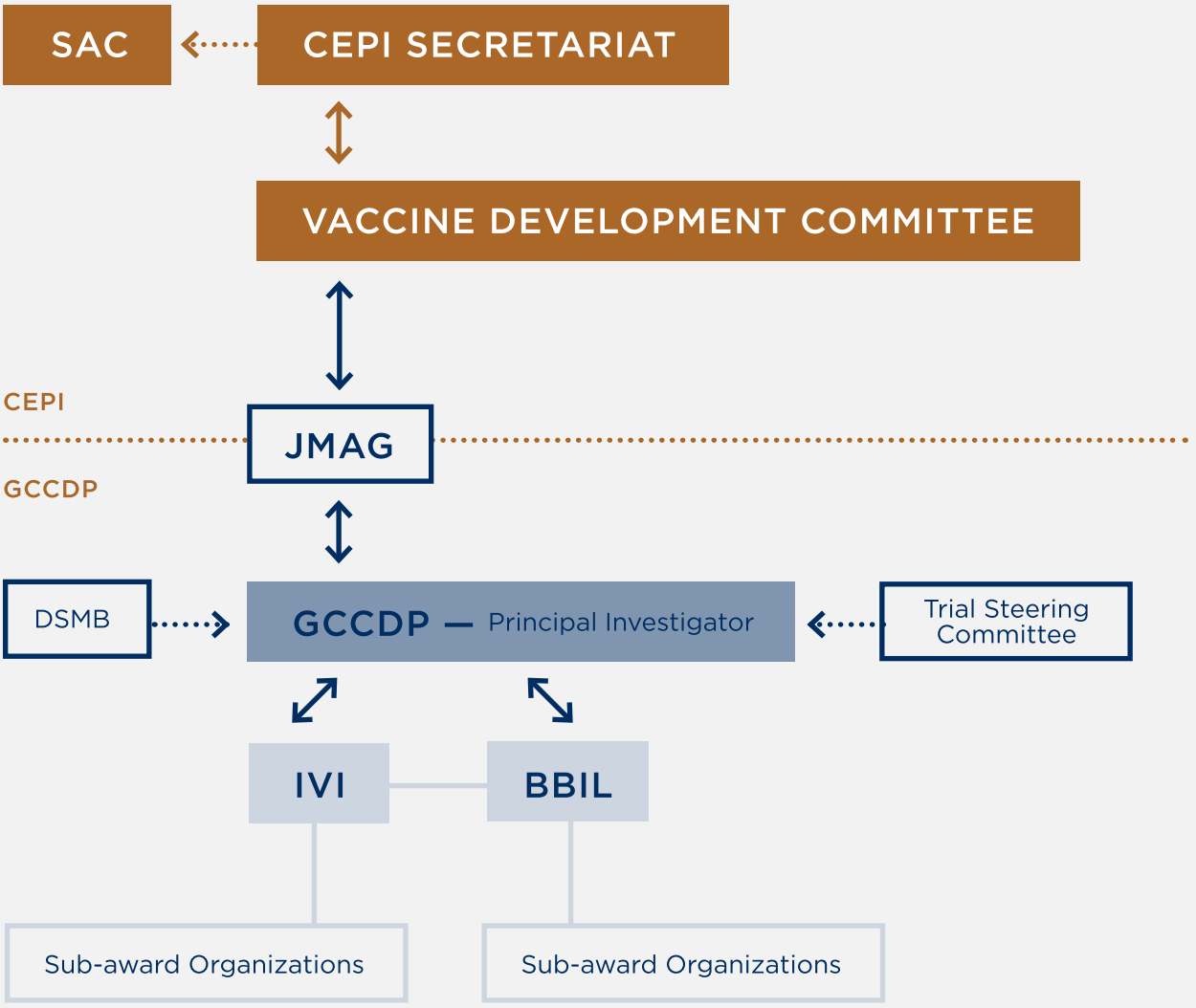
PARTIES	EFFECTIVE DATE	BRIEF DESCRIPTION
Valneva SE (assigned to Valneva Austria GmbH effective 1 Jan 2020) ('Valneva 1') and CEPI	1 April 2019 (Date Signed: 24/07/2019)	"VLA1553, a Lyophilized, Single-Dose, Live-Attenuated Chikungunya Virus Vaccine" under CfP3i. The objective of this project is the development of Valneva's lyophilized, live-attenuated, single-dose chikungunya virus (CHIKV) vaccine (VLA1553) that will provide long-lasting protective immunity for travelers to and persons living in endemic regions. For the endemic market development to licensure Valneva aims to transfer the drug product manufacturing process to a local manufacturer. Activities under this Project include: Phase 3 Clinical Trial Activities, CMC activities, WHO PQ, correlate protection activities, enabling sciences, and reproductive toxicology studies.
Themis Bioscience GmbH and CEPI	3 June 2019	"MV-CHIK vaccine candidate live recombinant measles vectored vaccine, based on the Schwarz measles vaccine strain" under CfP3i. The objective of the project are activities required for the start of the Phase 3 clinical program and the implementation of the Chikungunya vaccine clinical development program, pathway to EMA/FDA and LMIC licensure, and WHO Prequalification of the licensed vaccine.
BBIL/IVI International Limited AND International Vaccine Institute and CEPI	27 May 2020	"Global Chikungunya vaccine Clinical Development (GCCDP) is a collaboration between BBIL/IVI International Limited (BBIL) and the International Vaccine Institute (IVI) to advance the clinical development of a novel chikungunya vaccine candidate, BBV87 inactivated (beta propiolactone) whole virion vaccine developed using the strain CHIK/03/06 derived from an Indian (2006) isolate of the East, Central, South African (ECSA) genotype and grown on Vero cells. The vaccine is formulated with 0.25 mg of alum as an adjuvant" under CfP3i. The objective of the project is to advance the clinical evaluation of a novel chikungunya vaccine candidate, BBV87 and to accrue additional safety and immunogenicity data by conducting Phase II/III clinical trials outside of India in three endemic countries in Latin America and South East Asia.
Valneva Austria GmbH ('Valneva 2') AND CEPI	19 July 2024 (Pre-activities start date 1 September 2023)	"Expanding the Profile of Live-Attenuated chikungunya Vaccine" for VLA1553, VLA1555, VLA1556, a Lyophilized, Single-Dose, Live-Attenuated Chikungunya Virus Vaccine under CfP3iii. The objective of the project is to technology transfer (DP Lyo process) to the Serum Institute of India Private Limited (SII), and conducting clinical and effectiveness studies including in endemic regions to investigate long-term antibody persistence, demonstrate safety and immunogenicity in an adolescent population, and identify optimal dose level in a pediatric population. With the development of the additional CHIKV product, the following codes are used to distinguish between the different products: • VLA1553: VLA's chikungunya vaccine candidate (IXCHIQ) • VLA1555: Drug Product manufactured by IB following tech transfer from VLA • VLA1556: Drug Product manufactured by SII following tech transfer from VLA

The project governance of each award is illustrated below:



**CEPI is an observer*

Themis/Valneva/CEPI



BBIL/IVI/CEPI

Interviews

CEPI facilitated interviews with key CEPI personnel and external partners while the Center for Transformational Health Law (CTHL) arranged for one interview with three civil society representatives. After reviewing key personnel included in the agreements made available for review, the CTHL Team developed semi-structured interview scripts specific to the roles of CEPI personnel. The interview times ranged from 30 to 70 minutes in duration. Consent was sought from the interviewees and their responses and quotes are kept anonymous in this report. In some instances, the observations of interviewees have been augmented with reports from the news media and scientific literature. The interviews consisted of questions regarding CEPI's Equitable Access Policy, the CHIKV agreements entered with partners, and the negotiations surrounding these agreements. Perceived barriers and facilitators to implementation of the Policy were explored, as were interviewees' views on how CEPI performed against its equitable access approach.

DISCUSSION

Access to Vaccine Products and Platforms

Given their differing platforms, regulatory approaches, and points of development, CEPI's Equitable Access Policy and Equitable Access Framework are well-integrated and well-tailored to each of the development partners. The Valneva candidate was the most advanced into Phase III clinical trial planning and therefore the Valneva 1 development agreement focused on planning for Phase III in an endemic country, facilitating a manufacturing partner in an LMIC, agreeing on a regulatory strategy for an endemic country, and specifying commercial benefit terms. As one of the interviewees commented, "the Valneva agreement was one of the first of others to follow that essentially looked more at an end product or a licensed product. CEPI pushed equitable access right from not just having a stake in what was to be developed, but all the way through to a product that was going to be ready for use in people who needed them". CEPI's investment was primarily targeted at shaping the development strategy to focus on endemic regions.

Development

The agreements incorporate varied approaches to pricing, including aligning with CEPI's Cost Guidance Policy and the Gates Foundation's framework for determining appropriate product costs. One agreement specifically mandates that vaccines be distributed in endemic countries and LMICs at affordable prices, factoring in the diverse income levels of these regions while ensuring economic sustainability for manufacturers. Another agreement adopts a tiered pricing model and commits to making best efforts to supply vaccines to non-profit organizations and global procurement agencies such as UNICEF (which acts as Gavi's purchasing agent) and PAHO, at volumes and prices tailored to their specific needs.

The Equitable Access provisions in some agreements emphasize achieving clinical safety and efficacy benchmarks, navigating regulatory pathways, and ensuring readiness for emergency use. In some agreements, equitable access extends further to include the consistent supply of vaccines to all LMICs with demand, ensuring availability at an affordable price.

Manufacture

One of the agreements requires the Awardee/Trusted Collaborator/Sub-Awardee/LMIC Manufacturer to commercialize the product in public health systems in endemic and LMIC countries only at a price that is affordable for such markets, but at a sustainable price. The same agreement also broadened CEPI's support to expand the awardee's manufacturing partnerships from one to two and potentially other markets.

This agreement also delineates explicit supply commitment obligations. The awardee is required to ensure its sub-awardee (i) to the greatest extent possible, prioritizes the supply of product to public health systems in endemic and LMIC countries, taking into consideration public sector demand, production capacity and contractual obligations existing prior to any public sector purchase agreements; and (ii) shall use all reasonable endeavors to bid on applicable public sector tenders to provide such supply.

Some of the agreements do not mention specific technology transfer obligations or obligations to increase supply of the product in specific quantities. General language around technology and information transfer is provided in these agreements. An interviewee reflected on CEPI's approach towards technology transfer, noting a significant shift following the COVID-19 pandemic. One of the agreements (that did not provide for specific technology transfer provisions) was negotiated at a time when technology transfers were mainly focused on achieving reduced prices, a requirement an LMIC manufacturer often satisfies. However, technology transfer now forms a central component of CEPI's equitable access approach and is a tool for 'geo-diversification'. CEPI engages in technology transfer discussions mostly (i) to diversify sources of the product, (ii) in some cases to bring it to a place of low affordability, and (iii) in some cases to ensure that the product is more widely available in times of crisis.

Deployment

One of the initial agreements provides CEPI access to direct use under specified circumstances of a one-year rolling safety stock. CEPI may direct use of those doses under circumstances of outbreak or increased outbreak preparation need. Pursuant to an outbreak notice, the agreements grants CEPI the right to determine how the safety stock or any product manufactured may be used and to whom it may be provided in an affected territory.

Another agreement requires the awardee to ensure that any LMIC Manufacturer, with certain exceptions, makes specific contributions to CEPI: (i) until the rolling safety stock has been established by each LMIC Manufacturer, the LMIC manufacturer, at its own cost, maintain and make available to CEPI an investigational product reserve of drug product; (ii) the LMIC manufacturer, at its own cost, produces a one-year rolling safety stock of finished drug product; (iii) details of the safety stock are provided to the global Technical Advisory Group to monitor Global Virtual Pooled Inventory ("TAG-GVPI") once the TAG-GVPI is established. In case of an outbreak or increased outbreak preparation need, CEPI may direct use of such safety stock by giving notice in writing to the awardee.

VLA 1553 (IXCHIQ) was licensed by the U.S. FDA on November 9, 2023 and is therefore available for deployment in both routine and emergency circumstances. In the early months of 2023, a significant rise in CHIKV cases in Paraguay raised the possibility that CEPI may exercise its rights to the rolling safety stockpile of what was later approved as IXCHIQ. That episode raised important questions for CEPI's agreements including the interests of the manufacturer, should such a deployment take place; the demand and interest by the government of an affected territory; and the effect of such a deployment on licensure.

In context of transparency, questions around the stewardship and access to safety stockpiles have been raised at CEPI Board's Equitable Access Committee (EAC). One of the interviewees noted that, "for the [Equitable Access] Committee, the main concern was the replicability and transparency in the selection process. It is important to consider if every decision is based on a replicable framework. A process that is known, transparent, documented and one which anyone can use and arrive at the same results… equity is about avoiding both mistakes of permission and omission". Interviewees suggested that stockpiles generally should be treated as a global public good, the stewardship and use of which, including CEPI's rights to direct use, required collaborations with international organizational partners.

A specific rolling safety stockpile right is not provided in some agreements; parties in these agreements are required to discuss in good faith the utilization of so-defined project results under circumstances of "outbreak" or "increased outbreak preparation need" and CEPI may request the manufacture and/or maintenance of a stockpile of investigational product during an outbreak. Some agreements define "outbreak" with respect to only WHO or national government declarations, while other agreements specify declarations made by "one or more public health agencies" with an implicit or ambiguous possibility of including regional public health agencies like PAHO. Across agreements, references to "outbreak" are consistently paired with mentions of an "increased outbreak preparation need," which CEPI determines at its discretion after consulting with experts.

Some of the agreements provide for more specific obligations in preparation and response to an outbreak. These include two specific obligations - increasing the supply of products available and transfer of technology to sub-awardee manufacturers, including LMIC manufacturers.

One of the agreements includes additional terms relevant to an outbreak in its traveler's market countries as well as initial price points to supply drug product for purposes of conducting clinical trials in LMICs. Only one agreement specifies product access for healthcare workers who may be responding to a territory experiencing an outbreak.

Project Continuity

All agreements with CEPI require the awardee to propose a third party/trusted collaborator as an alternative to itself and gives the right to CEPI to request the awardee to undertake additional product development, including the pursuit of regulatory approvals and licensure with the aim of addressing the needs of a territory affected by outbreak. All four agreements also give CEPI the right to request the awardee to undertake the manufacturing and maintenance of a stockpile of investigational product or product of a size reasonably determined by CEPI for use in a territory affected by an outbreak. This stockpile of investigational product is distinguished from the "rolling safety stockpile" in the Valneva 1 agreement which anticipates the FDA approval granted on November 9, 2023.

Similarly, all agreements reserve CEPI's right to exercise a Public Health License to develop, manufacture, market and/or supply supported vaccine product worldwide, provided that all end users are located in a territory affected by an outbreak, and that all prerequisite conditions to the exercise of the license have been met. There are differences between the agreements as to Public Health License terms which CEPI may wish to revisit.

In enabling equitable access, CEPI also aims to diversify manufacturing geographically. Although subawardee agreements were not available for CTHL to review, the available agreements and interviews revealed key challenges. Specifically, the regulatory and market conditions for subawardee manufacturers in Brazil and India suggest that CEPI may need to develop guidance or templates for downstream transactions where it cannot or should not be directly involved.

Commercial Benefits

All four agreements with CEPI addressed commercial benefits. This could be in the form of revenue shared with CEPI to support future awards or through measures that ensure equitable access. In determining appropriate Commercial Benefits in the funding agreements, CEPI has worked with awardees to ensure that risks and benefits of product development and commercialization are shared proportionately. Importantly, one of the interviewees noted that commercial benefits are not derived from sales in LMICs, ensuring that affordability and access in these regions remain a priority. Any revenue-sharing contributions are directed towards supporting CEPI's program activities, furthering its mission to enable equitable access.

Some agreements provide suggestive mechanisms for benefit sharing which may include: sharing of profits, including the sale of a priority review voucher, other than those arising from activities directly related to the curtailment of an outbreak, as a way to support CEPI's future awards; a specific commitment in relation to equitable access; a commitment to participate in future award programmes; the allocation of certain percentages of product doses for distribution after the end of the project as determined by CEPI; the provision of in-kind services in support of CEPI's mission; or in other appropriate ways agreed with CEPI.

Dissemination and Publication of Project Data and Results

All four agreements with CEPI encourage and require (timely) public disclosure and 'open access' publication of project data and results. One of the agreements prescribes timelines for publication of project data and results, including pre-clinical studies. The awardees are required to provide CEPI with access to all data and information, including all pre-clinical and clinical study data produced or arising as a result of the Project (Project Data). Agreements also mandate regular reporting of project data and materials to JMAG, and sharing with the research community Project Data relevant to topics of interest to the community.

Public disclosure of clinical data and results is required in as close to real time as possible. According to an interviewee, "data ought to be shared and this is designed so for a purpose… they will be shared either to compare so that we [CEPI] makes decisions on which ones to go forward or shared in such a way that there could be certain commonalities in terms of assessment of development of assays, the development of reagents, the development of whatever that are required to be used in a common way for all the developers."

One of the agreements largely allocates project data to which the sharing obligation applies to an agreement at the JMAG. The agreements differ in important respects as to both content and process of data sharing. Awardees are under an obligation to provide summaries of project results through the JMAG for which CEPI may thereafter make reasonable requests.

Monitoring Implementation of Equitable Access

One of the agreements requires an Equitable Access Group (EAG) to be established within 6 months. The EAG is charged with regularly monitoring the progress of and advancing awardee's commitment to EA and the LMIC manufacturer is also to be part of the EAG. An Equitable Access Plan (EAP) annexed to the agreement draws together the equitable access provisions throughout the agreement text. After establishing the EAG, the party to the agreement is required to keep both JMAG and the EAG updated of its EAP progress. According to one interviewee, the EAG will focus on meeting access milestones, reviewing and revisiting the EAP, reviewing pricing data, and monitoring equitable access commitments. There does not appear to be a sustained governance mechanism whereby the CEPI Board's Equitable Access Committee is apprised of developments over the course of project progress nor a mandatory voice for equitable access policies at the JMAG. These are lessons learnt from CfP3i.

RECOMMENDATIONS

The above Review has analyzed CEPI's Equitable Access Policy, Equitable Access Framework, and CfP3i equitable access guidance in light of their purpose. The Equitable Access Policy and Equitable Access Framework aim to offer guidance on equitable access principles without confining otherwise contractual terms that advance CEPI's mission. The following recommendations are based on the discussion and analysis above and speak broadly to the governance of portfolios like CfP3i and CfP3iii as well as agreements specifically.

Governance Recommendations

Relative to COVID-19 vaccine development agreements, and with the important qualification that the Chikungunya development agreements and ensuing activities unfolded over the course of the COVID-19 pandemic, CEPI Board's Equitable Access Committee played a less prominent role over the course of the Chikungunya agreements' negotiation and operationalization than they did for COVID-19. Integrating equitable access officers from CEPI into the JMAG or creating more regular EAC review of quarterly reports may help in ensuring that equitable access commitments are realized.

1. CEPI's Equitable Access Policy and Framework should be integrated into CfP3i governance

While CEPI's Equitable Access Policy and Equitable Access Framework are reflected in standard contractual terms, there does not appear to be a sustained governance mechanism whereby the Equitable Access Committee is apprised of developments over the course of project progress nor a designated voice for equitable access policies at the JMAG. In any given JMAG meeting, equitable access may be discussed by CEPI representatives to the JMAG, including business development and other representatives, but it is one of many topics on the agenda. One of the agreements establishes an Equitable Access Group, integrates to some extent the Equitable Access Lead into the JMAG, and creates an Equitable Access Plan to better communicate EA terms appearing across development agreements. These changes were adopted as part of CEPI's broader internal efforts aimed at enhancing equitable access at the governance and partnership levels. It is advised that these features be more detailed and particularly with respect to the latter, that the additional benchmarks be integrated into the plan through the quarterly reports. Interviewees indicated that scheduling of EAC meetings was uneven and that the EAC was currently settling into its routine after a number of transitions.

2. CEPI should consider developing internal criteria for when questions should be referred to the CEPI Board's Equitable Access Committee

As between its COVID-19 vaccine development agreements and the CHIKV vaccine development agreements, the participation of the EAC and the thresholds for questions

that should be referred to it differed. In the interest of transparency and replicability, CEPI may wish to consider development of internal criteria that may guide project leads, counsel, and other CEPI staff for when matters arising during negotiations should be weighed by the Equitable Access Committee and advice issued. Such criteria may include questions of novelty, cost, and divergence from CEPI's standard policies.

3. As CEPI's work expands across the global vaccine supply chain, it may need to develop more extensive policies for downstream technology transfer and consider additional internal guidance as its role in shaping market dynamics evolves

While CEPI itself does not engage in procurement, its influence extends to how its funding partners establish manufacturing and commercialization arrangements. The successful development of such partnerships where CEPI is not a signatory to the agreements raises new questions about CEPI's role and interests. As those partners apply for licensure, interact with Gavi, UNICEF, and WHO, and other global suppliers, and increase their role in the commercialization of vaccines to low- and middle-income countries, CEPI may wish to further develop policies and guidance for terms it may or should influence in downstream agreements. This guidance may direct CEPI's efforts at enabling equitable access and transparency where it is not a party or observer for downstream partnerships.

4. CEPI should consider developing asset repositories and accompanying dashboards

As CEPI progresses through its 2.0 phase and with the evolving emphasis on transparency in its EA principles, it is advisable for CEPI to develop a comprehensive repository of its assets, including rights to direct the manufacturing, maintenance, and use of stockpiles and intellectual property access rights. This repository could be visualized with at least information on the date that rights commence, a summary statement as to the contents of its rights, including those rights expressed in vaccine quantities, and triggers for the exercise of rights. This initiative would enhance transparency, accountability, and equitable access to the 'public goods' over which CEPI retains access rights. As one of the interviewee's suggested, such asset repositories would make it easier to scrutinize implementation of equitable principles. Specific measures could include:

Identify and Classify Assets:

- CEPI's tangible and intangible assets, such as IP rights, rights to direct stockpiling and stockpile use, manufacturing rights, and technology platforms.
- Consider classifying assets by accessibility, relevance to equitable access, and operational readiness.

Develop a Digital Repository:

- Build a secure, searchable online platform that details CEPI's rights.

- Include metadata fields such as asset location, accessibility status, licensing details, and stakeholders.

Integrate Dashboards:

- Create dashboards with real-time data on the status of stockpiles (including expiry) and distribution metrics.
- Incorporate visual analytics to track alignment with equitable access principles.

Stakeholder Collaboration:

- Engage with funders, partners, and governments to align data transparency protocols.
- Collect inputs for periodic updates and validation of asset information.

Transparency and Communication Strategy:

- Publish periodic reports summarizing the repository's key data and insights. Example: **WHO Global Vaccine Market Report**
- Provide controlled access to external stakeholders, ensuring the protection of proprietary and sensitive data.

Examples of global databases and repositories related to vaccines/medicines:

- **WHO's COVID-19 mRNA Vaccine Technology Transfer Hub**
  WHO has established a repository and coordination mechanism to facilitate technology transfer for mRNA vaccines in LMICs. The initiative promotes open sharing of knowledge, intellectual property, and manufacturing processes, particularly through its network of technology transfer hubs globally.
- **WHO Global Vaccine Market Dashboard**
  This dashboard provides an overview of vaccine availability, affordability, and accessibility, highlighting gaps in vaccine supply and equity issues. It supports transparency and aids stakeholders in assessing the global vaccine market.
- **Gavi, the Vaccine Alliance – Vaccine Market Dashboard**
- **UNICEF Covid-19 market dashboard**
- **Medicines Patent Pool (MPP)**
  MPP acts as a repository for voluntary licenses of essential medicines, allowing generic manufacturers to produce and supply critical health products in low- and middle-income countries. This structure ensures broader access to medicines and intellectual property sharing.

5. CEPI should review its experience to date with COGS+ approaches and how similar results could be alternatively achieved

In general, pricing of vaccines for equitable access has been facilitated by aggregating demand from countries and raising sufficient funds to finance large-scale demand ensuring upfront discounting and reducing long-term risk for manufacturers. This is, in essence, the model used by Gavi and UNICEF, the PAHO Revolving Fund, the African Vaccine Acquisition Trust, and governmental purchasers. This model may not be applicable for many CEPI-funded vaccines because, assuming they are not supported by one or more of the above parties, they will lack a purchaser or purchasers of sufficient scale.

The use of cost models to investigate pharmaceutical COGs is an alternative and potentially complementary approach to equitable access. Medical countermeasures can benefit from significant cost of goods (COGs) reductions for active pharmaceutical ingredients, including starting materials. A holistic approach to identifying, developing, and evaluating optimized synthetic routes, which includes detailed COGs modelling, provides a rapid means to increase availability, update and application of vaccines/therapeutics in global markets. Such information may not only be a substitue for COGs+ but it could also be a monitoring mechanism in a COGs+ pricing model. For example, CEPI could still require COGs and pricing data to ensure awardees are complying with their obligations.

COGs modelling, to assess cost saving opportunities, can include a focus on manufacturing environments and facilities amenable to global public health and the identification of key parameters using sensitivity analyses. Factors could include the costs associated with manufacturing in different geographies or for different regulatory authorities, and the cost of raw materials at different volumes for more segmented markets. COGs models can continue to inform the focus of future development efforts on the most promising routes for additional cost savings.

CEPI could establish independent third-party evaluations/auditors of manufacturing costs to create regional/country standardized pricing benchmarks, ensuring transparency and fairness. Using organizations like the WHO's C-TAP as a model for pooling knowledge could streamline this process.

CEPI's engagement with third-party service providers to oversee equitable pricing and contract compliance can be expanded to ensure consistent evaluation of cost structures without compromising intellectual property rights or commercial interests.

According to civil society representatives, who only had access to the template Chikungunya vaccine development agreement issued pursuant to CfP3i and available at **https://ghiaa.org/** as well as the SEC filings, CEPI does not sufficiently press its leverage with respect to information demands that might substitute for COGs+ mechanisms. Manufacturers in low- and middle-income countries need specific information to build their capacity, they argue, and CEPI could use its leverage more forcefully to require broader disclosure.

6. CEPI should work with organizational partners to develop a safety stockpile management framework

CEPI should consider engaging with international partners such as WHO, PAHO and Gavi on developing a global stockpile framework that ensures equitable access. Such a framework may be

annexed or adjacent to a Global Virtual Pooled Inventory (GVPI) kept for purposes of emergency response. As the GVPI is finalized, it could also be tailored to CEPI's stockpile use rights.

7. CEPI should undertake demand and procurement assessments earlier in its processes

Given the justifications for CfP3i and CfP3iii, which are significant and well aligned with CEPI's equitable access approach, it would nevertheless benefit CEPI, including its equitable access commitment, to map demand and procurement as early as possible. To better align CEPI's upstream R&D investments with both technology transfer and procurement organizations like Gavi, understanding how a priority vaccine will enter markets will help CEPI plan for equitable access. Early assessment will enhance the alignment of CEPI's push mechanisms with Gavi's and governments' pull mechanisms.

Agreement Recommendations

1. More detailed requirements for equitable access monitoring should be included at the JMAG and in quarterly reports

While one of the agreements included an Equitable Access Plan, an Equitable Access Group, and an Equitable Access Lead, the structure of the JMAG for the CfP3i agreements was largely technical and operational according to interviewees. It is recommended that each JMAG include the Equitable Access Lead from CEPI charged with addressing equitable access terms and implementation and that the issue of equitable access be raised at least quarterly.

2. CEPI should consider defining commercially reasonable endeavours

One agreement specified the profile of a pharmaceutical partner that would be considered for purposes of commercially reasonable endeavors analysis. CEPI may consider in current and future projects whether such a definition may advance its equitable access mission or whether it may rely instead of the robust body of English case law that would inform obligations should a dispute arise.

3. CEPI should review agreement dispute resolution provisions for adherence to CEPI interests

The dispute resolution clauses across the agreements with CEPI included both broadly applicable clauses in "General Provisions" as well as some subject-specific dispute resolution provisions applicable to, for example, sharing of project results with the research community and CEPI remedies should it exercise its public health license rights. In the data sharing context for example, requiring the Scientific Advisory Committee to serve as final arbiter increases the chance that CEPI's policies will be observed. Given the importance of dispute resolution for

CEPI's interests, especially equitable access interests and the public health license, CEPI may wish to consider reserving injunctive remedies for itself, in other words only CEPI would be entitled to injunctive relief for priority interests like data sharing and the Public Health License.

4. Determination and Inclusion Agencies Determining "Outbreak" Status and Inclusion of Healthcare Workers in CEPI Agreements

While the CTHL Team understands the need for each agreement and each partner to be evaluated in its own context, the priority given to healthcare workers in one agreement and the inclusion of regional public health authorities in another may have broader implications beyond the specific partner. Given that the recent IHR (2005) revisions emphasize the importance of healthcare workers and that some regional public health authorities hold significant influence, CEPI should consider these factors in future calls and agreements. CEPI should consider these factors in future calls and agreements.

CONCLUSION

As many interviewees noted, the achievement of licensure of a safe and effective CHIKV vaccine by one of CEPI's partners is a critical win for those vulnerable to CHIKV as well as the global health community broadly. It demonstrates decisively that well-designed processes can lead to interventions against diseases for which a commercial market is unlikely to develop or may not mature in certain regions of the world where the disease may disproportionately affect vulnerable populations. Moreover, the licensure of VLA1553 (IXCHIQ) has proliferated the research and clinical work that may lead to better routine and emergency capacities including manufacture and availability in countries with CHIKV endemic regions, indications for use during pregnancy, and combination with existing immunizations including yellow fever. The CfP3i and CfP3iii CHIKV programmes further identified and cultivated manufacturing and technology transfer relationships in Brazil and India that may advance its efforts to bring interventions it supports closer to the populations that need them. While these new relationships have also raised new considerations, the aim of accelerating and enabling access in LMICs has clearly been advanced through CfP3i and CfP3iii.

With respect to governance, the interviewees identified turnover at the EAC and accompanying delays in meeting characterized much of the CfP3i period although the one agreement concluded under CfP3iii that CTHL reviewed included more provisions and mechanisms addressing equitable access.

Civil society representatives argued that CEPI could go further in releasing the pricing and cost of goods data. Although this Review urges some measures for consideration as well as some specific changes to development agreements to advance its equitable access approach, it should not distract from the broader conclusion that CEPI's investments have played a critical role and promise to deliver not only additional safe and effective CHIKV vaccines, but also boost the capacity of public health planners and vaccine manufacturers worldwide thereby enabling equitable access to these vaccines for those living in endemic countries.

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