Management Response
Mid-term Review of CEPI 2.0 Strategy

Evaluation Title: *CEPI 2.0 Mid-term Review Final Report*
Evaluation Completion Date: September 2024
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Purpose and scope of the evaluation: At the beginning of 2024, the Coalition for Epidemic Preparedness Innovations (CEPI) commissioned Itad and Market Access Africa (MAA) to conduct an independent Midterm Review (MTR) of CEPI 2.0. The primary objective of this review is to assess progress against CEPI's 2.0 Strategy at its midpoint. Launched in 2022, CEPI's five-year strategic plan aims to prepare, transform, and connect the world to effectively respond to the next Disease X by compressing vaccine development timelines to as little as 100 days after the identification of a novel virus. This MTR had two main goals: 1) to assess the relevance, coherence, fidelity, effectiveness, impact, governance, and management of CEPI's operational model and strategy; and 2) to identify lessons learned, capture good practices, and generate recommendations that will inform and strengthen the implementation of the remaining period of CEPI 2.0.

I. Overall Management Response

CEPI welcomes the insights and recommendations from the Mid-term Review (MTR). Since its inception CEPI has placed learning, evolving and striving to do better at the heart of its culture, so independent, external assessments are a necessary and useful tool for us as an organisation, and for our Board and Investors. We would like to express our gratitude to the evaluation team, Itad and Market Access Africa, for delivering an insightful and thought-provoking report. We also wish to thank the Independent Evaluation Committee and its Chair for their leadership and expertise in ensuring CEPI receives a high-quality, actionable report.

The MTR was conducted halfway through CEPI's second five-year funding cycle (2022-2026), and seven years into CEPI's existence. It provides an important opportunity for CEPI to take stock of progress against the CEPI 2.0 strategy and identify areas where the organisation needs to sharpen its focus or course correct to achieve its aims, building on previous evaluations including the 2023 Board effectiveness review and the independent assessment of CEPI 1.0. Conducting the MTR at this stage was intentional: the insights it provides will contribute meaningfully to ongoing discussions around the CEPI 2.0 timeline, expected deliverables, and any needed adjustments of focus or direction. They will also help lay the foundation for CEPI's next strategic phase and the development of plans for CEPI 3.0.

Key Insights from the MTR

CEPI 2.0 is an ambitious strategy, conceived in 2021 at the height of the COVID-19 pandemic. It built on CEPI's learnings in 1.0 and COVID-19, carried programmes initiated during these phases forward, and added new areas of focus. The MTR recognizes the significant ambition of CEPI 2.0 and acknowledges that there will be delays in achieving some goals. It also recognizes that by elevating its ambition CEPI was able to galvanize global support for its strategy, and for the 100 Days Mission, which has evolved from a high-level concept just a few years ago to a life-saving pandemic preparedness plan which, today, is embraced by the G7 and G20 and has been embedded into health security strategies all around the world.

We are pleased that the MTR highlights some of the many programmatic achievements that have been driven by CEPI's ambition, including breakthroughs in vaccine development for many of CEPI's priority pathogens, such as the first licensed Chikungunya vaccine, the first-ever Lassa fever and MERS vaccines in Phase II trials, and vaccines for Nipah and Rift Valley fever approaching Phase II trials. The MTR also acknowledges CEPI's vital contributions to expand global networks of laboratories, manufacturers, scientists, and regulators that are building critical capabilities for the 100 Days Mission, and the progress CEPI is making to advance scientific innovations that could transform vaccine development as we know it today.

The MTR commends CEPI's contribution to the global COVID-19 response, during with the organisation supported seven vaccines to licensure and conceptualized and co-led COVAX which delivered two billion doses of vaccine to 146 countries, saving an estimated 2.7 million lives in the lower

income countries eligible for free doses. And it acknowledges the strength of CEPI's commitment to equitable access and the notable progress being made through the implementation of the Equitable Access Framework which addresses equity across CEPI's scope of work.

Importantly, the MTR also identifies areas for adjustments or additional effort, focusing on themes that address both CEPI's engagement with its external environment and partners, and the way the organisation operates internally.

It provides helpful insights into how CEPI can more effectively engage with the broader world to further the goal of preventing future pandemics. CEPI has always been clear that CEPI cannot achieve its goals alone, so further clarifying how and why we work with partners – and where the handoffs should be as more CEPI-backed products progress towards licensure – will be critical in our next phase.

And it recommends measures that could help to strengthen CEPI's organisational effectiveness and refine the way it defines and measures progress, building upon work that is well underway to bolster CEPI's leadership capacity and was a major area of focus in 2024.

The MTR findings complement other recent analyses conducted by CEPI, concluded after the submission of the MTR. Together, these analyses have helped us to assess CEPI's strengths and weaknesses, to understand its achievements, and to identify where renewed focus and strategies are needed as it moves ahead.

The analyses show that CEPI's $2.25bn programmatic investments to date have remained true to CEPI's goals and areas of focus, with some necessary adaptation on the way based on ongoing learnings.

Since its inception, CEPI's funds have been strategically allocated in line with the organisation's priorities: nearly $600m for priority pathogen and broadly protective coronavirus work, over $100m on Disease X work, and $1.4bn on COVID-19 (which had dedicated funding, and may be viewed as a paradigmatic Disease X). During CEPI 2.0, the allocation of CEPI funds across the strategic pillars of Prepare, Transform and Connect has remained closely aligned with the CEPI 2.0 Investment Case.

The analyses highlight that CEPI has achieved its COVID-19 aims in full, is on track to meet its goals for most of the CEPI 1.0 programme and is well placed against certain CEPI 2.0 goals, with some way to go on others. And they reinforce that CEPI's impact and catalytic effect have been significant across its scope of work, from advancing product and platform development through to thought leadership and fostering partnerships and action from others on concepts such as COVAX, the 100 Days Mission, and a growing global focus on viral families.

CEPI's spend estimates have tended to be accurate, while some activities have seen delays which has and will generate lessons that inform how activity is taken forward as well as planning for CEPI 3.0.

The analysis and proper accounting of CEPI's achievements elicits the hypothesis that investing in CEPI should be viewed as investing in specific programmes as well as in an organisation with capabilities that make it a causal agent in responses as well as in advancing the 100 Days Mission. And the Marburg outbreak in Rwanda in 2024 demonstrates that CEPI's activities work to build partnerships and capabilities that are then drawn on to achieve impact rapidly in an outbreak.

It is worth reflecting on the nature of the outputs and outcomes CEPI works towards. Delivering products is foundational, is tangible and gives CEPI legitimacy as an actor in the system. That noted, CEPI's understanding of what is needed to achieve its vision and the organisation's mission is broader than that, and includes a relentless focus on working towards the 100 Days Mission and influencing the ecosystem and other actors to take actions towards bigger goals, as well as a view that the sum of CEPI's activities is significantly greater than the parts. CEPI provides the delivery of specific outputs while it also invests in, and is itself, a capability for the world that works toward and catalyzes outcomes.

Response to MTR Recommendations

Overall, CEPI Management views the MTR as a balanced report. Many of the recommendations affirm and support ongoing initiatives, while others highlight areas requiring more attention. Broadly, we see three types of findings:

- Areas where **CEPI Management has already identified and anticipated issues with actions taken or new work initiated prior to the MTR.** Examples include efforts to enhance management effectiveness and increase the efficiency of internal operations and investment management

systems, organisational restructures, and dedicated initiatives to improve employee wellbeing and growth. These efforts will require sustained focus.
- Areas where CEPI **needs to increase our efforts**, such as strengthening our partner selection and engagement processes, and developing more systematic, organisation-wide learning practices.
- Areas CEPI Management has **not yet addressed**, such as enhancing strategic clarity of CEPI's role in the Pandemic Prevention, Preparedness, and Response (PPR) ecosystem, and our end-to-end objectives related to 2.0 strategic investments

Overall, CEPI Management broadly agrees with the MTR findings and its six recommendations, many of which, as stated previously, affirm and enhance initiatives and actions that are already in progress. In some cases, we agree only partially with specific aspects of the recommendations; where applicable, we've clearly outlined our rationale in the action plan below.

The recommendations are individually important but also overlap. In order to structure how we respond most effectively, we believe there are four major focus areas to take forward and against which to judge progress:

- **External Context**, which involves clarifying CEPI's role within the broader ecosystem and its ability to respond effectively to public health emergencies
- **Partnerships**, which looks at CEPI's vaccine development partners and identifying handoff points to others, in the context of a dynamic ecosystem;
- **Internal operations & strategic decision-making,** which focuses on CEPI's internal functions, including internal approval processes, grant/alliance management, overall organisational effectiveness, and strengthening strategic decision-making processes; and
- **Progress tracking and organisational learning,** which includes work on improving CEPI's Theory of Change (TOC) and Key Performance Indicators (KPI), defining success for our equitable access work, and organisational learning.

Below is a high-level summary of our response to the MTR recommendations. In formulating our response, we focused on harmonizing overlapping recommendations, de-duplicating actions, and consolidating efforts to enhance coherence and impact.

Recommendation Area 1: Clarify CEPI's role and prioritise the CEPI 2.0 scope of work

We partially accept this recommendation, recognizing the critical importance of aligning CEPI's role within the broader ecosystem and clearly articulating our goals for each priority area, including our relationships with other actors. However, we believe that over specifying the boundaries of CEPI's role within the ecosystem could limit the flexibility that enables us to respond effectively to emerging health threats and capitalize on new opportunities as they arise. For example, CEPI's important contributions to the global COVID response were driven by context and need rather than the prior definition of CEPI's role in such a response. When it comes to 100 Days Mission and the vaccine development pipeline, CEPI sits early or upstream from many of our ecosystem partners. In this regard, agility and flexibility early in a crisis is absolutely critical.

Our recent no-regrets responses to H5N1, Marburg, and Mpox illustrate how flexibility in our role enables us to add significant value in addressing emerging health threats. With the proposed actions underneath this area, we will strive to balance clarity and focus in our role and discipline in execution with the flexibility that allows CEPI to innovate and adapt in a rapidly changing landscape. By maintaining a dynamic approach, we can effectively respond to evolving challenges and opportunities while ensuring that our core mission remains intact.

Recommendation Area 2 - Clarify how CEPI works to achieve its strategic objectives and reformulate the results framework to measure progress

We fully accept and welcome this recommendation. CEPI's 2.0 Theory of Change (ToC) and results framework were initially developed during the COVID-19 pandemic, and since then our activities, initial assumptions (of, e.g., costs, timelines, partner availability), and understanding of how CEPI has impact in the world have evolved significantly.

Building on the foundational work from Recommendation Area 1, we will update both our 2.0 ToC and results framework to more accurately reflect our current portfolio and how we measure progress. We

envision this as a rearticulation rather than a complete rewrite of our organizational ToC, ensuring it better aligns with how we operate and engage with the broader ecosystem.

By clarifying our strategic objectives and refining our results framework, we aim to enhance our ability to measure, track and communicate our impact, ultimately supporting CEPI's mission.

Recommendation Area 3 - Continue to embed a comprehensive and flexible approach to equitable access

Management welcomes the MTR findings regarding our equitable access approach and fully acknowledges the necessity to continually evolve and integrate this approach throughout our portfolio. A key aspect of this evolution will be the development and piloting of archetype models to categorize CEPI's portfolio programmes, ensuring alignment with CEPI's role and the essential needs for equitable access. These archetypes will further facilitate end-to-end considerations across Strategic Roadmaps, clarifying opportunities for transitions to and from ecosystem partners.

In line with CEPI's ongoing commitment to transparency, we will continue to publish and share relevant work and insights related to our equitable access approach. This will foster greater understanding and engagement among our partners and the broader community, reinforcing our dedication to equitable access for all.

Recommendation Area 4 - Finalize and embed an evolved approach to partner selection and engagement and strengthen the relationship management function –

CEPI Management welcomes and fully accepts the need to continue to evolve our approach to partner selection, engagement, and relationship management, including with multinational corporations (MNCs) as part of a diversified portfolio of partners. As CEPI continues to navigate an increasingly complex landscape, it is essential that we are clear on CEPI and partners' respective incentives and requirements so as to refine our approach and processes for identifying and engaging with partners who align with our strategic objectives and values.

To address this recommendation, we will take specific actions to deepen our understanding of potential partners and identify and engage with those who can effectively contribute to our mission. This will involve building on the archetype model introduced in Recommendation Area 3 to strategically fill gaps in our portfolio. In parallel, we will prioritize enhancing our relationship management capabilities, drawing on best practices in Alliance Management, to cultivate and sustain high-impact partnerships, including with MNCs.

Recommendation Area 5 - Continue to clarify decision making pathways and engagement of governance committees

CEPI continues to evolve as an organization and manages an increasingly complex portfolio of investments. Management recognizes the critical importance of refining our governance and decision-making processes to ensure that these remain fit for purpose, with a particular focus on strategic as well as financial delegations, and optimizing the guidelines and ways of working that support effective investment towards our mission. We note that there are a number of investment areas in activities beyond vaccine development that need a better framework for decision-making.

We are committed to revising and streamlining these procedures and updating their supporting documentation, to ensure they continue to enable efficient and effective decision-making while fostering a transparent and collaborative environment.

Recommendation Area 6 - Further strengthen management culture, capabilities and practices.

We fully embrace this recommendation and think the specific actions in this area serve as foundational elements for the success of all our other initiatives. By nurturing a robust management culture and enhancing our capabilities to ensure alignment and prioritization across the organisation, we set the stage for achieving our broader mission and objectives.

As outlined in the action plan below, several important changes, including the reorganization of a number of divisions and departments within CEPI, are currently in progress and will require careful monitoring to ensure the desired results. We also recognize the necessity of taking enhanced action to facilitate alignment and prioritization across departments, ensuring that all CEPI staff clearly

understand the organization's objectives and how their work directly supports these goals. Actions undertaken in this area will further complement the actions under Area 1 and 2 (i.e. clarify CEPI's role, revise our theory of change and results framework), to enable CEPI teams to work cohesively towards common objectives. Furthermore, we are committed to strengthening our learning systems and processes to foster an environment of continuous improvement and collaboration.

CEPI Management is fully committed to implementing the actions outlined as part of this document, recognizing their essential role in our organization's success. As noted earlier, the six recommendation areas are deeply interconnected, with each complementing and reinforcing the others to form a cohesive set of initiatives. The actions we commit to in response to the MTR will be integrated into our core planning and monitoring processes, ensuring effective tracking and accountability. We are excited to make steady, measurable progress, and we are committed to sharing regular updates with our Board and Investors as part of our dedication to transparency and continuous improvement.

II. Action Plan

Recommendation Area I: Clarify CEPI's role and prioritise the CEPI 2.0 scope of work

1.1 Analyse and more clearly define CEPI's role and end-to-end scope vis-à-vis partners in the R&D&M & global health ecosystem to enable a clear view of the areas of overlap, gaps, strengths &commitment to equitable access.

Management Response

Partially Accepted – Management recognizes the importance of clarifying CEPI's role in the broader Pandemic Prevention, Preparedness, and Response (PPR) ecosystem. Since CEPI's inception - and throughout implementation of the second five-year strategy (CEPI 2.0), CEPI has taken specific steps to analyze our role relevant to medical countermeasures development as well as the 100 Days Mission. We will utilize this MTR as an opportunity to bring those analyses together, further iterate and update their findings, and identify whether additional knowledge gaps exist for future work (e.g. within a CEPI Learning Agenda [or 6.4 below] or to be considered for a future CEPI 3.0)

Key Actions	Responsible	Expected Completion Date (MM/YY)
Action 1: Update analysis of CEPI's role across the 100 Days Mission pillars, including synergies with therapeutics and diagnostics stakeholders	**Lead:** GSPB	Q1 2025
Action 2: Update mapping of CEPI's position in the broader research, development, and manufacturing (R&D&M) value chain, including relationships with other PPR ecosystem partners	**Lead**: GSPB	Q1 2025

1.2 Based on analysis and decisions taken in response to 1.1, re-evaluate the end objective and plans for each pathogen programme & Disease X, considering the possibility that objectives for the programmes may be significantly different from one another &in many cases will not involve end-to-end development by CEPI.

Management Response:
Accepted

Key Actions	Responsible	Expected Completion Date (MM/YY)
Action 1: Review and update (if necessary) implementation roadmaps (Strategic Roadmaps), factoring in learnings to date, outbreak readiness, likely outputs by CEPI 2.0 completion, and desired end state (e.g. phase II candidate versus licensure)	**Lead**: R&D (Programme Teams)	Q2 2025, dependent on 1.1 April or June Board

1.3 Based on a clear understanding of CEPI & partner roles & responsibilities derived from the analyses conducted for recommendations 1.1 and 1.2, structure and advance negotiations around clear 'hand

offs' from CEPI to partners for both upstream and downstream activities and for ecosystem strengthening.

Management Response:
Accepted. The action proposed under this specific recommendation also support recommendation Area 3 (3.1)

Key Actions	Responsible	Expected Completion Date (MM/YY)
Action 1: Develop and deploy pathogen archetype models to categorize CEPI's portfolio programmes, ensuring alignment with CEPI's role and equitable access needs. Archetypes will further support end-to-end considerations across Strategic Roadmaps, clarifying opportunities for hand-offs to-and-from ecosystem partners.	**Lead**: ABD	3Q 25

Recommendation Area 2: Clarify how CEPI works to achieve its strategic objectives and reformulate the results framework to measure progress

2.1. Alongside actions to respond to recommendations area 1, update Theory of Change to reflect the agreed portfolio of work and CEPI's contribution to 100 Days Mission, realistic outcomes, structure, and the nuanced ways in which CEPI works and interacts within the broader global R&D ecosystem to achieve its mission.

2.2. Using decisions taken on CEPI's role under recommendations area 1 & the updated ToC as a guiding framework, update the CEPI 2.0 KPIs & targets to reflect CEPI's prioritised scope of work for the remainder of 2.0, including the use of interim milestones and process indicators.

Management Response
Accepted – We fully accept and welcome this recommendation. CEPI's Theory of Change and its associated results framework were developed during the COVID-19 pandemic, and many of our activities and initial assumptions (e.g. cost, timelines, partner availability) have since evolved. Building on the foundational work from Recommendation Area 1 and the emerging evidence and learnings to date, CEPI will update its Theory of Change to better reflect desired results in CEPI 2.0 – and a foundation for CEPI 3.0. CEPI's results framework will also be revised as needed to better align with this evolving evidence and prioritized scope of work.

Key Actions	Responsible	Expected Completion Date (MM/YY)
Action 1: Update the 2.0 Theory of Change to clarify causal pathways between activities, outputs, outcomes, and desired impact. This will be based on emerging evidence, refined assumptions and insights from Recommendation Area 1 to ensure that all aspects of CEPI's work are accurately represented and tell a cohesive story.	**Lead:** GSPB	4-6 months, subject to work in area 1.
Action 2: Update CEPI's results framework, along with associated KPIs and targets, to align with the revised Theory of Change and learnings to date. This will include establishing realistic, evidence-based targets.	**Lead**: GSPB	Shortly after ToC finalisation
Action 3: Build in a periodic review process for CEPI's Theory of Change and results framework to ensure they remain fit for purpose, and continue to adapt based on emerging evidence/learnings/portfolio reviews (this will also support 6.4)	**Lead**: GSPB **Key Contributors**: R&D, MSC, ABD, EIR, P&R	As part of above

Recommendation Area 3: Continue to embed a comprehensive and flexible approach to equitable access

3.1. Distinguish clearly in equitable access planning between pathogens likely to cause outbreaks primarily in LMICs, for which the primary access challenges may be to find a manufacturing partner & ensure downstream systems for distribution & delivery, and those that pose a potential

pandemic threat, for which the greatest challenge may be to secure supply for LMICs in the face of HIC competition.		
Management Response: **Accepted.** Actions from 1.3 will address this recommendation.		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Please refer to actions under 1.3		
3.2. Continue implementing a bespoke approach to equitable access provisions in partner contracts, guided by the EAF, the nature of the partnership, and the mutual objectives sought		
Management Response: **Accepted –** the MTR acknowledges CEPI's ongoing efforts to secure EA provisions- this is a core part of CEPI's work and we see this recommendation as endorsement on continuing our current approach		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Continue securing tailored equitable access outcomes for different deal needs and partner selection aligned with CEPI's Equitable Access Framework.	**Lead:** ABD	ongoing
Action 2: Increase the publication of CEPI materials related to its Equitable Access work and key insights to date	**Lead:** ABD, EIR	Q4 2025

Recommendation Area 4: Strengthen partner selection, engagement, and relationship management		
4.1. Finalise and embed the evolved approach to proactive partner selection and engagement based on technical capability and organisational mandates, guided by the finalised and agreed partner archetypes, to ensure partnerships are structured to fill identified gaps in the end-to-end approach for each pathogen and for PPR, in support of CEPI strategic objectives and equitable access.		
Management Response: Accepted		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Develop and maintain an up-to-date, comprehensive mapping of potential partners, including MNCs, that could address CEPI's portfolio needs, as identified in 1.2 and partner archetypes as outlined in 1.3.	**Lead**: ABD	Q3 2025 **September Board**
4.2. Continue to seek ways to further engagement with MNCs (a current gap in CEPI's partnership arrangements) to advance R&D&M objectives for priority pathogens and in support of Disease X and PPR objectives.		
Management Response: Accepted		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: (Integrated with 4.1) Increase understanding of MNCs priorities and incentives for partnering, and explore further thought partnership in order to support a diverse portfolio of partners and ensure we can adequately address gaps	**Lead:** ABD	Ongoing
4.3. Strengthen CEPI's partner relationship management function		
Management Response: Accepted		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Develop and deploy a cohesive approach for CEPI's partners management, including awardees, based on Alliance Management best practice	**Lead**: ABD	Q2 2025

Recommendation Area 5: Continue to clarify decision making pathways and governance engagement		
5.1 Continue to clarify who is responsible for different types of decision making, within management and governance arrangements, and in what scenarios, and (a) further streamline decision making; and/or (b) consider decentralizing decision-making responsibility from the Board/Committees to management where appropriate. **5.2 Continue to strengthen the documentation prepared by management for governance committee meetings.**		
Management Response **Accepted.** We fully accept and welcome these two recommendations. Given the evolution of CEPI's organization, and the complexities of implementing a broad portfolio of investments and activities, Management recognizes the need to revise internal decision-making procedures to ensure they are streamlined where possible & fit for purpose. Management also recognizes the need to revise documentation and decision processes to ensure they are trackable and included in records management.		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Review and update decision making processes and pathways/engagement with governance bodies to enhance their efficiency and effectiveness, while improving clarity and understanding across the organization	**Lead**: GSPB, R&D	Q2
Action 2: Revise and communicate documentation templates, guidelines, and committee secretariat functions.	**Lead:** GSPB	Q1

Recommendation Area 6: Further strengthen management culture, capabilities, and practices		
6.1. Implement plans to establish the new Executive Leadership team with a strong emphasis on cross-department, division and functional collaboration and decision-making in support of CEPI's role.		
Management Response: Accepted		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Finalize CEPI re-organization and convene Extended Leadership Team quarterly to discuss and decide on strategic and organizational matters, ensuring effective cross-departmental collaboration	**Lead:** CEO, DCEO, ED People & Org	Ongoing
Action 2: Implement annual leadership and matrixed management trainings at all levels of the organization	**Lead:** Ops	Annual
Action 3: Review and implement any necessary actions based on CEPI staff wellbeing surveys results in collaboration with the NCDIC/CEPI Board on an annual basis	**Lead:** All Executive Directors	Annual
6.2. Review the project management structure for grantee projects to ensure clear lines of decision-making between CEPI and the grantees; and further strengthen the programme management function with the new risk framework, IMS and other systems fully embedded		
Management Response: **Accepted:** Management welcomes this recommendation and has already begun addressing it. The Project Management Office (PMO)'s internal reorganization, approved by the Executive Directors in mid-2024 and now underway, directly tackles the key elements of this recommendation. The PMO reorganization is designed to enhance internal customer focus across the organization and support continuous process improvements.		
Key Actions	**Responsible**	**Expected Completion**

		Date (MM/YY)
Action 1: Finalize Project Management Office re-organization and reform to ensure improved internal customer orientation across all CEPI teams and support continuous process improvements	**Lead:** Operations, R&D	Q1 2025
Action 2: Advance and finalise the operationalization and embedding of IMS, IES, new risk framework and grant/ project management system (ie.. Salesforce) across the organisation	**Lead**: Operations	Q2 2025
6.3. Ensure there is clarity among all staff on how projects are expected to report on and deliver project-level results and contribute to wider outcomes of relevance to the portfolio and strategic objectives.		
Management Response **Accepted** – CEPI Management accepts this recommendation. We believe that actions planned in recommendation areas 1 and 2 (such as clarifying CEPI's role, updating our theory of change, and refining the results framework) will partially address this recommendation. The additional action proposed below will further strengthen internal alignment.		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: (Building on Recommendation Areas 1 and 2) Ensure CEPI's role, objectives, and progress are clearly communicated and cascaded across the organization. This will include stronger linkages between individual staff, team and organizational annual goals & Board approved objectives.	**Lead:** CEO, DCEO, COO, GSPB, Comms	Q3 2025
6.4. Develop and implement systematic learning processes at a project, department, cross-department and organisational level focused on both technical delivery and ways of working to improve implementation of CEPI 2.0, and to inform a next phase of activity.		
Management Response **Accepted.** We fully accept and welcome this recommendation. Building on the foundational work from Recommendation Areas 1 and 2, CEPI will develop and implement an organization-wide learning agenda that will support cross departmental collaboration, help to fill in key evidence gaps, and foster a culture of continuous improvement. This agenda will be designed to support evidence-based decision-making and ensure that learning is embedded into CEPI's strategic and day-to-day operations.		
Key Actions	**Responsible**	**Expected Completion Date (MM/YY)**
Action 1: Building on existing systems and work done under Recommendation area 1 and 2, develop an organization-wide learning agenda to promote cross-departmental knowledge sharing, address evidence gaps, and facilitate evidence-based decision-making.	**Lead**: GSPB	Learning questions to be identified as part of work for Area 1 and 2; supporting processes & tools to be developed by end of 2025

CEPI 2.0 Midterm Review Final Report

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Disclaimer

The views expressed in this report are those of the evaluators. They do not necessarily represent those of CEPI or any individuals and organisations referred to in the report.

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Contents

List of acronyms

Africa CDC	Africa Centres for Disease Control and Prevention
AI	Artificial Intelligence
AVMA	African Vaccine Manufacturing Accelerator
AVMI	African Vaccine Manufacturing Initiative
BARDA	Biomedical Advanced Research and Development Authority
BPBC	Broadly Protective Betacoronavirus
CDC	Centers for Disease Control and Prevention (US)
CEPI	Coalition for Epidemic Preparedness Innovations
CEPI 2.0	CEPI's second and current strategy period
CfP	Call for Proposals
CMC	Chemistry, Manufacturing, and Controls
CoP	Correlates of Protection
COVAX	COVID-19 Vaccines Global Access
CSU	Colorado State University
DAC	Development Assistance Committee
DCVMN	Developing Countries Vaccine Manufacturers Network
EAF	Equitable Access Framework
EID	Emerging Infectious Disease
EMA	European Medicines Agency
EQ	Evaluation Question
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
GHIC	Global Health Investment Corporation
HERA	Health Emergency and Preparedness Response Authority
HIC	High-Income Country
IAVI	International AIDS Vaccine Initiative
IC	Investors' Council
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations

i-MCM-Net	Interim Medical Countermeasures Network of Networks
IMS	Investment Management System
IP	Intellectual property
JCG	Joint Coordination Group
JMAG	Joint Management Advisory Group
KII	Key Informant Interview
KPI	Key Performance Indicator
LMIC	Low and Middle-Income Country
MAA	Market Access Africa
MCM	Medical Counter Measure
MGCCP	Management and Governance Capabilities, Culture and Practice Framework
MHRA	Medicines and Healthcare Products Regulatory Agency
MNC	Multinational Pharmaceutical Corporation
MOU	Memorandum of Understanding
MSC	Manufacturing and Supply Chain
MTR	Midterm Review
NIH	National Institutes of Health
OECD	Organisation for Economic Co-operation and Development
PAHO	Pan American Health Organization
PDP	Product Development Partnership
PPR	Pandemic Preparedness and Response
PSMB	Portfolio Strategy and Management Board
R&D	Research and Development
R&D&M	Research & Development & Manufacturing
RfP	Request for Proposals
RVF	Rift Valley Fever
RVMC	Regionalized Vaccine Manufacturing Collaborative
SAC	Scientific Advisory Committee
SCARDA	Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response
SRA	Strategy Roadmap Area

ToC	Theory of Change
ToR	Terms of Reference
UK	United Kingdom (of Great Britain and Northern Ireland)
UNGA	United Nations General Assembly
UNICEF	United Nations Children's Fund
US	United States of America
USD	University of California, Davis
USFDA	United States Food and Drug Administration
VRDMC	Vaccine Research & Development & Manufacturing Committee
WHO	World Health Organization
WUR	Wageningen University & Research

Currency symbols

$	US Dollar
CAD	Canadian Dollar
€	Euro

Executive summary

Introduction and background

The Coalition for Epidemic Preparedness Innovations (CEPI) commissioned Itad and Market Access Africa (MAA) to conduct an independent midterm review (MTR) of CEPI 2.0. The overall objective of the MTR is to assess progress against CEPI's 2.0 Strategy. The MTR will:

- assess the relevance, coherence, fidelity, effectiveness, impact, governance and management of CEPI's operational model and strategy
- identify lessons learned, capture good practice, and generate recommendations to inform and strengthen the implementation of the remainder of CEPI 2.0.

The MTR approach is utilisation-focused and theory-based, drawing on the Theory of Change (ToC) developed by the MTR team in the inception phase. The assessment used a mixed-methods methodology to answer the evaluation questions (EQs) set out below.

Key limitations include: the time frame to conduct the MTR; the breadth and highly specialised nature of the CEPI portfolio, which required substantial technical expertise to be brought into the MTR team; data availability; balancing the number of interviews with available resources and stakeholder availability; the risk of relying on self-reported views of internal stakeholders; and challenges in implementing the proposed methodology.

Findings

Table E1 provides a summary of the main findings, structured by each component of the MTR, which are further detailed under each workstream in the main report.

Table E1. Summary of key findings

Component	Key findings
Relevance	• The CEPI 2.0 Strategy and 100 Days Mission set out a grand vision for future outbreak and pandemic preparedness which is highly relevant to country, regional, global and partner priorities, notably those in low and middle-income countries (LMICs) whose needs in terms of access to Covid-19 vaccines had not been met in a timely way. • CEPI 2.0 represents a substantial expansion in CEPI's role established under CEPI 1.0 to include later stages of clinical development and downstream issues such as manufacturing and ecosystem strengthening as key components within an end-to-end approach to ensure equitable access. • CEPI 2.0 also represents a shift in the level of emphasis placed on unknown EIDs (Disease X) and pandemic preparedness, implying a greater role in issues that are more likely to affect all regions and countries. While CEPI retains its unique focus on equitable access in LMICs, many other research and development (R&D) funders, including agencies of HIC governments, are active in this space, necessitating coordination and a nuanced approach within a much more complex landscape than under CEPI 1.0. • CEPI is pursuing a set of activities that are highly relevant and aligned to the CEPI 2.0 strategic objectives and will justifiably contribute towards their achievement. However, a range of stakeholders referred to the lack of a clear articulation of how CEPI's investments link together for the achievement of higher-level goals, stemming from the structure of the CEPI 2.0 Strategy and ToC around three pillars that do not reflect how CEPI works, what it does, or what it seeks to achieve for each pathogen. • A central issue for CEPI relates to the breadth of its work under CEPI 2.0 and, more importantly, to the role it plays as part of an end-to-end approach to vaccine

	development and ensuring equitable access. Although there is a widely shared view that CEPI should put in place stronger 'hand-offs' to other organisations as part of an end-to-end approach, what CEPI should do when other partners are not willing or able to address identified issues is unclear. Expanding too far beyond CEPI's core area of comparative advantage in R&D is felt by many to pose a significant organisational and strategic risk. Not doing so, in the knowledge that critical pieces of the end-to-end approach are missing, is felt by others to pose an equally significant risk to achievement of CEPI's strategic objectives and equitable access.
Partnership	• CEPI has significantly expanded the number and scope of its partnerships in response to the needs and challenges posed by CEPI 2.0. CEPI is continuing to transition to a proactive, strategic approach for choosing and managing its partners in a differentiated manner according to the nature of the partnership and the mutual objectives sought.
Coherence	• CEPI was created to fill an evident gap in the vaccine ecosystem for R&D and to ensure equitable access for vaccines in response to EIDs that affect populations in LMICs; this remains an area where CEPI's role is unique and adds considerable value. • Several other agencies of HIC governments invest in common areas with CEPI for infectious disease threats that are more likely to affect all regions and countries. While CEPI retains a unique single focus on LMICs and equitable access, it is not always clear if or how CEPI's work in these areas is synergistic or duplicative of the work of others, although it has sought to engage with these entities to promote alignment. • CEPI has sought to align with global health partners in addressing downstream barriers to equitable access, advanced the scope of its collaboration with regional initiatives in the Global South, and initiated work to build partnerships with manufacturers in support of specific R&D projects to advance specified innovations and through a manufacturing network.
Management and governance	• The CEPI Board and overall governance function works reasonably well. The interaction between management and governance committees could be strengthened to aid efficiency and engagement in strategic decision making. • Substantial challenges within the Management Team have impacted on CEPI's ability to deliver against the CEPI 2.0 Strategy. These stem from the Covid-19 pandemic and the CEPI 2.0 Strategy itself, each of which has required substantial organisational strengthening for CEPI to respond effectively.
Fidelity	• Given that CEPI 2.0 represents a significant shift in CEPI's role and portfolio, planning for strategy operationalisation (execution) was insufficient. This was, however, further complicated by CEPI's active role in responding to the Covid-19 pandemic and the timing and limited success of fundraising activities in 2022. This has required substantial remedial prioritisation action. • Despite, and often in response to, the uncertainty and delays caused by the greatly expanded scope of activities in CEPI 2.0, the Management Team has advanced a significant body of work since 2022. This has included work related to its governance function, at the policy level, in strengthening management operations, and for new and existing programmatic activities. • Nonetheless, there has been a substantial underspend against the CEPI 2.0 budget to date, in part due to over optimistic spending projections. A range of efforts have been implemented to strengthen operational systems and drive implementation. Although this has led to some advances, implementation remains well behind what was initially planned, and without immediate reprioritisation to increase the breadth of activity, this will result in a substantial underspend at the end of CEPI 2.0.
Programmatic effectiveness	• Analysis of the CEPI portfolio indicates that substantial progress has been made in implementing and achieving results against many areas of the CEPI 2.0 Strategy, albeit with evidence of mixed effectiveness by pathogen and Strategy Roadmap Area. • CEPI's investments and wider role in responding to Covid-19 are widely considered to have been effective, as are its investments in R&D and enabling science for BPCV,

	Chikungunya, Lassa Fever and Rift Valley Fever (RVF), which have all demonstrated strong programmatic progress. • Evidence of effectiveness is less clear for investments related to MERS and Nipah, for which further programmatic progress is required. • Newly introduced investment areas for CEPI 2.0, such as Disease X and Manufacturing and Supply Chain, require more time to demonstrate results.
Effectiveness in decision making	• CEPI is a technically astute organisation that is able to identify issues and areas where there is a significant need for intervention to achieve CEPI's strategic objectives. Robust governance procedures are also in place to ensure the technical quality of new investments. However, in such a dynamic ecosystem with so many gaps and barriers to achieving CEPI 2.0 strategic objectives, CEPI has struggled to sufficiently prioritise its efforts across the portfolio to optimise performance within available resources.
Equitable access	• CEPI demonstrated a strong commitment to ensuring equitable access to vaccines during the Covid-19 pandemic. The Equitable Access Framework (EAF) builds on this experience by setting out a comprehensive approach to addressing equity across CEPI's scope of work. • In practice, CEPI has sought to advance the objective of equitable access in a range of ways across the portfolio, both through the choice of vaccine candidates appropriate for LMIC settings and to arrangements for manufacturing and access to vaccines once they get to market.
Impact	• There has been substantial programmatic progress across many areas of the CEPI 2.0 Strategy and towards the strategic objectives. However, many of the key performance indicator (KPI) targets are unlikely to be attained by 2026. This reflects both slow programmatic progress in some of areas of the strategy and the fact that the KPIs themselves are poorly defined and with overly optimistic targets. • Overall, much progress has been made against Strategic Objective 1, to prepare for known epidemic and pandemic threats. With the acute phase of the Covid-19 pandemic ending, CEPI's investments across its portfolio have promoted the development of priority pathogen vaccines and have contributed to reducing the risks of further coronavirus pandemics. • Some progress has been made against Strategic Objective 2 to transform the response to the next novel threat, albeit with work delayed in some areas. • Progress has also been made against Strategic Objective 3 to connect stakeholders and experts in EIDs to enable rapid countermeasure development, effective response and equitable access for those in need.
Learning	• There is mixed evidence on the extent to which CEPI has a strong learning culture. Although a range of monitoring and review processes takes place, there appears to be a lack of critical analysis and learning generated. It is also unclear whether adequate systems and processes are in place to support cross-team collaboration and learning. • The key learnings from CEPI 2.0 identified by the MTR fundamentally relate to the challenges associated with adopting and implementing a new strategy, especially one that represents such a radical strategic shift as CEPI 2.0 and that requires enhanced operational capacities to deliver.

Conclusions

In the midst of the Covid-19 pandemic, CEPI 2.0 and, later, the 100 Days Mission helped to galvanise global commitment to CEPI's mission: 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. However, as compared to CEPI 1.0, Covid-19 and CEPI 2.0 pose a range of very challenging issues for CEPI to deal with. This fundamentally relates to an expansion of CEPI's role and scope beyond R&D development to Phase II to include licensure and the full suite of downstream issues that affect equitable access, including manufacturing and ecosystem strengthening. It also critically relates to the increased level of emphasis placed on Disease X and pandemic preparedness, for which other R&D funders, including agencies of HIC governments, are active and where the issues surrounding product development and equitable access are very different than for CEPI's priority pathogens. CEPI has made good progress in addressing the implications of this strategic shift, notably through the EAF and its evolving work to define pathogen and partner archetypes to guide ways of working across the portfolio. However, this has taken time, and there remain divergent opinions as to what CEPI's role should be and how it should engage with other partners as part of an end-to-end approach.

Overall, the process tracing methodology employed to assess causal inference has not been able to confidently validate the contribution claim that CEPI's actions and activities are being implemented as intended and that the assumptions underpinning the ToC are working as intended to achieve the desired outcomes and strategic objectives. To do so would require further evidence of timely investments being made and progress towards outputs, outcomes and strategic objectives. The evidence collected and analysed through the MTR suggests that much programmatic progress has been made, providing an encouraging signal that the contribution claim could be validated at a later date, but potentially after the CEPI 2.0 period. The justification for this statement and the primary reasons for a lack of progress to date are articulated below.

Planning for CEPI 2.0 was inadequate, in part because it took place during a pandemic and because fundraising took place within the implementation period; this has contributed to a disconnect between the programmatic progress that CEPI is making, which is not always well understood, and the level of ambition that stakeholders expect of CEPI (for instance with Lassa fever, where strong programmatic progress has been made but product licensure within the CEPI 2.0 period is expected by some stakeholders, despite this being unattainable). The context has also evolved substantially since CEPI 2.0 was developed, as have CEPI's ways of working in response to its expanded role; the strategy does not fully capture this.

Strategy operationalisation has also been severely challenged for a range of reasons linked to Covid-19, the timing of fundraising, the need to radically shift approach, and an almost constant cycle of reprioritisation which ensued after a slow start to the CEPI 2.0 period. These issues relate fundamentally, although not exclusively, to the operational capacity within the Management Team, which has been strained by the effort required to implement CEPI 2.0. There are high expectations for the reorganisation and plans to recruit additional senior leaders to the Management Team, although it remains to be seen whether this will be sufficient to strengthen capacity for the effective execution of CEPI 2.0 in the remainder of 2024 to 2026.

Strategy operationalisation has also been challenged by a difficult operating environment, notably linked to Covid-19 (both its acute phase and as the emergency response was wound down), ongoing electoral political uncertainty which may substantially change global policy priorities, fiscal constraints, and a rapidly evolving multilateral and regional landscape for PPR.

Although spending and implementation progress has been slower than anticipated in some areas, notably when measured against the CEPI 2.0 budget, substantial programmatic progress has been made in the CEPI 2.0 period. This progress has built effectively on the R&D advances made under CEPI 1.0, with further R&D progress and advances within an end-to-end approach for the achievement of equitable access. Notable achievements have been in: the registration of Covid-19/SARS-CoV2 vaccines supported by CEPI; continued development progress being made for broadly protective betacoronavirus (BPBC), Lassa fever and RVF, as well as the advancement of plans to adapt a licensed Chikungunya vaccine to ensure it is accessible to LMICs and for a broader age range; expansion of the manufacturing network and initiation of several innovation projects; and establishment of laboratory, clinical and regulatory networks to strengthen global preparedness and response.

These achievements demonstrate CEPI's ability to select and support strong R&D partners, subject to some attrition, to advance vaccine candidates for priority pathogens and manufacturing where there is significant unmet need. CEPI's work on rapid response technologies and under the Disease X programme continues to show promise, but progress has not been as quick as expected.

In line with the scope of CEPI 2.0, CEPI has also embarked upon, and in many cases has made significant progress in, advancing its agenda for enabling science. Although CEPI's role in this area is the source of some debate, evidence suggests that in many instances its investments have been critical to both making R&D progress and overcoming barriers to R&D progress and ensuring equitable access.

CEPI has reaffirmed its commitment to equitable access, including through development decisions, publication and operationalisation of the EAF, and implementation efforts in CEPI 2.0.

A key strength of the CEPI portfolio is its focus on preventive vaccines for multiple pathogens and the opportunity that this provides for technologies and related science to be applied across programmes and for Disease X in support of the 100 Days Mission. There is good evidence that CEPI capitalised on technological commonalities during the Covid-19 pandemic, with platforms now being used to develop vaccines for Disease X and Lassa. Enabling science from MERS has also been useful in the Covid-19 and BPBC programmes. However, ensuring technological alignment across a diverse portfolio that is formed iteratively and that promotes innovation affecting other parts of the portfolio will remain a challenge. Regular reviews and end-to-end planning to promote such alignment and ensure a 'line of sight' between early stage and downstream activities for each programme may be beneficial. It should though be noted that although many further opportunities for shared benefit exist across programmes, ultimately much of the progress on an individual programme relies on efforts specific to that vaccine or pathogen. Another challenge of the portfolio is its sheer complexity, which is further magnified by access commitments and cross-cutting issues such as biosecurity, which, albeit important, place a substantial burden on internal staff and partners. This complexity will increase substantially as the portfolio matures and CEPI engages more substantively in activities related to late-stage development, licensure and vaccine deployment. CEPI's ability to structure clear 'hand-offs' to partners will become especially important at this juncture.

CEPI's work to coordinate and collaborate with industry, R&D funders, regional partners, country governments and regulatory bodies, as well as through its participation in all manner of global forums (e.g. G7. G20, the United Nations General Assembly), demonstrates the high esteem in which the organisation is held and the significant soft power it has cultivated within the global health architecture. This has been used to good effect in a number of areas to promote global

and regional models for regulatory alignment and pandemic preparedness and response (PPR) and to promote the need for and benefits of CEPI-supported vaccines when they reach the market (e.g. for Lassa fever). There is also emerging evidence that CEPI's work in support of the Pandemic Treaty, global PPR forums such as the Global Pandemic Preparedness Summit, and work with individual partners such as the National Institutes of Health is helping to promote equitable access principles as the foundation for a future global response, linked to the presence of a manufacturing network.

CEPI faces several fundamental challenges to achieving its 2.0 strategic objectives. First, as noted above, CEPI's expanded role has strained the capacity of the Management Team and, despite ongoing efforts to prioritise its many programmes, it is not clear that it has yet managed to define a feasible set of core activities.

Second, and related to this, CEPI has not yet fully clarified its role relative to other actors in PPR, particularly the agencies of HIC governments, for response to an epidemic strongly affecting these countries. In this and in other areas, there is a need for more explicit differentiation of CEPI's role across pathogens, which involve a mix of early and late stage R&D investments, pose outbreak threats of different types, and have quite different sets of active partners which CEPI can work alongside as part of an end-to-end approach.

Third, although its overall R&D portfolio is broad, it has relatively few investments and candidates in each of its vaccine programmes, leading to high development risk. CEPI is seeking to address this by reducing reliance on single technology platforms and leveraging R&D developments for other products to the extent possible.

Fourth, its vaccine development programmes continue to rely primarily on small and medium-sized biotechs, which may not have the expertise or capacity needed for later-stage R&D, regulatory approval, and manufacturing at scale. CEPI has struggled to date to engage with the multinational pharmaceutical corporations (MNCs) who have this expertise, notably as the interests of these companies (which are highly variable) and the terms on which they may be willing to engage with CEPI are, in general, quite different from those of the smaller biotechs on which CEPI has primarily relied to date. There is, however, merit in continuing to pursue such engagement in the preparedness phase in preparation for a future response. This constraint can be addressed in part, but probably not through CEPI's partnerships with manufacturers in the Global South.

Finally, for some of its programmes addressing pathogens primarily posing a threat to specific regions, demand and its implications for vaccine use and sustainable supply are not yet well understood. CEPI and its partners have expanded their efforts to address this challenge as part of its strengthened end-to-end approach, although this requires considerable continued effort for the remainder of CEPI 2.0.

At the midpoint in the CEPI 2.0 strategic period, there are now some difficult choices to be made by the CEPI Management Team and the Board in relation to the breadth and scope of CEPI's activity, and how to scale up CEPI's level of spending and programmatic activity to address the above-noted challenges and meet stakeholder expectations and the CEPI 2.0 strategic objectives.

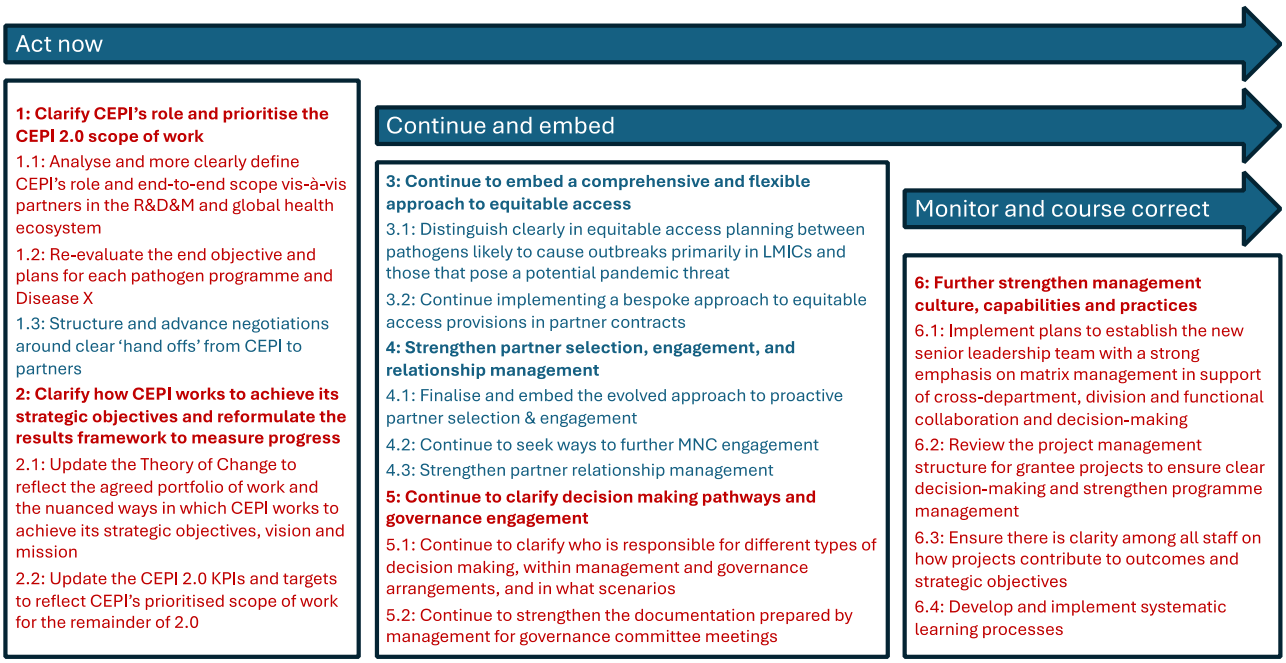
Recommendations

Recommendations have been developed by the MTR Team based on the MTR findings and conclusions, with input from the CEPI Management Team as a primary MTR user. More detail on

this process, and on the recommendations themselves and who is responsible for actioning them is provided in the recommendations section of the main report.

Recommendations under the first four areas are mutually supportive of each other and structured to provide a suggested chronological sequence of actions. Recommendations in areas five and six are designed to enable actions in response to other recommendations and wider CEPI 2.0 Strategy operationalisation.

The recommendations can be grouped into three categories, as summarized in the diagram below. The red recommendations are, in the view of the MTR Team, the most time critical recommendations to address to advance CEPI 2.0 strategy operationalisation.



Recommendations area 1: Clarify CEPI's role and prioritise the CEPI 2.0 scope of work

Recommendation 1.1 (Act now): Analyse and more clearly define CEPI's role and end-to-end scope vis-à-vis partners in the R&D&M and global health ecosystem to enable a clear view of the areas of overlap, gaps, strengths, and commitment to equitable access. The primary objective of this analysis is to facilitate strategic decisions about where and how CEPI should act within an end-to-end approach to most efficiently and effectively achieve its strategic objectives, delineating between an active funding role, a catalytic role, and an advocacy role. Secondarily, this recommendation is intended to inform decisions about strengthening the partner model (explored further under recommendations area 4). Although respective roles in the ecosystem have historically been understood in a general way, the global health ecosystem has been affected by the demands of the pandemic while strategic cycles and leadership changes have also had an impact on partner priorities. This recommendation is aimed at creating a fresh view of the current partner landscape and enable a forward view of their priorities, to inform CEPI's.

This analysis should be conducted in a comprehensive way and summarised for strategic decision-making purposes by CEPI Executive Leadership and the Board. For example, the end-to-end continuum can be depicted as upstream R&D, clinical trials, and downstream activities (e.g. registration, manufacturing, demand estimation) and portrayed over a multi-year horizon for the end-to-end approach, with caveats to express the dynamic ecosystem in which it operates. This analysis should include an assessment of strengths and weakness of CEPI and of

partners against activities on the continuum, an evaluation of commitment to equitable access for each partner, and an assessment of the ability to structure clear 'hand offs' to partners, in part based on historical experiences of partner engagement.

Recommendation 1.2 (Act now): Based on the analysis and decisions taken in response to recommendation 1.1, re-evaluate the end objective and plans for each pathogen programme and Disease X, considering the possibility that objectives for the programmes may be significantly different from one another and in many cases will not involve end-to-end development by CEPI. This approach should build on the work the Management Team has already advanced to develop pathogen archetypes, which should be refined to consider the likelihood of a pandemic or local/ regional outbreak, potential outbreak frequency, expected volumes of demand for a vaccine and other factors, and considering CEPI's role for each pathogen category both before and during an outbreak. The objective of this analysis is to facilitate strategic decisions on CEPI's role for each programme and will incorporate information on partner priorities and capabilities. Decisions on CEPI's role should also be based on, or at least made in full knowledge of, the willingness of partners to engage. If partners are not willing or able to engage, whether and how CEPI decides to assume a role that is perhaps outside of its core area of comparative advantage should be decided by the Executive Leadership and Board *a priori* and clarified with stakeholders.

The associated planning process should consider the full range of activities associated with each programme, including upstream and downstream activities, and CEPI's intended funding, catalytic and/or advocacy role at each stage, linked to a well-defined allocation of resources required to deliver on this, to determine precisely what CEPI does and how it does it. At this mid-point in the CEPI 2.0 strategic period, the Executive Leadership will need to decide how to act quickly while encouraging staff ownership and engagement in such a process.

Recommendation 1.3 (Act now): Based on a clear understanding of CEPI and partner roles and responsibilities derived from the analyses conducted for recommendations 1.1 and 1.2, structure and advance negotiations around clear 'hand offs' from CEPI to partners for both upstream and downstream activities and for ecosystem strengthening. These 'hand offs' should form the basis of high-level agreements/memorandums of understanding between CEPI and partners, with an intent to structure more detailed and operational agreements over time and where appropriate.

Recommendations area 2: Clarify how CEPI works to achieve its strategic objectives and reformulate the results framework to measure progress

Recommendation 2.1 (Act now): Alongside actions to respond to recommendations area 1, update the Theory of Change to reflect the agreed portfolio of work and CEPI's contribution to the 100 Days Mission, realistic outcomes, structure, and the nuanced ways in which CEPI works and interacts within the broader global R&D ecosystem to achieve its mission. This should articulate the different ways in which CEPI works across pathogens and for Disease X in both preparedness and response, and in relation to partners for each, showing where there is overlap and differentiation. It should also communicate the complexity of CEPI's work, the contextual influences upon CEPI and its contribution to the broader R&D&M ecosystem, and the assumptions that underpin the Theory of Change.

Recommendation 2.2 (Act now): Using decisions taken on CEPI's role under recommendations area 1 and the updated Theory of Change as a guiding framework, update the CEPI 2.0 KPIs and targets to reflect CEPI's prioritised scope of work for the remainder of 2.0, including the use of interim milestones and process indicators. It is recommended to:

- Structure KPIs along the end-to-end continuum by priority pathogen and for Disease X according CEPI's planned activity and the nature of its role vis-à-vis partners. This provides an opportunity to help clarify expectations on what can be achieved within the remainder of CEPI 2.0 and to clearly demonstrate results for the 2022-2026 period.
- Consider including targets beyond 2026 where this relates to longer-term results that CEPI 2.0 activities will contribute towards and that relate to the CEPI 2.0 strategic objectives, 100 Days Mission, and CEPI vision and mission. These can be carried over to the design of a future phase of activity.

Recommendations area 3: Continue to embed a comprehensive and flexible approach to equitable access

Recommendation 3.1 (Continue and embed): Distinguish clearly in equitable access planning between pathogens likely to cause outbreaks primarily in LMICs, for which the primary access challenges may be to find a manufacturing partner and ensure downstream systems for distribution and delivery, and those that pose a potential pandemic threat, for which the greatest challenge may be to secure supply for LMICs in the face of HIC competition.

Recommendation 3.2 (Continue and embed): Continue implementing a bespoke approach to equitable access provisions in partner contracts, guided by the Equitable Access Framework, the nature of the partnership, and the mutual objectives sought. Such an approach should seek to reduce instances where such provisions act as a barrier to partner engagement, including for MNCs. Separately, while the specific commercial details of contracts may be confidential, CEPI should seek to publish the broad intent of the provisions included for PPR and covering different types of outbreaks.

Recommendations area 4: Finalise and embed an evolved approach to partner selection and engagement, and strengthen the relationship management function

Recommendation 4.1 (Continue and embed): Finalise and embed the evolved approach to proactive partner selection and engagement based on technical capability and organisational mandates, guided by the finalised and agreed partner archetypes, to ensure partnerships are structured to fill identified gaps in the end-to-end approach for each pathogen and for PPR, in support of CEPI strategic objectives and equitable access. Further:

- *For R&D&M partners,* partnership agreements should be established with incentives aligned to the mutual objectives sought, clearly defining how investments and capabilities built in a preparedness phase are expected to be utilised in a future outbreak (e.g. for technology transfer and utilisation of manufacturing capacity). CEPI should also seek to identify barriers to R&D partners submitting proposals for CEPI funding and where feasible, look to address them; and more clearly communicate to partners CEPI's priorities and decision-making processes.
- *For other partners (e.g. countries, regional organisations, other R&D funders, DFIs, multilateral and global health partners, networks)* partnership agreements should be established with clear hand-offs in place and well-defined expectations, from both perspectives, on what respective roles should be. This may vary for instance by region and country, even with the same partner based on organisational priorities and funding, and depending on the presence of partners across different geographies. Such an approach must also differentiate expectations in a preparedness phase from an emergency footing to maximise synergies and reduce duplication of efforts, and

potentially in the situation of a global pandemic, seek ways to avoid destructive competition for doses, from which LMICs would likely again emerge the losers.

Recommendation 4.2 (Continue and embed): Continue to seek ways to further engagement with MNCs (a current gap in CEPI's partnership arrangements) to advance R&D&M objectives for priority pathogens and in support of Disease X and PPR objectives. Specifically, it is recommended to:

- Advance work to understand MNC motives and barriers to engaging with CEPI.
- Continue to look at entry points for engaging MNCs, including through R&D&M and PPR projects, flexibly employing equitable access provisions so as not to deter engagement (see recommendation 3.2).
- Consider what CEPI can offer developers (e.g. access to the vaccine library in the event of a pandemic) as an incentive to engage.
- Continue engagement with industry representatives (e.g. IFPMA and DCVMN via the JCG) and expand direct MNC engagement where possible (e.g. by inviting select stakeholders to join portfolio review meetings and via ongoing communication between CEPI and MNC leadership).

Recommendation 4.3 (Continue and embed): Strengthen CEPI's partner relationship management function. For R&D&M partners, whose relationships are usually managed at the project level, there is a need to consider how to most efficiently engage with partners across CEPI's different teams and matrix management system. It is also recommended, however, to engage with partners on a strategic level with senior level ownership within CEPI of relationships with partners that can foster mutual trust and leverage CEPI's soft power in pursuit of its objectives. Such relationships will be increasingly important as CEPI furthers its strategic partnerships which relate to multiple areas of the CEPI portfolio.

Recommendations area 5: Continue to clarify decision making pathways and engagement of governance committees

Recommendation 5.1 (Continue and embed): Continue to clarify who is responsible for different types of decision making, within management and governance arrangements, and in what scenarios, and (a) further streamline decision making; and/or (b) consider decentralising decision-making responsibility from the Board/Committees to management where appropriate.

Recommendation 5.2 (Continue and embed): Continue to strengthen the documentation prepared by management for governance committee meetings. This should include succinct information on the background context of issues, point in time financial and operational progress status, and clear decision points for the meetings. A general principle should be to use language to be inclusive of all members while ensuring key issues as well as the risks and implications of potential options are clearly articulated. Ensure all relevant documents are structured to support strategic decision making.

Recommendations area 6: Strengthen management culture, capabilities and practices

In addressing the recommendations for this area, CEPI should seek to balance the need to retain agility while working to systematise processes and ways of working commensurate with the size of CEPI's management team and the scale of its activities.

Recommendation 6.1 (Monitor and course correct): Implement plans to establish the new Executive Leadership team with a strong emphasis on cross-department, division and functional collaboration and decision-making in support of CEPI's role. This will help to enable end-to-end line of sight for vaccine candidates including proactive identification and management of opportunities and barriers for R&D&M and bringing products to market.

Recommendation 6.2 (Monitor and course correct): Review the project management structure for grantee projects to ensure clear lines of decision-making between CEPI and the grantees; and further strengthen the programme management function with the new risk framework, IMS and other systems fully embedded. It is further recommended to:

- Develop consistent and timely processes and templates for communication and feedback with grant applicants during the Calls for Proposals process.
- Improve matrix management and collaboration within and between programme teams by engendering a stronger organisational culture of multidisciplinary work and the modelling of cross-divisional work by Executive Leadership (see recommendation 6.1).

Recommendation 6.3 (Monitor and course correct): Ensure there is clarity among all staff on how projects are expected to report on and deliver project-level results and contribute to wider outcomes of relevance to the portfolio and strategic objectives. It is recommended to:

- Engage staff early in modifications to the end objective and plans for each pathogen programme and Disease X, the Theory of Change and Results Framework so that there is organisation-wide support for their adoption and reporting.
- Ensure that management decisions impacting projects or teams, as well as their rationale, are clearly communicated back to relevant staff. Identify, embed and communicate the channels available to staff to input into decision-making processes and/or to question or provide feedback on decisions.

Recommendation 6.4 (Monitor and course correct): Develop and implement systematic learning processes at a project, department, cross-department and organisational level focused on both technical delivery and ways of working to improve implementation of CEPI 2.0, and to inform a next phase of activity.

1. Introduction

1.1. Overview of the report

The Coalition for Epidemic Preparedness Innovations (CEPI) commissioned Itad and Market Access Africa (MAA) to conduct an independent midterm review (MTR) of CEPI 2.0, CEPI's second strategy. This report presents findings and conclusions based on the data collection and analysis process. Recommendations will be provided separately in August 2024.

The report is structured as follows:

- The remainder of Section 1 presents the purpose, objective and scope of the MTR.
- Section 2 presents a summary of: the evaluation framework and approach; data collection, analysis and synthesis methods; and limitations.
- Section 3 presents findings.
- Section 4 sets out the MTR conclusions.

This is supported by the following annexes, provided separately:

- Annex 1: Stakeholder groups and key informants interviewed
- Annex 2: List of documents reviewed during data collection phase
- Annex 3: Theory of change (ToC)
- Annex 4: Evaluation framework
- Annex 5: Evaluation methods and analytical tools
- Annex 6: Mapping conclusions to evaluation findings.

1.2. Background

CEPI, established in 2017, pursues its mission of accelerating the development of vaccines against epidemic and pandemic threats by advancing candidate vaccines against known priority pathogens, supporting the development of vaccine platforms to allow rapid development and production of vaccines against new threats, and working with others to build the ecosystem necessary to ensure rapid and equitable access to vaccines in future pandemics. With the emergence of Covid-19, CEPI responded quickly by investing in a large portfolio of vaccine candidates and joining Gavi, the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) in co-leading the COVID-19 Vaccines Global Access (COVAX) initiative, the centrepiece of the global effort to ensure equitable access to a range of Covid-19 vaccines.

CEPI 2.0, a five-year strategic plan with a budget of $3.5 billion (later revised to $2.6 billion), outlines ambitious goals to enhance global preparedness against infectious diseases. These include initiatives to shorten vaccine development timelines and expand vaccine access and manufacturing capabilities globally. Linked to this strategy is the 100 Days Mission – the aim of being able to develop a vaccine in 100 days against the next new pandemic threat. In pursuing these goals, CEPI operates in a complex and dynamic landscape, with numerous new national, regional and international initiatives to enhance pandemic preparedness and response (PPR), a new focus on regional vaccine development, manufacturing and procurement, and the challenge of sustaining global focus as pandemic preparedness competes with other global priorities.

1.3. Purpose of the MTR

The MTR provides an opportunity to capitalise on lessons learned from the first two and a half years of implementation of CEPI 2.0 (2022 to mid-2024), the recommendations from the evaluation of CEPI 1.0 and various monitoring and review exercises, to support CEPI to leverage current successes towards achieving its strategic objectives by 2026 and to course correct as necessary to respond to changes in internal priorities and the external context. Furthermore, in the current global context, in which discussions on pandemic preparedness are live and a wide range of agencies is involved in thinking through how global cooperation can best be achieved for the next epidemic/pandemic, CEPI's ability to better define its role, strategy and value-add in a complex and shifting space is more important than ever. This MTR intends to support this understanding and provide a solid basis on which CEPI can continue to implement CEPI 2.0.

1.4. Objectives

The overall objective of this assignment is to assess progress against CEPI's 2.0 Strategy. The overall purposes are to:

- assess the relevance, coherence, fidelity, effectiveness, impact, governance and management of CEPI's operational model and strategy
- identify lessons learned, capture good practice, and generate recommendations to inform and strengthen the implementation of the remainder of CEPI 2.0.

1.5. Scope

As above, and as derived from the request for proposals (RfP), the MTR assesses the relevance, coherence, fidelity, effectiveness, impact, governance and management of CEPI's operational model and strategy. Equity is also considered as a cross-cutting issue. These categories and the EQs that sit within them have been organised into four workstreams. Each workstream has a guiding overarching question encompassing both the summative and the formative nature of the MTR. This categorisation and organisation of workstreams informs our approach and analytical framework.

Figure 1. Categorisation and organisation of EQs from the RfP

Overarching question	**Workstream A:** To what extent is CEPI 2.0 focusing on the right things?		**Workstream B:** How well is CEPI 2.0 being operationalised and how can it be strengthened?			**Workstream C:** To what extent is it likely that the intended results will be achieved?	**Workstream D:** What lessons can be drawn and recommendations be made to move forward?
Category in the RfP	Relevance	Governance & management	Coherence	Fidelity	Effectiveness	Impact	Lessons learned
Related EQ	EQ1	EQ2	EQ3	EQ4	EQ5	EQ6	EQ7

The MTR is focused on the choices that were made to design CEPI 2.0 and on implementation and results from 2022 to mid-2024. As such, it looks back from recent experiences to answer the

EQs, examining key decision points and choices made, to understand the relevance, coherence, fidelity, effectiveness, impact, governance and management of CEPI's operational model and strategy. The lessons learned will inform forward-looking recommendations that apply to the remainder of CEPI 2.0. This temporal scope is applied to all the EQs, taking into account the dynamic changes that have occurred to the organisation and the context in which it operates.

1.6. Primary and secondary users

As per the RfP, the primary audience for this evaluation is the Board and its committees, investors, and the CEPI Management Team. However, the evaluation outputs will likely be of interest to a range of other stakeholders, including potential CEPI investors, CEPI partners and actors operating in the same ecosystem as CEPI for vaccines and other biologic countermeasures against epidemic and pandemic threats, and the global health community in general. As such, we understand that the final evaluation report will be a public document.

2. Evaluation approach

2.1. Overview of the evaluation design and approach

The overall evaluation approach is utilisation-focused and theory-based, drawing on the ToC developed by the MTR Team in the inception phase of this assignment, as presented in Annex 3. The assessment used a mixed-methods methodology to answer the EQs set out below.

2.2. Evaluation questions

After careful consideration of the EQs posed in the RfP, the EQs presented in **Error! Reference source not found.** were agreed as part of the Inception Report. A detailed evaluation framework is presented in Annex 4, including the approaches for data collection and analysis for each EQ.

Table 1. EQs by workstream and category

Workstream A: To what extent is CEPI focusing on the right things?	
Relevance, including equity	
EQ1	**To what extent is CEPI focusing on the right things?**
EQ1.1	To what extent is the CEPI 2.0 Strategy appropriate for achieving its mission and objectives?
EQ1.1.1	To what extent is the CEPI 2.0 Strategy responding appropriately to relevant country, regional, global and partner/institutions' needs and priorities?
EQ1.1.2	To what extent is the CEPI 2.0 Strategy engaging in appropriate activities to achieve its objectives?
EQ1.1.3	To what extent is the CEPI 2.0 Strategy engaging in appropriate partnerships to achieve its objectives?
EQ1.2	To what extent does the evidence support CEPI's 2.0 Theory of Change (ToC)?
EQ1.2.1	To what extent [does the ToC] identify appropriate indicators, outcomes and assumptions?
EQ1.2.2	To what extent [does the ToC] provide a pathway for CEPI to achieve its mission?
Governance and management	

EQ2	**To what extent are CEPI's management and governance systems fit for purpose vis-à-vis implementation of the programme of work?**
Workstream B: How well is CEPI 2.0 being operationalised and how can this be strengthened?	
Coherence	
EQ3	**Is CEPI's work coherent with, and does it add value to the work of, other institutions/organisations working on vaccine-preventable diseases?**
EQ3.1	To what extent is CEPI 2.0's work synergistic with other institutions/organisations working on vaccine-preventable diseases?
EQ3.2	To what extent is CEPI's 2.0 work adding value to and avoiding duplication of efforts with partners?
Fidelity	
EQ4	**To what extent has 2.0 implementation proceeded as intended?**
Effectiveness, including equity	
EQ5	**How effectively has CEPI's 2.0 Strategy been implemented?**
EQ5.1	To what extent is CEPI making appropriate decisions to advance progress towards its strategic objectives and outputs as articulated in its 2.0 programme document and associated results framework?
EQ5.2	To what extent is CEPI, through its 2.0 Strategy, working to advance equity vis-à-vis access to vaccines and advancing manufacturing partnerships?
EQ5.3	What are the main drivers and barriers identified to advance towards strategic objectives? What mechanisms, if any, have been established to address barriers?
Workstream C: Is CEPI on course to achieve the 'right results'?	
Impact	
EQ6	**What is the plausibility of CEPI meeting its strategic objective and outputs/targets for 2.0?**
Workstream D: What lessons can be learned for the remainder of the 2.0 strategic period and beyond?	
Lessons learned	
EQ7	**What lessons can be drawn with respect to design, implementation and interim results that should or could lead to refining CEPI's Theory of Change, results framework, indicators or operations moving forward?**

2.3. Data collection methods

Document and literature review. A desk review of CEPI documentation has been completed, including for all available annual reports, strategy documents, results frameworks, Board meeting minutes and governance papers, evaluation reports and other secondary data available to inform the evaluation findings. A literature review has also been conducted. Our review of these documents was structured in such a way as to ensure that all relevant data was assembled against each of the workstreams and EQs, supporting the team to systematically analyse the available data and trace back from findings to the evidence and data sources upon which they are based. A full list of documents is provided in Annex 2.

Key informant interviews (KIIs). KIIs have been carried out using a semi-structured interview protocol, and we have retained written notes for all KIIs, as well as audio files where agreed by

interviewees. In total, 14 stakeholders were interviewed as part of the inception phase and 56 stakeholders were interviewed in the data collection phase. These stakeholders were selected (purposively sampled) based on their knowledge and expertise in relation to CEPI 2.0, the EQs, the aim to capture diverse perspectives, and stakeholders' position within and outside of CEPI's management and governance structures.[1] A list of stakeholders is provided in Annex 1.

2.4. Data analysis and triangulation

As agreed in the Inception Report, for data collected through the methods described above, we have employed a range of analytical approaches (described in detail in Annex 5):

- **Qualitative analysis of interview data.** Qualitative evidence collected through all interviews conducted was coded to the same evidence matrix as that used for the structured document review, linked to the process tracing exercise, the ToC and the EQs. Where possible (given the need for anonymity), qualitative data has been disaggregated to reflect the perceptions of different groups of stakeholders.
- **Quantitative analysis.** We have conducted quantitative analysis where data was available, for instance on financial data, staff headcount numbers, project counts, and in relation to the achievement of key performance indicators (KPIs).
- **Benchmarking to best practice in strategy development.** This benchmarking supported, in combination with other methods, analysis of the likelihood that the strategy will achieve its mission and strategic objectives. This included examination of the design of the ToC and whether the structures and processes supporting its implementation are adequate to achieve the desired outcomes. This work was informed by the KIIs and document and literature reviews to determine whether the strategy includes the right activities to meet its strategic objectives.
- **Stakeholder and landscape analysis.** We have conducted a stakeholder mapping exercise to identify stakeholders within CEPI and the ecosystem in which CEPI operates to build an understanding of what they do, how this relates to CEPI's role, the 2.0 Strategy and the CEPI portfolio, and their potential role in the achievement of strategic objectives.
- **Context analysis.** We conducted a context and timeline analysis to underpin our understanding of the context in which CEPI 2.0 was designed and operationalised. First, we reviewed CEPI documents and data to create a coherent timeline and generate descriptions related to these timeline events. The analysis covered the time period 2021 to 2024, i.e. from when 2.0 was first being designed up to date. We also included internal and external events against the backdrop of which the design and implementation of CEPI 2.0 took place. Finally, we created a visual timeline (see Annex 5.3) with the objective of situating the evaluation in the wider context, which is of particular importance because of the shifting environment and landscapes in which CEPI 2.0 operationalises.
- **Partnership typology.** Drawing on a document review, we mapped the purpose and scope of existing CEPI partners in relation to the 2.0 Strategy strategic objectives and against

[1] We sought to capture a mix of stakeholders from CEPI's leadership and programme teams, partner agencies, the CEPI Board and advisory committees, country governments and regional health bodies, regulatory agencies, funding partners, the private sector – including manufacturers, product development partnerships (PDPs), technical experts and civil society – and well-informed individuals external to CEPI. This set of stakeholders captures a diverse mix of geographic backgrounds and experiences.

the dimensions of a partner typology (dependency, responsibility, tension, influence, diverse perspectives) to understand the nature of the relationship and partnership. We then drew on the findings from the stakeholder analysis to compare CEPI's partners with the broader global research and development (R&D) stakeholder landscape, to determine whether CEPI has the right mix of partners to achieve its objectives and, if it does not, what needs to change.

- **ToC analysis.** We benchmarked the ToC included in the CEPI 2.0 Monitoring and Evaluation Framework (2021) against good practice in ToC development. In doing so, we tested the appropriateness of the activities, outputs, outcomes and mission, as well as the causal pathways between them. Because CEPI's current ToC does not include explicit assumptions, we mapped these as part of the inception phase and then tested them against the evidence collected as part of process tracing and other data collection activities as part of the MTR. Our assessment of whether these assumptions have held in practice is presented in Annex 5.5.
- **Capability, culture and practice mapping and assessment.** This has been used to ascertain whether the right capabilities, culture and practices were/are in place to best enable and support CEPI's operations and to understand the way accountability works between key stakeholders at different levels and the reasons or drivers for any failures or successes. The evidence collected in relation to each component of the capability, culture and practice framework is presented in Annex 5.6.
- **Process tracing.** We have collected and collated data in a manner consistent with the process tracing exercise set out in the Inception Report. Analysis of the evidence collected in relation to each process tracing test is presented in Annex 5.7 alongside a mapping of this to the findings in the main report, to demonstrate how it has been used to inform the report across the EQs. The exercise has also enabled an overall assessment against the contribution claim; this is presented as a conclusion.
- **Deep dive analysis.** This area of analysis was challenging to operationalise, in terms of both gaining access to project-level documentation and scheduling interviews with R&D partners in a timely manner to allow for robust analysis prior to deliverables. On reflection, it was realised by the MTR Team that the requested prioritisation of portfolio analysis by the Independent Evaluation Committee, which was agreed in the final Inception Report, diminished the added value of the deep dives. On receipt of the Independent Evaluation Committee and CEPI comments on the Draft Report, it was agreed that the MTR would integrate the data collected from all interviews, including the data collected related to deep dives, within the report but that the deep dives would not be presented as stand-alone sections. This has been completed.

2.5. Limitations

Like all evaluations and strategic reviews of this nature, the approach has both strengths and limitations, mostly shaped around resourcing and time frames, on which we reflect below.

Time frame to conduct the MTR. As per the RfP, the MTR was envisioned to take place with the inception phase from January to March 2024 and the data collection process in April and May 2024, leading to a Draft Report on 31 May 2024 and a Final Report in July 2024. In practice, Itad was contracted only on 17 April 2024, and although an Inception Report was submitted on 31 March 2024 as per the agreed deadline, multiple revisions were requested before being agreed by the Independent Evaluation Committee on 14 May 2024. During the inception phase it was also identified that a greater number of KIIs would be required than had originally been budgeted for, to cover the scope of work and to implement the proposed methodology. This was agreed by CEPI on 21 May 2024. As such, this substantially compressed the data collection phase and meant that not all data could be collected and analysed in advance of the Draft Report being submitted on 31 May 2024. Efforts have been made to complete data collection and analysis for this Final Report.

Breadth and highly specialised nature of the CEPI portfolio. As noted in the MTR findings, CEPI engages in a very broad scope of work, and does so in highly technical and specialised areas. The highly complex nature of the organisation makes a strategic review such as this very challenging and resource-intensive to operationalise. Although the MTR team had strong global health and immunisation expertise, at CEPI's suggestion an external consultant with expertise in vaccine research, development, manufacturing and regulatory systems was brought in to analyse the CEPI portfolio in depth. Although this consultant did not have an evaluation background per se, the addition of deep sector knowledge has added considerable value.

Data availability. As noted in the MTR findings, much of the documentation produced by the CEPI Management Team for its various governance committees focuses on providing general progress updates, a summary of the issues, and plans for the future. The MTR was provided with guided access to some aspects of the internal Salesforce or Investor Management System (IMS) portals which restricted the information available and the level of analysis that could take place. Screenshots were provided on request, but the team was not able to access any systematic reporting of project-level progress in relation to annual and CEPI 2.0 milestones and objectives. In addition, the MTR did not interview project-level staff (see next limitation below). As such, a significant challenge was encountered in simply understanding whether planned activities had been implemented and were achieving outputs and results in line with plans. This limited the MTR's ability to systematically assess both the efficiency/fidelity of implementation and effectiveness of CEPI's portfolio investments. This assessment relied upon various portfolio-wide reports, notably the Annual Portfolio Reviews and Annual Progress Reports to discern implementation progress and results, which was triangulated against KPI reporting (where relevant) and spending patterns across the portfolio as a marker of progress. As such, the report often highlights areas of strong and less-strong programme progress, rather than systematic assessments of efficiency and effectiveness by pathogen and SRA.

Further, CEPI's higher-level reporting was found to often lack substantive critical analysis of why issues in implementation have arisen and the context in which they have arisen, what CEPI has done well and less well, what CEPI can and cannot do differently, what the trade-offs would be if CEPI were to engage differently, and the questions that need to be answered or decisions

made. This made it challenging for the MTR to reflect on all of the barriers and drivers of CEPI 2.0 implementation and results.

Balancing the number of interviews with available resources and stakeholder availability. Good practice when using a snowball approach would be to continue identifying new key informants until the point where no new data, categories or relationships seem to be emerging. Unfortunately, time and resources have meant that we have not been able to reach this point, and this must be acknowledged as a limitation. Moreover, the team has been unable to interview several intended stakeholders representing industry, other R&D funders, multilaterals and civil society (although others from these categories have been interviewed), owing to scheduling difficulties. As alluded to above, although the number of key informants was increased after the inception phase, at the guidance of the Independent Evaluation Committee the number of CEPI staff interviewed was kept to a minimum and focused on senior technical staff, the strategy team and leadership. Project-level staff were not interviewed, which is likely to have limited the depth of our understanding on project progress. More resources or greater stakeholder availability would have meant, again, a wider evidence base to support findings and recommendations. However, the team is confident that the evidence collected and analysed is sufficient to formulate sound conclusions and actionable recommendations.

Analysis draws upon self-reported views of internal stakeholders. Stakeholders were purposively sampled to capture a wide range of key stakeholders involved in the management and governance of CEPI across different aspects of the portfolio, R&D and other grantees and multilateral partners, as well as stakeholders external to CEPI from a diverse mix of perspectives. This gives us an interesting and nuanced picture of CEPI 2.0 from a range of different viewpoints. However, we are reliant on the candour of those respondents and their perceptions, which may be subject to bias in a range of ways. For instance, it may be that there are differences in the extent to which respondents felt enabled – through knowledge, trust or other constraints – to provide a full reflection on CEPI 2.0. Our approach to dealing with this is to acknowledge that it is likely to be an issue with the qualitative data collected and to be mindful of this when analysing data. In addition, by seeking to capture a mix of stakeholder perspectives, we have largely been able to triangulate evidence from multiple sources to develop findings.

Challenges in implementing the proposed methodology. As noted in the MTR findings, the CEPI 2.0 ToC is structured by strategic objective and does not reflect how CEPI works, what it does, or what it seeks to achieve for each pathogen and Strategy Roadmap Area (SRA). The revised MTR ToC (developed with some but not all CEPI senior management) better reflects the breadth of CEPI's activity, causal pathways for each strategic objective and the assumptions that underpin them, although it still does not accurately represent how CEPI works to achieve its mission (which would require articulation of CEPI's highly differentiated ways of working across the portfolio and by pathogen and SRA, depending on partner capacities and willingness/ability to engage to address downstream barriers to equitable access). Not having a well-formulated ToC presented a challenge to operationalising this theory-based evaluation. The process tracing exercise was designed in full knowledge of this limitation. Although still helpful for structuring the MTR data collection and analysis process, it has been conducted at a reasonably high level and has not been able to fully capture all of CEPI's ways of working to enable results. Although this is appropriate and reasonable for an MTR, a more in-depth exercise would be required to make stronger causal claims, and this will be expected from an end-of-term review/evaluation.

Other challenges were experienced the deep dive analysis and in operationalising the partnership typology analysis. For the former, the data collected from all interviews, including

the data collected related to deep dives, has been integrated within the report but the deep dives are not presented as stand-alone sections. For the latter, although the proposed 'standard' was broadly used to structure the analysis, the absence of data for some partners meant that the sample was not representative and limited the use of quantitative analysis to elucidate findings. As such, rather than a systematic stand-alone analysis, indicative insights were used to triangulate with other data sources to inform the MTR findings.

2.6. Strength of evidence

In line with good evaluation practice, we have assessed the strength of the evidence, using the framework shown in Table 2.[2]

Table 2. Strength of evidence framework for evaluation findings

Rating	Strength of evidence assessment criteria for findings
Strong (1)	Evidence comprises multiple data sources, both internal (e.g. CEPI management and Board) and external (good triangulation from at least two difference sources, e.g. document review and KIIs, or multiple KIIs of different stakeholder categories), which are generally of good quality.
Moderate (2)	Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation, e.g. only documents of KIIs from one stakeholder category) of decent quality.
Limited (3)	Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based or is generally based on data sources that are viewed as being of lesser quality.
Poor (4)	Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence. Additional evidence should be sought.

[2] Assessing the strength of evidence through triangulation of data sources and methods is widely accepted as appropriate in the evaluation literature, drawing on the work of Patton (1999) and Denzin (1978). Communicating the strength of evidence through a rubric-based approach is more recent but also accepted as being in line with best practice in the evaluation literature, as communicated by Aston (2020) and Aston and Apgar (2023).

3. MTR findings

This section presents our findings and supporting evidence against the EQs. These are structured by the three evaluation workstreams.

3.1. Workstream A: Design

3.1.1. Introduction

This workstream is focused on the Organisation for Economic Co-operation and Development's (OECD) Development Assistance Committee (DAC) evaluation criterion of relevance, unpacking the evidence base to inform an assessment of the extent to which CEPI's 2.0 Strategy has focused on the right things, as well as whether CEPI's governance and management arrangements have been appropriate.

3.1.2. Findings

EQ1.1: To what extent is the CEPI 2.0 Strategy appropriate for achieving its mission and objectives?

Headline findings	The CEPI 2.0 Strategy and 100 Days Mission set out a grand vision for future pandemic preparedness which has helped to gain traction around the need for ecosystem and systems strengthening. CEPI 2.0 represents a substantial expansion in CEPI's role established under CEPI 1.0, to include later stages of clinical development and downstream issues, such as manufacturing and ecosystem strengthening, as key components within an end-to-end approach to ensure equitable access. CEPI 2.0 also represents a shift in the level of emphasis placed on Disease X and pandemic preparedness, efforts which are LMIC-focused but engage in issues likely to affect all regions and countries, and for which other R&D funders, including agencies of high-income country (HIC) governments, are active. This shift better positions CEPI to respond to future global pandemics but has dramatically increased the complexity and breadth of issues that CEPI seeks to address and the landscape in which it operates. The CEPI 2.0 Strategy document is also set out at a very high level and does not make clear where CEPI's role should begin and end, which has led to confusion and differing expectations as to where the organisation's efforts should be placed; expanding too far beyond its core area of comparative advantage is felt by many to pose a significant organisational and strategic risk. Not doing so, in the knowledge that critical pieces of the end-to-end approach are missing, is felt by others to pose an equally significant risk to achievement of CEPI objectives and equitable access.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 1: The CEPI 2.0 Strategy represents a substantial shift in CEPI's role, as established under CEPI 1.0, from a focus on R&D to Phase II, to include end-to-end support for an expanded set of pathogens and development of technology platforms. It includes CEPI's input from R&D to product licensure alongside manufacturing and ecosystem strengthening to ensure equitable

access. Although not explicit, the CEPI 2.0 Strategy also places more emphasis on Disease X and pandemic preparedness, efforts which are LMIC-focused but engage in issues likely to affect all regions and countries, and for which other R&D funders, including agencies of HIC governments, are active. This responds to the recognised need for a radical shift in the ecosystem for ensuring equitable access to vaccines for LMICs in the event of a global pandemic and represents an extension of the role CEPI played in response to Covid-19. In this light, many stakeholders across all the groups interviewed reflected that CEPI 2.0 is a necessary global strategy for the achievement of CEPI's goal to develop vaccines that respond to epidemics and pandemics and that are accessible to all who need them. Setting out a grand vision at this time, including the aspirational 100 Days Mission, was necessary for inspiring global engagement and support.[3] The inclusion of areas of work beyond vaccines, such as diagnostics, therapeutics, manufacturing and ecosystem strengthening, is an acknowledgement that equitable access to vaccines requires an end-to-end approach.

Finding 2: The CEPI 2.0 Strategy document is set out at a high level, with broad objectives related to three pillars – Prepare, Transform and Connect – that do not clearly reflect how CEPI works or what it seeks to achieve. It is also not clear where CEPI's role within each would begin and end. CEPI 2.0 was developed in 2021, when CEPI was in the midst of responding to the Covid-19 pandemic, and was developed in a short time frame. Some CEPI staff referred to significant partner engagement in the strategy development process; others noted a lack of consultation among CEPI's technical staff.

Data on the relevance and suitability of the CEPI 2.0 Strategy itself was collected and analysed against four best practices for high-impact strategic planning (having a clear purpose; ensuring a strong operating model is in place to deliver the strategy; data is collected, analysed and learned from; a strategic culture exists within the organisation to underpin the other three areas - see Annex 5.1). Evidence and findings related to the first component are presented here, and other components are presented throughout the report.[4]

A wide range of stakeholders interviewed referred to the CEPI 2.0 Strategy document as being high-level and without a clear articulation of how the three pillars – Prepare, Transform and Connect – link together. What CEPI planned to do within each priority pathogen[5] and for other SRAs as part of an end-to-end approach, alongside the role of others and in a manner that contributes in a holistic way to the desired objectives, is also not detailed. Several key informants, including CEPI staff and governance committee members, commented that CEPI 2.0 had not been as well thought through and coherent as might ordinarily be expected of an organisational strategy. This extends to the technical feasibility of the CEPI 2.0 strategic objectives and the 100 Days Mission, which key informants, notably CEPI staff with technical backgrounds, suggested could never have been achieved within the CEPI 2.0 time frame. Linked to this is the "practical impossibility" of CEPI spending the requested $3.5 billion within a five-year period.

[3] A range of stakeholders referenced countries such as Brazil, India, Senegal and Indonesia adopting the 100 Days Mission concept, with Indonesia including it as a core theme of its G20 presidency.

[4] This includes EQ1.1.2, EQ1.1.3, EQ2 and EQ7.

[5] Priority pathogens for CEPI 2.0 are Chikungunya, Lassa Fever, MERS, Nipah, and Rift Valley Fever. Mpox was added as a priority pathogen in late 2023. CEPI also works with other novel viral threats with epidemic or pandemic potential also known as "Disease X", which is a Strategy Roadmap Area.

Although the process of strategy development is somewhat understandable given the pressing issues at play in 2021, evidence suggests that having such a high-level and overly ambitious strategy that directed the organisation to work in a fundamentally new way created a substantial problem for management and, notably, for technical teams in determining how to operationalise it. Several key informants among CEPI's staff and governance committee members noted that since CEPI 2.0 was developed, management has built its own understanding of what is required to achieve the strategic objectives and has sought to retrofit activities based on the experiences and learnings of early strategy operationalisation, a process which is still ongoing. Such changes are expected from an adaptive organisation working in a dynamic global context.

EQ1.1.1: To what extent is the CEPI 2.0 Strategy responding appropriately to relevant country, regional, global and partner/institution needs and priorities?

Headline findings	CEPI 2.0 was designed in the middle of the Covid-19 pandemic to respond to country, regional, global and partner needs and priorities, notably those in LMICs, whose needs in terms of access to Covid-19 vaccines had not been met in a timely way. Although much has changed since 2021 which is not captured by the strategy, CEPI 2.0 activities remain broadly aligned with and supportive of global, regional and national strategies, priorities and needs.
Evidence strength	**1:** Evidence comprises multiple good quality data sources which has been triangulated to derive the findings.

Finding 3: CEPI 2.0 was designed to respond to country, regional, global and partner needs and priorities. The document review and a range of stakeholders from all groups interviewed reflected that CEPI 2.0 and the 100 Days Mission were designed to be, and have remained, highly relevant to global needs, which reflected regional, country and partner needs and priorities. In particular, interviewees noted that CEPI's role in the development of vaccines against epidemic and pandemic threats, particularly where there is little commercial incentive to do so, is unique and critical. Several developments in the global Research & Development & Manufacturing (R&D&M) ecosystem have occurred since the launch of CEPI 2.0 which were not envisaged:

- Negotiation on the draft WHO Pandemic Treaty, which has been delayed by several points, including the sharing of vaccines and material with pandemic potential – points which reflect on the ambitions of CEPI 2.0.
- Greater political prioritisation of the importance of regional/sovereign manufacturing capacity as a mechanism to overcome the vaccine access issues experienced during the Covid-19 pandemic. At the same time, due to the pandemic there is a significant overcapacity in vaccine manufacture among multinational pharmaceutical corporations (MNCs).
- The need for greater coordination across the global R&D ecosystem to maximise efficiency and collaboration, avoid duplication and leverage the work of other stakeholders in PPR. The Joint Coordination Group (JCG) (established by CEPI), xVAX and the interim Medical Countermeasures Network of Networks (i-MCM-Net) are initiatives that are supporting this coordination.
- The selective engagement of MNCs in the global R&D ecosystem, each of which has specific motivations for product development and grounds upon which they will engage. Their role in the pandemic and in recent epidemics has likely caused these industry

players to evaluate the extent and manner in which they may engage in future crises that call on their capabilities.

Other developments identified by the landscape analysis that have arisen since the development of CEPI 2.0 and which are not addressed by it include:

- Reduced demand for Covid-19 vaccines since the peak of the pandemic.
- Reduced political engagement and financial support for PPR.
- Recent or upcoming elections in several countries partnering with and/or supporting CEPI, including South Africa, the United States of America (US), the United Kingdom (UK), India, Indonesia, and European Union (EU) countries, including France, Italy and Spain. This has created and will create periods of uncertainty over the future of political and financial support for global PPR initiatives.
- The launch of new organisations, e.g. the Health Emergency and Preparedness Response Authority (HERA) and the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), and the continuation of others, such as the Biomedical Advanced Research and Development Authority (BARDA), that are contributing to the global PPR. Unlike CEPI, these organisations have a remit that is both national and global.
- A greater awareness of the importance of biosecurity and biosafety because of the lessons learned from the Covid-19 pandemic.
- The development of new manufacturing technologies, including the use of AI.

CEPI's response to these global trends and developments, which continue to evolve, is detailed in discussion of EQ1.1.2.

Finding 4: CEPI 2.0 activities broadly align with and support global, regional and national strategies and priorities. CEPI's portfolio under 2.0 aligns with several global instruments, including WHO's R&D Blueprint[6] for priority pathogens and key amendments to the International Health Regulations passed in June 2024.[7] These amendments included improving international collaboration and coordination, ensuring equitable access to vaccines, and timely sharing of information and data during health emergencies. CEPI's role in accelerating development of and equitable access to vaccines could contribute to core components of the Pandemic Treaty, which is currently under discussion and which CEPI is contributing to. In a continuation of activities to promote the 100 Days Mission, CEPI co-hosted the Global Pandemic Preparedness Summit in July 2024 in Rio de Janeiro and has built the mission into its five strategic partnerships (discussed below). The mission has also been embraced by the G7 and G20.

CEPI is responding to the lessons learned from Covid-19 for better collaboration and information sharing in several ways. New networks have been established and coordinated, such as the Centralized Laboratory Network and Regulatory Network, and CEPI has been an active participant in pandemic preparedness networks led by others (e.g. i-MCM-Net and xVAX).

[6] https://www.who.int/teams/blueprint

[7] https://www.who.int/news-room/questions-and-answers/item/international-health-regulations-amendments

At a regional level, CEPI is collaborating with regional and national bodies – e.g. HERA, SCARDA and BARDA, which have a national/regional and global remit – on the development of medical countermeasures and in pandemic/epidemic preparedness. CEPI has also increased its engagement with regional bodies such as the Africa Centres for Disease Control and Prevention (Africa CDC) and the Pan American Health Organization (PAHO). It has also responded to the need for decentralised manufacturing capacity by initiating the Regional Manufacturing Network and working with Global South manufacturers to produce vaccines in line with country priorities. This includes, for instance, collaborating with the Indonesian government and manufacturing industry to accelerate the development of mRNA vaccines and to identify regional vaccine needs.

EQ1.1.2: To what extent is the CEPI 2.0 Strategy engaging in appropriate activities to achieve its objectives?

Headline findings	CEPI is pursuing a set of activities that are highly relevant and aligned to the CEPI 2.0 strategic objectives and will justifiably contribute towards their achievement. However, a range of stakeholders referred to the lack of a clear articulation of how CEPI's investments link together for the achievement of higher-level goals. Such an articulation would better enable management to demonstrate how its work to address downstream barriers to equitable access and its work in ecosystem strengthening support the achievement of strategic objectives, which would help to align stakeholders' views on whether activities are appropriate and relevant. A central issue for CEPI relates to the breadth of its work under CEPI 2.0 and, more importantly, to the role it plays as part of an end-to-end approach to vaccine development and ensuring equitable access. There is a widely shared view that CEPI should put in place stronger 'hand-offs' to other organisations as part of an end-to-end approach, but what CEPI should do when other partners are not willing or able to address identified issues is unclear. Also required is a more explicit differentiation of CEPI's role in preparation for and response to outbreak threats of different types, and specifically what CEPI's role should be in a pandemic scenario and how this should inform CEPI's scope of work in the preparation phase.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 5: CEPI is pursuing a set of activities that are highly relevant and aligned to the CEPI 2.0 strategic objectives. As explored through analysis of CEPI's portfolio and as set out in Annex 5.10, CEPI is engaging in a set of activities that fall within the remit of CEPI 2.0 and that will justifiably contribute towards the three strategic objectives as well as some others.

Prepare: Activities align with the strategic objective. Some areas of variance or where there is a lack of clarity include CEPI's work on Covid-19 vaccines, which has been downgraded and refocused on broadly protective betacoronavirus (BPBC) and sarbecovirus, considered by stakeholders and the MTR Team to be technically appropriate. CEPI's work in therapeutics and diagnostics has had a lower focus and has been related to priority pathogens, which was a planned approach under CEPI 2.0. Work explored for Ebola and Zika (detailed below), neither of which is a priority pathogen, was not explicitly detailed in CEPI 2.0 but links to Disease X activities and some earlier work under CEPI 1.0 on Ebola.

Transform: CEPI has advanced activities relevant to all areas of the strategic objective. There has also been early-stage (Phase I) work for Mpox, which was added as a priority pathogen in late 2023 and is linked to Disease X. CEPI has also undertaken work to understand the potential impacts of artificial intelligence (AI) on its investments, such as by modelling zoonotic spillover risks. CEPI has also supported the development of SK bioscience's AI-generated Covid-19 vaccine SKYCovione, which has been listed on WHO's Emergency Use Listing and has received full marketing authorisation by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK. Although this work was not part of the initial vision for CEPI 2.0, given the potential disruption of AI, researching and investing in AI activities is important for futureproofing CEPI's portfolio. In interviews, a few CEPI staff and its R&D&M partners pointed to the need for CEPI to monitor developments in, and risks to, the use of AI, as well as to understand and harness AI to increase the pace of development, among other things, but not to become directly involved in its development. CEPI's work to date aligns with these expectations.

Connect: CEPI is pursuing relevant activities to the strategic objective. Additional activities not included in CEPI 2.0 include drafting the Biosecurity Strategy, which (in draft form) has five streams of work. This appears to be a vital addition, given the lessons learned from Covid-19 and the potential risks to CEPI's investments. Another activity under way is the mapping of downstream enablers and barriers to product access. This appears to be appropriate and is supported by several stakeholders, including staff, funders, governance committee members, and R&D&M partners, who see this as critical and who thought that CEPI's understanding of these factors needs to increase for it to better plan end-to-end product support. A few key informants representing CEPI staff and funders noted that CEPI could also build a better understanding of the impacts of climate change on its work and factor this into planning. Awareness of the intersection of the impacts of climate change on health is growing globally, so this also seems appropriate.

Finding 6: CEPI lacks a clear articulation of how its investments link together at the pathogen/SRA level relative to other actors, and of how the portfolio as a whole leads to the achievement of higher-level goals. In the view of the MTR Team, this likely has its origin in the CEPI 2.0 Strategy itself, which lacks a strong narrative linking the strategic objectives, mission, vision and 100 Days Mission together. Creating a cohesive narrative around the links between different levels of a strategy is a key best practice for high-impact strategic planning (see Annex 5.1). This view of the disconnect in the strategy and other strategic documents was reflected by several funders, staff and regional health organisation stakeholders in relation to the ToC (see below) and was noted as a barrier to CEPI operationalising the strategy. Some key informants noted that such an articulation would better enable management to demonstrate how its work to address downstream barriers to equitable access and in ecosystem strengthening supports the achievement of strategic objectives, which would help to align stakeholders' views on whether activities are appropriate and relevant. Although senior leaders within management are considered by CEPI staff to have a good understanding of how CEPI's activities link to strategic objectives, it is acknowledged that this is not embedded throughout the organisation (despite efforts to improve understanding) or at a governance level, with investors eager for such clarity.

Finding 7: There is some (limited) evidence to suggest that not all CEPI activities are well designed to meet strategic objectives. This MTR is not tasked with assessing the technical validity of activities selected and implemented by CEPI. However, several key informants, including CEPI staff and governance committee members, commented that projects were being implemented without a coherent understanding of how and why they fit into and support CEPI's higher-level

strategic objectives. One key informant noted that there was technological incompatibility between some of CEPI's investments, for instance between some of the areas of investment in vaccine libraries and their ability to be utilised by the technologies that CEPI invests in, and also that these technologies cannot reasonably be expected to be transferred at speed during an outbreak across the manufacturing network to capitalise on the full value of the platform. This stakeholder pointed to a need for CEPI to review its portfolio and move towards greater technological alignment between CEPI's investments. This is to some extent because CEPI investments in platforms, enabling science, manufacturing, and collaborative mechanisms have evolved iteratively; and that these investments drive changes and innovations in R&D and manufacturing processes. Such acknowledgement supports the need for regular reviews and end-to-end planning to capitalise on areas for technological alignment and highlight opportunities or inconsistencies in investment areas such that a 'line of sight' can be ensured between early stage and downstream activities for each programme.

CEPI's newly announced pandemic influenza 'live fire' exercise was also raised as an example of a project that ha**s** not been fully thought through strategically **as** the issues for pandemic influenza from an R&D perspective are already well documented, and there would be more value in focusing on other areas of the portfolio. It was, however, noted that AstraZeneca's involvement in this exercise was a good opportunity to engage and further a relationship with an MNC that is likely to be important to a future pandemic response. We note that conversations on this exercise are ongoing.

Finding 8: A central issue for CEPI relates to the breadth of its work under CEPI 2.0 but more importantly to the role it plays as part of an end-to-end approach to ensuring equitable access. The expansion of CEPI's role and portfolio strongly reinforces the need for strategic decisions on what CEPI does and how it does it. There was a resounding concern in the reviewed documents and among a large number of interviewed stakeholders outside of CEPI management, that CEPI's work was at risk of expanding too far beyond its key area of comparative advantage in making timely and high-risk investments in R&D. The key issue raised by stakeholders related to the greatly increased complexity of dealing with a portfolio of vaccine products advancing to later stages of development while also being called on to engage in downstream issues, which the capacity and skillset of management is not necessarily well matched to, leading to a dilution of focus and attention on R&D. Broadly, key informants fell into three categories:

- Those, mostly external to CEPI and some on CEPI's governance committees, who questioned whether CEPI should be engaging beyond a strict R&D focus on its priority pathogens and technologies, who suggested that CEPI's enabling science,[8] manufacturing, and ecosystem-strengthening activities were beyond the scope of what CEPI should be doing. These stakeholders had a clear view that CEPI's success would ultimately be judged by substantive R&D progress having been made and licensure achieved, without which CEPI would lose legitimacy and investor confidence in the near future.
- Those, from all stakeholder groups, who were not ideologically opposed to CEPI engaging in activities beyond a strict R&D focus but who considered that such activities should be

[8] Enabling science is considered as research and innovation activities that facilitate the development, assessment, and deployment of vaccines and other epidemic response tools. For CEPI, this includes work on platform technologies, biomarkers and correlates of protection, standards and assays, preclinical models, regulatory studies, epidemiologic studies, and manufacturing innovations to improve speed, scale and efficiency. Some aspects of this work fall under other areas of CEPI's portfolio, notably for Disease X.

directly linked to CEPI's R&D investments, for instance to ensure that manufacturing capacity is in place for those specific products and regulatory hurdles can be overcome. This would imply a limited role in broad enabling science and ecosystem-strengthening.

- Those, mostly within the Management Team and closest to the technical issues at hand, who felt that CEPI was engaging in activities only where there was strong justification to do so, even if this justification was based on the absence of others to conduct activities. This included a role for CEPI in ecosystem-strengthening activities, which were often viewed as high-impact and low-cost.

These divergent views existed among a range of external stakeholders, including CEPI staff, industry, CEPI's partners and funders, as well as those within CEPI's Board and governance committees; stakeholders described this divergence as problematic and in need of clarification for the organisation to move forward coherently.

Notable exceptions to the above categories, and where a majority of key informants outside of CEPI management had a clear view that activities were beyond what CEPI should be engaging in, related to supporting manufacturing capacity development to enable rapid scale-up of vaccine supplies in the event of a pandemic, and in working to stimulate country demand for specific products, both of which were viewed as the roles of other actors in the global health architecture (albeit noting the importance of CEPI understanding these issues to inform its role and approach). For the latter, multiple CEPI staff described a lack of guidance and clarity on what CEPI's role should be. However, it is worth noting that some stakeholders from the Global South felt that these roles were very important for CEPI to play, particularly for manufacturing in support of regional objectives, notably in Africa.

We note that the Board's prior guidance to management on CEPI's role has been high-level but clear in terms of not broadening its remit too much, defining where CEPI "leads, leverages and assists", and in ensuring its work is appropriate for CEPI and mission-focused.[9] Putting in place stronger 'hand-offs' to other organisations as part of an end-to-end approach has been much discussed, but there remains the key issue of what CEPI should do when other partners are not willing or able to address identified issues or barriers to equitable access.

Finding 9: Also lacking is an explicit differentiation of CEPI's role in preparation for and in response to outbreak threats of different types. CEPI has recognised the need to play different roles in different ways across the portfolio as part of an end-to-end approach, and its work on partner and pathogen archetypes is a promising start towards such differentiation. However, this framework is still in development and has not yet been formally adopted or used to inform ways of working across the organisation. In the view of the MTR Team, although such a framework can usefully inform decisions in many areas, its greatest value may be to draw attention to one enormously important set of scenarios: those involving a pandemic strongly affecting, or perceived to threaten, HICs. As the emerging archetypes analysis highlights, both the gaps in the ecosystem facing CEPI and the LMICs it seeks to support, and the tools available to CEPI, are very different for such a scenario, as compared to a regional outbreak primarily affecting LMICs. A clear strategy for this set of circumstances and the highly differentiated opportunities and constraints it would present is not yet evident.

[9] Minutes of Board meeting #24.

Beyond CEPI's defined work under CEPI 2.0 to promote equitable access principles as the foundation for a future global response, linked to the presence of a manufacturing network, important questions for CEPI's consideration include:

- In these circumstances, how much should CEPI invest in vaccine development, given that its investments are likely to be dwarfed by those of other funders?
- If, as is likely, the leading vaccines are developed primarily with HIC funding, limiting CEPI's leverage, what can or should CEPI do to promote access in LMICs?
- How can CEPI make use of the network of manufacturers it seeks to build?
- Should CEPI seek a role in tech transfer from product developers?
- To what extent can work on potential pathogens during the preparation phase help CEPI secure access concessions on HIC-funded vaccines during an outbreak?

The questions above are framed by the MTR Team; but several senior global health experts did suggest that CEPI's response to these questions should be guided by its experience and effectiveness of its investments in responding to Covid-19 (see Finding 37 on Covid-19).

EQ1.1.3: To what extent is the CEPI 2.0 Strategy engaging in appropriate partnerships to achieve its objectives?

Headline findings	CEPI has significantly expanded the number and scope of its partnerships in response to the needs and challenges of achieving the CEPI 2.0 strategic objectives. There are some types of partnerships that CEPI needs to strengthen, notably with MNCs, which remains an area of weakness given their capabilities in later stage product development and criticality to PPR and the outstanding questions raised under Finding 9. CEPI is continuing to transition under 2.0 to a proactive, strategic approach for choosing and managing its partners in a differentiated manner according to the nature of the partnership and the mutual objectives sought. This approach is considered by the MTR Team to be potentially valuable in helping to shape the organisation's internal and partner-facing approach to dealing with such a diverse portfolio and in communicating this approach consistently, both internally and to external audiences.
Evidence strength	**2:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings, although the absence of some data points for some partners limited the application of the partnership typology analysis.

Finding 10: Although CEPI 2.0 outlines the types of partners it plans to engage with and the approach and principles to partner engagement, it is a high-level document that does not detail the roles of these partners or the type or extent of engagement that CEPI seeks to strike with them. Such an articulation of partner engagement is considered best practice in strategy design (see Annex 5.1) but is missing from the strategy and is only partially addressed in subsequent programme documents.[10] Although, as noted below, CEPI has increased the number and scope of its partnerships in order to implement the expanded portfolio under CEPI 2.0, this has resulted in

[10] Such as CEPI 2.0 Programme Document, November 2021.

some confusion over where CEPI's role starts and stops vis-à-vis these partnerships. This view was expressed by many key informants, including staff, industry, governance committees, funders and international and regional health organisations. Management is in the process of designing and adopting a more proactive, tailored and strategic approach to engaging with partners to meet specific objectives, which vary by partner type (see Finding 13).

Finding 11: CEPI has significantly expanded the number and scope of its partnerships in response to the needs and challenges of achieving the CEPI 2.0 strategic objectives. As explored in the sections below, CEPI has funded a range of product developers and manufacturers to enable development and production of vaccines and other biologic countermeasures, as well as PDPs such as the International AIDS Vaccine Initiative (IAVI) and FIND. It has also worked to catalyse strengthening global pandemic preparedness through the establishment of networks for sharing of information, strengthening collaboration and leveraging comparative advantage, such as through the Centralized Laboratory Network and the Regional Manufacturing Network. The JCG serves to improve global coordination and inform CEPI's work, and CEPI has also participated in global networks such as i-MCM-Net and xVAX. In addition, CEPI is "well connected" and has advocated to and collaborated closely with key multilateral partners and mechanisms to strengthen the global R&D ecosystem and for epidemic preparedness. This has included work with WHO, Gavi and PAHO and advocacy to country governments through the G7 and G20 and events, including the Global Pandemic Preparedness Summit (July 2024).

In terms of the types of partners CEPI engages with, CEPI 2.0 included an ambition to increase engagement with middle income countries. Although the vast majority of portfolio investment is directed to companies based in the Global North (>80% is with companies based in the US, China, Korea, UK and Germany), a document from the Annual Portfolio Review meeting in 2024 cited a 14% increase in CEPI's partnering with organisations from the Global South since the launch of CEPI 2.0,[11] with a few key informants, mainly among CEPI staff, noting that progress was being made to increase engagement with a more diverse set of partners.

Finding 12: There are some types of partnerships that CEPI needs to strengthen. Partnering with MNCs engaged in vaccine R&D&M has been a long-standing challenge for CEPI. Several partnerships were, however, brokered during the Covid-19 pandemic, including with AstraZeneca, GSK and Johnson & Johnson. Although this has provided an entry point to continue discussion with some MNCs on broader partnership opportunities, several key informants, mainly among staff, CEPI's governance committees and industry, noted that the lack of strong subsequent engagement by MNCs presents a risk to the achievement of CEPI 2.0 strategic objectives. This is mostly because their expertise and capacity will be critical to rapidly developing and manufacturing vaccine products in the event of a future pandemic. However, the interests of these companies (which are highly variable) and the terms on which they may be willing to engage with CEPI will, in general, be quite different from those of the smaller biotechs on which CEPI has primarily relied to date. One key informant noted that the potential for surge capacity agreements with MNCs or sharing the intellectual property from CEPI's vaccine libraries in exchange for vaccine manufacturing capacity might be ways to increase engagement.

The MTR acknowledges, building from comments made by CEPI staff, that such engagement has been challenging in the post-Covid-19 context, in which many MNCs are 'suffering from a Covid-

[11] Day 1 Plenary Final – APR 2024.

19 hangover', reducing manufacturing capacity and evaluating future strategy for PPR. CEPI's shift away from narrow calls for proposals (CfPs) to broad agreements and strategic partnership agreements, including the deal with BioNTech, is promising, and it is understood that discussions with several MNCs are ongoing, with announcements forthcoming.

Finding 13: CEPI is continuing to transition under 2.0 to a proactive, strategic approach for choosing its partners. CEPI 2.0 noted that CEPI 1.0 lacked a "strategic 'one CEPI' approach" to partnerships with "limited categorisation/segmentation and prioritisation". Particularly for R&D partners, some CEPI staff reflected that CEPI had previously selected R&D partners based on technical competence in relation to the project objectives but not necessarily based on alignment of values, which had created issues later on, notably in relation to the desire to move past Phase II development to licensure and to ensure equitable access. It was felt by some stakeholders interviewed that some of these issues could have been averted had R&D partners been chosen more strategically.

CEPI 2.0 outlined a change in approach to partnerships to one of "strategic collaboration with specific partners" and "strengthening of internal structures to manage these partnerships". CEPI's establishment of strategic partnerships is a significant move in this direction. A few of CEPI's R&D grantees pointed to strengthened trust, efficiency and ability to forward plan and communicate between CEPI and some of these strategic partners, with whom CEPI intends to build long-term relationships around common goals.

Several staff, governance committee and R&D grantee key informants noted that CEPI is continuing to plan for a proactive and strategic approach to partnerships, with the development of a plan of action, recruitment of additional positions and strengthening of skills to improve CEPI's partnership management (which CEPI staff and partners interviewed suggested was needed).[12] As alluded to above, at the centre of this work is a framework of partner archetypes that represents the different sorts of partners CEPI needs to engage with to achieve its objectives as part of an end-to-end approach and for the different types of pathogens (and their associated global pandemic vs regional outbreak risks) that CEPI invests in. This approach is considered by the MTR Team to be potentially valuable in helping to shape the organisation's internal and partner-facing approach to dealing with such a diverse portfolio and in communicating this approach consistently, both internally and to external audiences.

[12] One example of poor relationship management raised during interviews related to CEPI's decision for Covid-19 R&D investments to switch from emergency use licensure as the goal to full licensure, which was described as a significant shift that created substantial delays but that was not communicated to the grantee directly.

EQ1.2: To what extent does the evidence support CEPI's 2.0 Theory of Change (ToC)?

EQ1.2.1: To what extent [does the ToC] identify appropriate indicators, outcomes and assumptions?

EQ1.2.2: To what extent [does the ToC] provide a pathway for CEPI to achieve its mission?

Headline findings	The CEPI 2.0 ToC is structured by strategic objective and does not reflect how CEPI works, what it does, or what it seeks to achieve for each pathogen and SRA. The revised MTR ToC better reflects the breadth of CEPI's activity, the causal pathways for each strategic objective and the assumptions that underpin them, although it still does not accurately represent how CEPI works to achieve its mission (which would require articulation of CEPI's highly differentiated ways of working across the portfolio and by pathogen and SRA, depending on partner capacities and willingness/ability to engage to address downstream barriers to equitable access). The CEPI 2.0 KPIs are also structured around the CEPI 2.0 strategic objectives and are not focused on what stakeholders consider to be important.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 14: The CEPI 2.0 ToC mirrors the CEPI 2.0 Strategy structure, and as such does not reflect how CEPI works, what it does, or what it seeks to achieve for each pathogen and SRA. The original CEPI 2.0 ToC was reviewed during the inception phase for the MTR, organised around KIIs and a facilitated participatory workshop. The review solicited a great deal of stakeholder feedback on the ToC, which highlighted some substantial shifts in thinking and approach since CEPI 2.0 was conceived, notably in relation to: the level of emphasis placed on Covid-19, which has reduced over time; how CEPI's different investments build on each other; how the three Strategic Pillars – Prepare, Transform and Connect – relate to and interlink with each other; and how CEPI orients itself to influence the dynamic ecosystem within which it operates (i.e. with shifting institutional priorities, geopolitical trends, and evolving technologies). As such, the CEPI 2.0 ToC was not felt to adequately represent how the organisation works to achieve results or provide a strong framework to measure progress against. This resulted in the MTR Team developing an updated ToC against which to conduct the MTR. This was circulated within the MTR Inception Report and is provided for reference in Annex 3.

Finding 15: Certain parts of the CEPI 2.0 ToC reflect good practice, but other areas fall short. The MTR Team conducted a ToC analysis by benchmarking CEPI's 2.0 ToC in the Results Framework 2021 against a good practice framework (see Annex 5.5). In summary:

- **Activities and outputs –** although descriptions of activities are included in the ToC, they are very broad and are not linked to specific outputs. There is no description of the resourcing that will support the activities and their outputs.
- **Outcomes –** the ToC includes high-level outcomes that are anticipated by 2026. These are generally measurable, using the KPIs listed in the Results Framework 2021. However, the ToC lacks intermediate outcomes, which are important for measuring interim progress during the five-year strategy. It is noted that CEPI does include interim milestones in its annual planning, although the MTR found some of these to be ambitious. Although the outcomes do identify what will influence the intended change, this is framed at a high level and is thus not specific enough. According to evaluation best practice, outcomes

need to be realistic, measurable and largely within the control of the entity implementing activities to meet them. More detail is provided on KPIs in the Results Framework.

- **Impact –** the ToC includes anticipated impacts of CEPI's work in the form of Sustainable Development Goals. The MTR questions whether use of the SDGs is appropriate as they are extremely high level and thus it could be challenging to show CEPI's contribution. The impacts in the ToC could be re-framed to be slightly more specific (and thus more measurable) in terms of CEPI's longer-term contribution to areas of the wider R&D&M ecosystem. These contributions are likely to be realised beyond the timeframe of the 2.0 Strategy.
- **Indicators –** the progress of most activities is monitored using the KPIs in the Results Framework. As noted below, many key informants, mainly CEPI staff or governance committee members, felt that the KPIs do not accurately reflect CEPI's portfolio of work or many of its supporting activities, e.g. building networks and partnerships.
- **Mission –** the mission in the ToC is generally appropriate and can be expected to come about as a result of the intended outcomes and, in turn, outputs, activities and inputs. However, the part of the mission about working so that vaccines and other biological countermeasures can be "accessible to all people in need" is aspirational, and (as set out below) at this midpoint of strategy implementation the extent to which CEPI will be able to contribute to this through its work on equitable access is unclear.
- **Causal pathways –** although there are generally logical causal pathways between each level of the ToC, the outcomes and the strategic objectives are set at a high level and thus require many other contributing factors outside the scope of CEPI's work to be achieved. In addition, the causal pathways are where the assumptions for the ToC lie, and these were not articulated in the Results Framework. The inclusion of intermediate outcomes would have helped to more clearly identify these causal pathways and ensure the validity of the assumptions underpinning them.
- **Assumptions –** The MTR ToC articulates a set of assumptions and found that some, but not all, have held (see Annex 5.5). Those that have not held relate to aspects of the CEPI 2.0 design that have generally not proven to be realistic nor feasible. These are, in turn, illustrated in the barriers to achieving the strategic objectives identified in Finding 47. These assumptions relate to the design of the portfolio, the ability of CEPI to deliver the CEPI 2.0 strategy, as well as the context in which CEPI works.

This ToC analysis affirms the MTR finding that although the original CEPI 2.0 ToC has elements that reflect good practice, its content and structure do not accurately reflect CEPI's current work or the assumptions that underpin it. As such, it does not paint an accurate picture of how CEPI is working to achieve its mission, nor is it a good guide for informing the monitoring and reporting of CEPI 2.0's outputs, outcomes and strategic objectives in its current form.

Finding 16: The revised MTR ToC better reflects the breadth of CEPI's activity, causal pathways for each strategic objective and the assumptions that underpin them, although it is still not felt to be a good representation of how CEPI works to achieve its mission. The collection of evidence against the ToC and testing of assumptions, including through process tracing (see Sections 5.5 and 5.7 of Annex 5), revealed that several of CEPI's 'process-related' levers are pivotal to the achievement of the ToC outcomes. These included levers related to good governance and management, effective communication and advocacy, high-level political support, equitable access principles and strategic partnerships. These need to be included in a ToC, because

monitoring their performance and adjusting these processes in response will be critical to achieving the strategic objectives. Analysis using process tracing, used to derive findings below against EQs, also generated evidence on the critical influence of the wider R&D&M context on CEPI's results, the assumptions underpinning the early implementation of activities, and the requirement for increased cross-functional collaboration among teams within CEPI.

Corroboration of the process tracing, interviews and document review led to the recognition that further updates are required in a range of areas, to reflect the nuanced ways in which CEPI works and interacts within the broader global R&D ecosystem to achieve its mission:

- The linkage between CEPI 2.0 and the 100 Days Mission should be clarified.
- The three CEPI 2.0 pillars articulate a false division of work, which in practice is driven by pathogen, for Disease X and for some other SRAs. However, much of CEPI's work is cross-cutting and cross-functional, and the ToC does not capture this.
- CEPI works in highly differentiated and nuanced ways across the portfolio and by pathogen and SRA, depending on partner capacities and willingness/ability to engage to address downstream barriers to equitable access. The ToC could be framed within a systems-based approach to demonstrate this.
- Enabling activities, including CEPI's governance and operational functions, to establish and manage partnerships should be reflected, potentially as levers.
- A clear narrative should accompany the ToC, articulating the causal pathways between all levels, how the levels collectively contribute towards the vision and mission, and the assumptions that underpin it, including in the early implementation of activities.
- External influences present in the dynamic global R&D&M ecosystem that impact on the achievement of CEPI's strategic objectives should be depicted in a version of the ToC.

We recognise that this revised conceptualisation of CEPI's ToC would represent a substantial departure from the original CEPI 2.0 ToC. It would likely involve an updated articulation of the outcomes that CEPI is working towards under the CEPI 2.0 Strategy, the assumptions that underpin the causal pathways, and the set of indicators used to measure progress towards intended results. However, the MTR Team believe that this revised approach would provide a more accurate representation of the complexity, dynamism and interlinked nature of CEPI's work, and that it could be used as the basis for CEPI to present a more nuanced, holistic and accurate picture of its work and results.

Finding 17: The CEPI 2.0 KPIs are not considered to (a) focus on what stakeholders consider to be CEPI's key results, (b) align around a technically feasible set of targets, or (c) provide a representative overview of programmatic progress being made towards the strategic objectives. This is partly because they are framed around the three CEPI 2.0 pillars rather than being structured around the objectives and roadmap for each pathogen, Disease X, and some other SRAs. This finding is based on the MTR's analysis of progress against the KPIs and its portfolio of work as well as on feedback from many stakeholders, primarily staff and those on governance committees. As one stakeholder described it, "The KPIs feel tangential to the daily work of the organisation."

In analysing data on the progress of CEPI against the indicators, the MTR Team noted that the following areas of improvement are necessary for the indicators to be able to accurately monitor progress across CEPI's scope of work. The indicators need to reflect and/or indicate:

- what is important to stakeholders in terms of what results they expect from CEPI
- what is feasible to deliver and the role that CEPI is expected to play, which varies dramatically by pathogen and SRA
- processes and intermediate level outcomes which can demonstrate linkage between activities and outputs and high-level outcomes
- how parts of the portfolio fit together for the achievement of strategic objectives
- which ones are largely within CEPI's control and which reflect where CEPI makes a contribution but where others are primarily responsible.

A critical function of updating the KPIs so that they accurately reflect CEPI's portfolio would be the ability to monitor and report on the progress of the portfolio at set points throughout the year. Although this is understood to be a function of the IMS, some stakeholders stated that this is not updated frequently and there is no visibility of such progress, which was problematic for decision making and risk management.

EQ2: To what extent are CEPI's management and governance systems fit for purpose vis-à-vis implementation of the programme of work?

Headline findings	The CEPI Board and overall governance function is considered to work reasonably well. Efforts to clarify the roles of each committee and ensure appropriate membership to fulfil these roles will address some of the issues identified. The interaction between management and the Board and governance committees could be strengthened to aid efficiency and engagement in strategic decision making. CEPI's decision-making processes are not always well understood by R&D partners, which can cause delays and frustration. Substantial challenges within the Management Team have impacted on CEPI's ability to deliver against the CEPI 2.0 Strategy. These stem from the Covid-19 pandemic and the CEPI 2.0 Strategy itself, each of which has required substantial organisational strengthening for CEPI to respond effectively, a process which is still ongoing for CEPI 2.0.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

The findings for EQ2 are based on the document review, including results from the Board Effectiveness Review 2023 and the Portfolio Strategy and Management Board (PSMB) Effectiveness Review and Terms of Reference (ToR) Analysis 2023, interviews and analysis using the Management and Governance Capabilities, Culture and Practice (MGCCP) Framework (see Annex 5.6).

Finding 18: The CEPI Board and CEPI's overall governance function are generally considered to work reasonably well. Very early in the Covid-19 pandemic, CEPI's governance function enabled a fundamental strategic pivot to focus efforts on supporting the response while retaining CEPI's core principles. Key informants reflected that this was a major strength that other organisations operating in global health could not manage in such a nimble and holistic manner. This was made possible by a very engaged and agile Board and Management Team at a time of real need.

The evidence generated through the document review, interviews with governance committee members and the MGCCP Framework analysis suggests that the Board is generally functioning well. It is engaging in critical analysis of issues brought to its attention and has a robust decision-making process which approves or rejects matters brought to its attention as appropriate for CEPI's portfolio and to uphold its mission.

Finding 19: A range of activities has sought to clarify the roles of each governance committee and ensure appropriate membership to fulfil these roles. Several issues still remain. Over the past 18 months, the roles of CEPI's governance committees have been articulated, ToR written, and decision-making mandates clearly articulated in terms of which committee should make a decision for a specified quantum of investment. In particular, efforts have been made to differentiate between the work of the PSMB and that of the Vaccine Research and Development and Manufacturing Committee (VRDMC).[13] Meanwhile, the Audit and Risk Committee is reported to be working with finance staff to manage the underspend and strengthen financial reporting. The Scientific Advisory Committee (SAC) is, reportedly, providing valuable input and effectively drawing upon external input to cover a wide range of topics, and the Investors' Council (IC) is generally functioning well.

However, challenges in the functioning of several of the committees remain. Notably, evidence suggests that the PSMB lacks the expertise to provide guidance on CEPI's investment portfolio strategy, which is its core responsibility, focusing instead on the technical aspects of proposals.[14] It is also unclear whether the PSMB's review of proposals is considered in final decisions. In addition, consideration of biosecurity and biorisk needs to be built systematically into capability and processes for the decision making of relevant committees; this is not the case at present, which poses a risk for CEPI. Plans are under way to incorporate this as part of the new Biosecurity Strategy, which is currently in draft form. It is also understood from the Board Effectiveness Review 2023 that the work of the Equitable Access Committee has been ad hoc and that systems and principles are yet to be developed and embedded in CEPI. IC members noted in the KIIs that they would like more information about CEPI's plans. A stakeholder noted that the role, reporting structure and decision-making authority of the External Relations Committee is not clearly defined. Both the key informants and the document review pointed to the need for more concise, timely and appropriate documentation for several of these committees (see Finding 20). One CEPI staff member noted that there does not yet exist, and that there is a need for, a decision-making structure in CEPI for decisions that are not R&D-related and that cut across multiple divisions.

In recent years CEPI has promoted greater diversity and balanced representation on its Board and committees. Evidence from the MGCCP Framework analysis and document review suggests that there is now good representation on the Board, including from the Global South, but that representation on some of the committees still needs to improve, for example the PSMB still needs strategic oversight expertise.[15]

Finding 20: The interaction between management and the Board and governance committees could be strengthened to aid efficiency. It was noted by some governance committee and staff

[13] 2023 Board Effectiveness Review CEPI Report & Recommendation.

[14] Ibid.

[15] Ibid.

key informants that Board meetings often include scientific/operational discussions or decisions which should be the remit of another governance committee or management. According to both the document review and some key informants, this might be a legacy of being a smaller organisation not so long ago and of the need for rapid discussion and response processes during Covid-19. However, this type of discussion should be the remit of the SAC and management, and when issues are unnecessarily escalated to the Board it results in delays to decision making.

The above stakeholders, the MGCCP Framework analysis and the documents reviewed raised issues related to the way in which information is communicated by management to the Board. Some investors, Board and governance committee members noted that meeting papers were often very long, were not provided sufficiently in advance of meetings and did not have a clear delineation of whether members were being provided with information as part of an update or were being asked for a decision.

While improvements have been made over time, notably since the 2023 Board Effectiveness Review, an observation made by the MTR Team and by a number of stakeholders was that much of the documentation produced by management for its various governance committees focuses on providing general progress updates, a summary of the issues, and plans for the future. However, the documentation lacks substantive but concise critical analysis of why the issues have arisen and the context in which they have arisen, what CEPI has done well and less well, what CEPI can and cannot do differently, what the trade-offs would be if CEPI were to engage differently, and the questions that need to be answered or decisions made, i.e. to engage in meaningful strategic discussion and decision making.

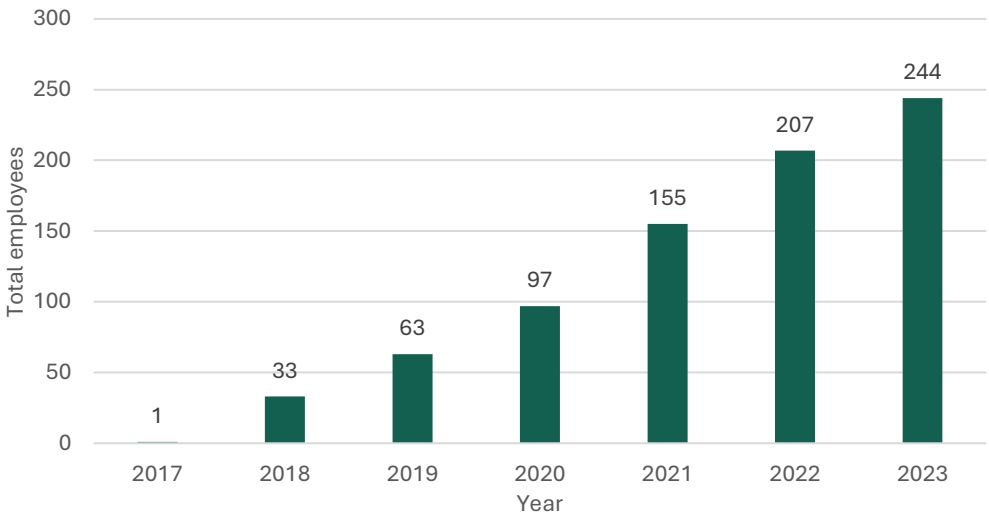
A few governance committee members raised an issue with how management collates information and reports to the Board and governance committees, which links to the above but also to the length of documentation provided. One senior CEPI staff member noted that the Strategy Team can, in some instances, take responsibility for writing Board papers without seeking the input of technical specialists, which had resulted in some discomfort at what had been presented and an overall feeling of disconnect between the Board and the technical teams responsible for conducting CEPI's day-to-day work. The practical unfeasibility of delivering the CEPI 2.0 strategic objectives and the 100 Days Mission was described as a case in point, as were the setting of stakeholder expectations around the licensure of a Lassa fever vaccine and other programmatic achievements within the CEPI 2.0 period. These issues are likely not mutually exclusive but interrelated.

Finding 21: CEPI's decision-making processes are not always well understood by R&D partners, which can cause delays and frustration. Many key informants, including multiple R&D partners, referred to excessive internal bureaucracy as causing delays, notably in relation to project selection and approval (particularly where CEPI has overly ambitious expectations of what can be achieved), contracting, making financial disbursements, and reporting requirements. CEPI has acknowledged and worked to resolve at least some of these issues, notably in relation to contracting. Nonetheless, as one key informant noted, *"They don't make their funding processes and their decision-making processes clear, either on their website, which is what other funders do, or under contracts. Approval processes quite often change and [we] will only be notified after it's happened. [Change requests] are sent to a committee, but [we] don't know when the meetings are – they don't make them public. If they approve, in many cases it then needs to go to a Board meeting for further approval. [We] don't know who's on these committees, and their recommendations to link up with [CEPI-funded] core labs or approved manufacturers have not been appropriate taking many weeks to resolve."*

Finding 22: Substantial challenges related to the Management Team's capabilities, culture and practices have impacted on CEPI's ability to deliver against the CEPI 2.0 Strategy. Evidence has been collected and analysed through a capability, culture and practices framework, which is set out in Annex 5.6 and used as the basis for presenting evidence to substantiate this finding.

Management was described by a number of stakeholders as working efficiently and effectively during the Covid-19 pandemic, which provided the 'North Star' for all to work on the response and the urgency with which it was undertaken. During this time, governance committee interviewees described management as being afforded substantial autonomy by the Board, which enabled it to operate in an agile manner, with staff wholly committed to a common goal. Emerging from the acute phase of the pandemic, a range of interviewees described staff as being understandably fatigued yet required to start delivering against a much broader and more ambitious 2.0 Strategy. As described above, the CEPI 2.0 Strategy documentation did not make clear how to operationalise it, nor did it include rigorously evaluated (and as such, feasible) pathogen-specific goals. During this time, the Board required a degree of realignment in terms of its role in oversight and decision making, from an emergency response to a routine footing. This meant that the style of management needed to change, with an increased role in complex, operational decision making under the expanded portfolio of CEPI 2.0. Further, CEPI's systems, processes and ways of working were widely considered by many key informants from all stakeholder groups to be inadequate for operating at the scale and breadth that CEPI 2.0 required, especially considering that the number of staff within the organisation had grown dramatically in a short space of time (see Figure 2) and that the organisation was operating over a number of different office locations and with some cultural challenges associated with home working. These factors created a highly pressured internal environment.

Figure 2. CEPI Management Team headcount over time



The process of how senior leadership provided guidance to the various teams within CEPI on operationalising CEPI 2.0 is unclear, although multiple staff described this as inadequate, contributing to a lack of cohesion across different teams.[16] Project-level staff were described by

[16] Specifically, key informants referred to a situation in which technical specialists were tasked with developing a set of activities to achieve the strategic objectives, which resulted in a long list of projects, ideas and concepts. However, the process of consolidating this into a coherent programme document was very challenging, with different ideas on what should and should not be prioritised, and with the lack of a central decision maker within management to guide prioritisation.

several senior CEPI staff as being focused on delivering project-level results but without necessarily understanding how and why the project was important for CEPI's higher-level objectives. As such, they were not necessarily working towards the most appropriate project results. Efforts have been made to address this issue, including through an internal roadshow and better communication to staff on CEPI's priorities through quarterly reviews, as well as a CEO presentation on the 100 Days Mission and the role of staff, which was in response to the 2023 Staff Survey.

Other stakeholders described a culture within the Management Team that is not conducive to delivering results – something that best practice in strategy development suggests is critical to successful delivery (see Annex 5.1). A few internal stakeholders noted that the Extended Leadership Team has not operated in a particularly cohesive manner to take decisions for CEPI to achieve "exponential impact potential". This lack of cohesion was linked to a perception by several CEPI staff and governance committee members that staff can be overly risk-averse in their decision making or prefer to gain consensus on an issue rather than take a decision directly. According to multiple staff informants, this was linked to a fear of failure, with one key informant suggesting that it was driven by a lack of incentives and accountability to achieve results. Linked to Finding 21, some CEPI staff noted a lack of clarity over internal decision-making processes, which affected the degree to which staff took decisions directly and the efficiency with which work was managed. Other CEPI staff referred to a lack of cross-team collaboration as a problem of CEPI's matrix management system, and others reflected that it was driven by challenging dynamics, a lack of trust and communications within CEPI's senior leadership, and the lack of a senior figure within the organisation to bring people together. As one key informant noted, *"I feel the matrix concept doesn't extend beyond the programme teams to the divisional or departmental leadership level. There's still a lot of siloing happening."* These findings were corroborated by the 2023 Staff Survey, which found that only 63% of staff agreed that CEPI's organisational values matched how they actually worked. Other results of such internal well-being surveys and the recent departure of several senior leaders suggest that the issues within the organisation have been substantial.

The hiring of new Deputy CEO and permanent Executive Directors, along with restructured lines of accountability between Executive Directors to the Deputy CEO and CEO, was identified in the MGCCP Framework analysis and in some governance committee KIIs as an opportunity to reset, although it will be critical to do so in a manner that encourages cross-team coordination and collaboration.

Along with strengthened financial and risk management approaches, and process adjustments arising from the Agility project, staff in general reflected that the organisation was on the right track towards strengthening internal operations. However, there remains a tension between (i) the desire for a flexible, vision-driven organisation that can maintain agility and responsiveness to issues as they emerge and (ii) the need to systematise processes and ways of working to focus attention on delivery and strengthen accountability for results. In the view of the MTR Team, striking the right balance will be challenging and will likely require adaptation over time.

Finding 23: Succession planning for the Chair of the Board (and CEO) is under way. The current Chair of the Board, Professor Jane Halton, and the CEO, Richard Hatchett, are very highly regarded by almost all external and internal stakeholders. They have been key to CEPI's creation, thought leadership and role during the Covid-19 pandemic, and also to the design of CEPI 2.0 as a bold new vision for the organisation as it moves forward. Both their terms are due to end within the CEPI 2.0 period, and this transition in the most senior levels of leadership

represents a period of significant reputational risk for CEPI as well as for its networks and engagement within the global R&D ecosystem. The MTR understands that succession planning is under way.

3.2. Workstream B: Implementation

3.2.1. Introduction

This workstream is focused on three DAC evaluation criteria: coherence, efficiency and effectiveness. Findings under EQ4 on efficiency focus on the portfolio as a whole. Findings under EQ5 on effectiveness include an assessment of efficiency and effectiveness for Covid-19 by priority pathogen and for Disease X/100 Days Mission, integrating CEPI's work across the portfolio, e.g. on enabling sciences, epidemiology, regulatory affairs and manufacturing. This helps readability and provides a reasonably comprehensive high-level view of CEPI's activities and the way they fit together.[17] Findings under EQ4 and EQ5 are based principally on an assessment of whether intended plans and results have been achieved, as per the ToC and via the process tracing exercise set out in Sections 5.5 and 5.7 of Annex 5.

3.2.2. Findings

EQ3: Is CEPI's work coherent with, and does it add value to the work of, other institutions/organisations working on vaccine-preventable diseases?

EQ3.1: To what extent is CEPI 2.0's work synergistic with other institutions/organisations working on vaccine-preventable diseases?

EQ3.2: To what extent is CEPI's 2.0 work adding value to and avoiding duplication of efforts with partners?

Headline findings	CEPI was created to fill an evident gap in the vaccine ecosystem for R&D and to ensure equitable access for vaccines in response to EIDs that affect populations in LMICs; this remains an area in which CEPI's role is unique and adds considerable value. Several other agencies of HIC governments invest in common areas with CEPI, such as for platform technologies and infectious disease threats that are more likely to affect all regions and countries. While CEPI retains a unique single focus on LMICs and equitable access, it is not always clear if or how CEPI's work in these areas is synergistic or duplicative of the work of others, although it has sought to engage with these entities to promote alignment. CEPI has sought to align with global health partners in addressing downstream barriers to equitable access, advanced the scope of its collaboration with regional initiatives in the Global South, and initiated work to build partnerships with manufacturers in support of specific R&D projects to advance specified innovations and through a manufacturing network.
Evidence strength	**2:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings, although the absence of some data points for some partners limited the application of the partnership typology analysis.

[17] We note, however, that the analysis may not cover the full breadth of CEPI's work, which, as communicated elsewhere in this report, is challenging to capture as part of a coherent narrative.

Finding 24: CEPI was created to fill an evident gap in the vaccine ecosystem for R&D and to ensure equitable access for vaccines to protect affected populations in LMICs against EIDs that have potential to develop into worldwide epidemics. CEPI was launched in 2017 against a backdrop of recent outbreaks of EIDs, in particular the West African Ebola epidemic. This outbreak showed that the vaccine development ecosystem was not responding to emerging threats and that there was an absence of international partners working to support vaccine development through to proof of concept (end of Phase II clinical trials).

Finding 25: The Covid-19 pandemic further validated the need for investment in vaccine R&D as well as in manufacturing and other downstream issues to ensure equitable access. CEPI took on a broader role in the Covid-19 pandemic, funding both vaccine development and manufacturing to support equitable access to Covid-19 vaccines, as well as co-leading COVAX. Although many agencies funded vaccine R&D&M for Covid-19 vaccines – some attached to HIC governments and with far larger resources at their disposal than CEPI – there remained a clear need for investment in R&D&M to expand global supply of vaccines at the very outset of the pandemic and for products suitable for application in the Global South to ensure equitable access for doses produced. CEPI was at the forefront of the global effort to ensure equitable access through its investments in both R&D&M for Covid-19 vaccines and its contribution to COVAX.[18]

Finding 26: Several new agencies have been established to fund medical countermeasures since the start of the Covid-19 pandemic, many with similar and overlapping objectives and activities, making the ecosystem in which CEPI operates more complex. Stakeholder and landscape mapping confirms that CEPI remains unique in its focus on ensuring equitable access to vaccines for EIDs that primarily affect LMICs. This is less clear for CEPI's work to ensure preparedness for infectious diseases that are more likely to affect all regions and countries, where other R&D funders, including agencies of HIC governments, are active. For the latter, while CEPI retains an LMIC focus in all of its work, the extent to which CEPI's work is synergistic or duplicative of the agencies of HIC governments is not always clear.

As called for through the Connect pillar of CEPI 2.0, CEPI is working to establish relationships with the agencies of HIC governments active in this space and striking collaborations where there are opportunities. For instance, CEPI organises global funders' meetings to share updates and strengthen alignment, which participants interviewed valued highly. CEPI has also struck agreements with HERA to cooperate in the development of medical countermeasures, SCARDA to strengthen global PPR, and the Global Health Investment Corporation (GHIC).[19] Some interviewees referred to the utility of the Medical Counter Measures (MCM) R&D Funders' Roundtable events that CEPI has co-chaired with or been hosted by HERA, the South Africa Medical Research Council and SCARDA in strengthening communication and commitment to collaboration for alignment of efforts.

The MTR also understands that discussions with the US National Institutes of Health (NIH) have advanced around the inclusion of equitable access provisions in out licensing agreements for intellectual property (IP), which could form the basis of a future area for collaboration with CEPI. Because the publicly available declarations reviewed by the MTR Team are very high-level,

[18] https://www.europarl.europa.eu/RegData/etudes/STUD/2023/740072/IPOL_STU(2023)740072_EN.pdf.

[19] https://cepi.net/scarda-and-cepi-collaborate-strengthen-global-pandemic-preparedness-and-response; https://health.ec.europa.eu/latest-updates/health-hera-and-cepi-agree-stronger-cooperation-development-medical-countermeasures-2022-10-24_en; https://cepi.net/cepi-and-ghic-collaborate-advance-vaccine-rd-emerging-infectious-diseases.

it is unclear whether the agreements specify any differentiation of roles based on the respective comparative advantages of each agency, either in the current pandemic preparation phase or in a response to a new pandemic. While this may be challenging due to evolving partner priorities, as CEPI's partnership archetypes work seeks to elucidate, such differentiation would be important to maximise synergies and reduce duplication of efforts, as well as to seek ways to avoid destructive competition for doses in a global pandemic, from which LMICs would likely again emerge the losers. Key informants also noted that this is a very crowded space and it is very challenging to keep abreast of all the different funders' priorities and investments in different products at a global scale in order to reduce duplication.

Finding 27: Despite evidence of CEPI being viewed as a new competitor for scarce resources by some global health initiatives, CEPI has worked to align with global health partners to address downstream barriers to equitable access. The document review and multiple internal key informants from a range of stakeholder groups outlined CEPI's substantial efforts to collaborate and align its activities with key partners. This has included participation through the WHO-led i-MCM-Net, the xVAX initiative, the CEPI JCG and other global forums, as well as work to map out priority actions and activities and establish Memoranda of Understanding (MOUs) with a range of agencies, including Africa CDC, Gavi, UNICEF and PAHO. Although the MOUs established are clearly a sign of progress in working to ensure synergy between these agencies, they are high-level and, like the agreements struck with other funders of biologic countermeasures, they do not appear to specify concrete commitments. There are, however, opportunities to advance these agreements. For example, in a situation wherein CEPI, Gavi and/or UNICEF could align decision-making processes and jointly agree to support a vaccine product, this could save multiple review processes. It could also provide an opportunity to align and significantly strengthen the incentives posed to vaccine manufacturers through coordinated push and pull mechanisms, leveraging CEPI's willingness to take significant R&D risk with Gavi's significant buying power and/or its investment in the African Vaccine Manufacturing Accelerator (AVMA). Aligning the prioritisation and decision-making processes of CEPI and WHO, for instance around pre-qualification, was also noted by key informants as something that could yield substantial benefit. It is noted, however, that in all these examples raised by key informants, a substantial shift in approach would be required by CEPI's partners – something that is outside of CEPI's control.

Some key informants described CEPI as walking a tightrope between not upsetting partners too much and trying to be transformative, particularly with WHO, where there has, reportedly, been some resistance to engaging with CEPI and yet where collaboration could have substantial benefit. These issues appear to be exacerbated by CEPI's engagement in downstream issues related to regulatory affairs and establishing procurement options to ensure equitable access – issues where other agencies are also active – rather than CEPI's work to support R&D.

Finding 28: CEPI has advanced the scope of its collaboration with regional initiatives in the Global South. A significant number of key informants stressed the importance of engaging at the regional level with Africa CDC, PAHO and others, who are poised to play a significant role in future PPR efforts. Internal and external interviewees were keen to reflect that CEPI's role should not be to lead regional efforts in this regard but to support, enable and contribute to locally driven efforts for regional preparedness. Africa CDC was noted by multiple key informants as a particularly positive example of where CEPI support had helped to strengthen the organisation and catalyse the interest and support of other funders in Africa CDC for a common objective to establish a regional PPR and vaccine manufacturing hub in Rwanda, although another key informant commented that this relationship and CEPI's support for a

regional approach could be further strengthened through shared strategy and decision making as well as CEPI having a regional presence; this is some distance away.

Finding 29: CEPI has also initiated work to build partnerships with manufacturers, in support of specific R&D projects, to advance specified innovations and through a manufacturing network. The details of these partnerships are explored below, but key informants were keen to understand from CEPI how it seeks to position itself, importantly through its role to host and fund the Regionalized Vaccine Manufacturing Collaborative (RVMC) vis-à-vis the various manufacturer associations that already exist – e.g. the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the Developing Countries Vaccine Manufacturers Network (DCVMN) and the African Vaccine Manufacturing Initiative (AVMI),. Overall, it was felt that CEPI could work more meaningfully to leverage these associations and networks to support the achievement of CEPI objectives.

EQ4: To what extent has 2.0 implementation proceeded as intended?	
Headline findings	As above, CEPI 2.0 represents a significant shift in CEPI's role and portfolio. Given this, planning for strategy operationalisation (execution) was insufficient but also challenged by CEPI's active role in responding to the Covid-19 pandemic and the timing and limited success of fundraising activities in 2022. This required remedial prioritisation action in the first year of CEPI 2.0. Despite, and often in response to, the uncertainty and delays caused by the greatly expanded scope of activities in CEPI 2.0, the Management Team has advanced a significant body of work since 2022 related to its governance function, at the policy level, in strengthening management operations, and for new programmatic activities. Nonetheless, there has been a substantial underspend against the CEPI 2.0 budget to date. This is in part due to over optimistic spending projections and identified as a significant strategic issue in early 2023, with a range of efforts subsequently implemented to strengthen operational systems and drive implementation. Although this has led to some advances, implementation remains well behind what was initially planned and, without immediate reprioritisation to increase the breadth of activity (to be further discussed and agreed at the August 2024 Board meeting), would result in a substantial financial surplus by 2026.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 30: Preparations were made for CEPI 2.0 in 2021, with an emphasis on strategy development and fundraising. Alongside the pressing programme of work around Covid-19 and CEPI's contribution to COVAX, there was substantial focus in 2021 around designing and launching CEPI 2.0 and securing the requested $3.5 billion to implement it. Efforts were also made to prepare for CEPI 2.0, including implementation plans, budgets, an assessment of CEPI's operating model (structure, resourcing, governance, systems/processes and ways of working) and plans to strengthen it to meet 2.0 needs. A Chief Operating Officer was also hired and the Partnerships, Policy and Access team formed to lead the work on these areas. Despite this, some key informants suggested that this preparatory work was conducted at a high level, partly due to the uncertain nature of fundraising, being focused on Covid-19, and challenges in bringing different teams together to consolidate thinking into a coherent programme document.

Finding 31: The timing and success of fundraising activities in 2022 required substantial remedial prioritisation action, which took time and effort away from delivery in the first year of the CEPI 2.0 implementation period. CEPI 2.0 launched on 1 January 2022, in the midst of the Covid-19 pandemic and just prior to the war in Ukraine unfolding from February 2022. CEPI's budget for 2022 was presented to the Board in December 2021, with approval granted for the first six months of the year. Following the Global Pandemic Preparedness Summit, held in March 2022, where $1.5 billion of an overall ask of $3.5 billion was raised for CEPI 2.0, a revised budget was presented to and approved by the Board in April 2022 for the remainder of 2022. This left the need for extensive further fundraising – including from key donors that were unable to pledge at that time, such as the US – and flexible CEPI 2.0 implementation arrangements to manage an unpredictable funding situation.

At the April 2022 Board meeting in Bergen, the Board expressed concern at the Management Team's proposal to proceed with its planned activities for 2022 (justified, in part, based on the accepted need to overprogramme) and advised on the need to prioritise, given its fundraising status, and to be explicit in how this process has been carried out, to ensure that both Board and management had a shared level of comfort. According to CEPI staff, validated by a review of the related documentation, the resulting prioritisation exercise undertaken by the Management Team was a substantial one which involved the SAC, and it was presented to the Board in September 2022, with the Board commenting on the importance of ongoing portfolio management and high-quality implementation decision making.[20] Further reflection on the portfolio then took place through the Annual Portfolio Review meeting in November 2022.

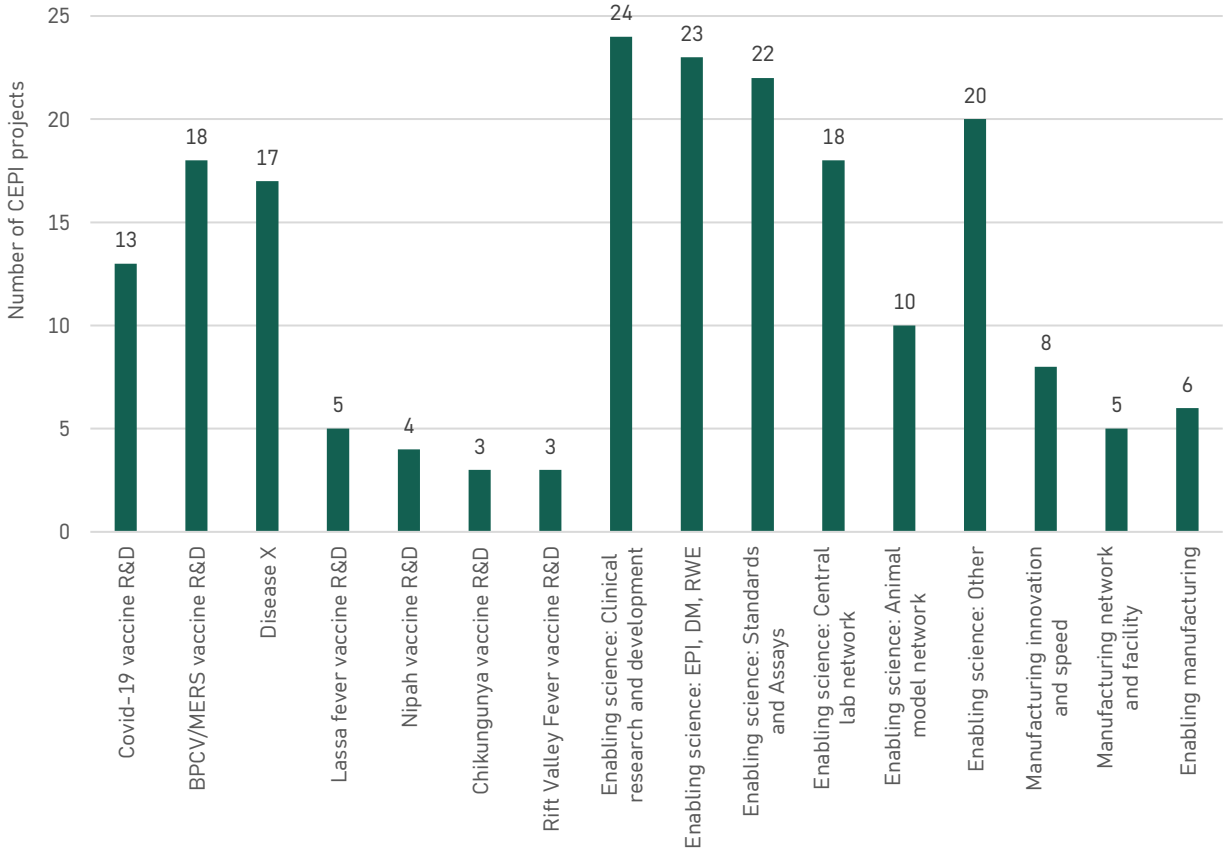
Figure 3. highlights the effect of this reprioritisation between the $3.5 billion plan and a prioritised $2.6 billion plan, which mostly affected the budget for Disease X and enabling science.

Finding 32: The Management Team has advanced a significant body of work since the inception of CEPI 2.0 related to its governance function, at the policy level, in strengthening management operations, and for new programmatic activities. As noted in Finding 19, this has included updating the ToR for many governance committees, seeking to clarify roles and responsibilities and streamline processes. At the policy level, substantial work has been put into the updated Manufacturing Strategy, a Regulatory Strategy, and the Equitable Access Framework (EAF). As noted in Finding 13, work is also ongoing to evolve CEPI's approach to partner selection and management for the achievement of common outcomes, including through the use of pathogen and partner archetypes. An expansive programme of work has also been implemented to strengthen management operations, notably for risk management, with a new Risk Management Framework developed and adopted, financial management and staffing (discussed below).

In terms of the actual CEPI portfolio, CEPI has managed almost 200 separate projects since inception, many of which have been active in the CEPI 2.0 period to date across the strategy areas (see Figure 3.).

[20] Summary of Minutes of Board meeting #19.

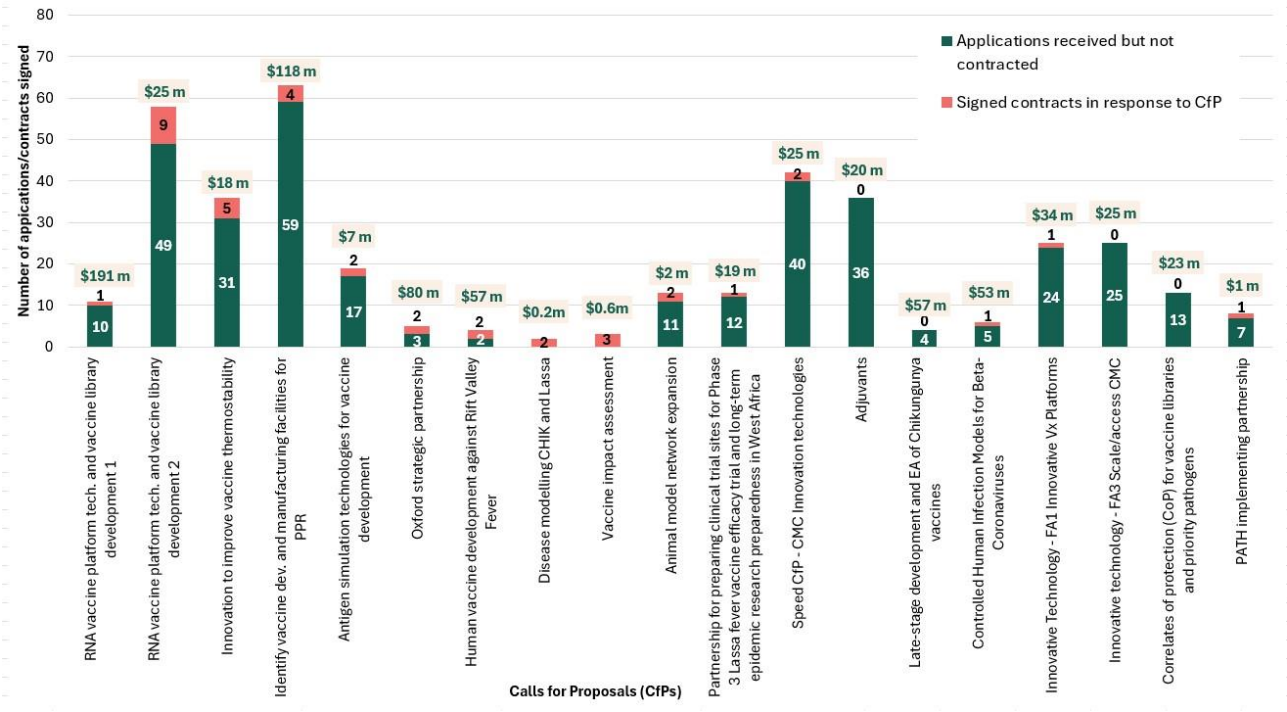
Figure 3. Number of CEPI projects that have been active since CEPI inception (2017) to mid-2024[21]



CEPI has also released at least 35 CfPs since 2022, including for vaccine development (notably for Chikungunya, Rift Valley Fever (RVF) and filovirus), manufacturing, enabling science, scientific research, and ecosystem strengthening. Figure 4 presents the CfP name and total budget and the number of applications received and contracts signed for a selection of the larger CfPs launched during the CEPI 2.0 period and where data was available; these are presented in chronological order.

[21] Data provided by the Management Team.

Figure 4. Sample of CfPs by name and total budget and the number of applications received and contracts signed (2022 to mid-2024)[22]



Finding 33: There has been a substantial underspend against the CEPI 2.0 budget to date, which was identified as a significant strategic issue in early 2023. Despite a substantial underspend against the CEPI 2.0 budget in 2022, the Board minutes indicate that the Management Team did not consider this to be a serious issue until early 2023.[23] It was, however, articulated as a significant priority at the June 2023 Board meeting, in the knowledge that there would again be a substantial underspend in 2023 before spending was expected to accelerate in 2024.

Although stakeholders were keen to note that spending alone is not a great proxy for implementation progress, there was also widespread acknowledgement that this did reflect a lack of progress in strategy operationalisation. For brevity and readability, implementation progress by priority pathogen and SRA is presented in findings against EQ5.

[22] Data provided by the Management Team, sourced via IMS.

[23] In December 2022, the cash balance of over $1 billion was presented as a mechanism to provide flexibility for further investment. (Summary of Minutes of Board meeting #20).

Finding 34: The underspend is related to a range of factors, including many that are outside of CEPI's control (but that could largely have been predicted) and some that are directly within CEPI's control. Analysis of the evidence collected suggests that this most notably relates to:

- The strong attention and direction of effort towards Covid-19 at the outset of CEPI 2.0, which had consequences for wider CEPI 2.0 Strategy operationalisation.
- Uncertainty and delays caused by the expanded scope of 2.0 activities, compounded by the Board's request for an initial reprioritisation process. Evidence suggests that this has taken substantial time for management to work through.
- Unrealistic timelines and associated budgets for project initiation and implementation, as well as overly optimistic assumptions as to the pace at which R&D progress would be made to reach the more expensive later stages of vaccine development.

Finding 35: Following a concerted effort to increase strategy implementation, a range of investments was accelerated towards the end of 2023 and into 2024, which increased the rate of spend. This started with the Sprint Project in Q3 and Q4 of 2023, which was designed to focus the organisation on execution. This transitioned to the Investment Management Control Tower, operationalised through the IMS. The IMS offers an end-to-end investment and analysis tool that enables analysis of project resources, bottlenecks and challenges to strengthen visibility of the project pipeline and forecasting. Early experiences suggest that this system has potential, but it is still in the process of being embedded and fully utilised across the organisation.[24]

Also of note has been CEPI's shift from relatively narrow CfPs to broad calls and the adoption of strategic partnership agreements. There is evidence that this approach reflects the reality that many deals are made on the back of senior leadership engagement and that it is working, with several strategic partnership agreements signed and in discussion, and with the broad CfP launched in October 2023 attracting a high number of applications.[25]

Nonetheless, as shown in Figure 5, actual spending to May 2024 (almost the midpoint in CEPI 2.0) is still, at $652 million, substantially below the $2.6 billion prioritised plan.[26] While there is a realistic expectation that spending will increase exponentially as the R&D portfolio matures (with costs increasing as products advance along the development pathway), without modification to CEPI's investment plans, and noting that opportunities for further investment within the existing plans were considered to be quite limited, the Management Team forecast (in June 2024) expenditures of $300 million–$400 million per year between 2024 and 2026, leaving an unexpended balance of $700 million–$1,200 million by the end of the CEPI 2.0 period (2026); the 'planned spend' column in Figure 5 reflects the median, where CEPI would have unspent 2.0 funds of $900 million. This was noted by the Board and key informants as posing a significant political risk to CEPI, with the potential to undermine future fundraising efforts.

[24] 2023 Board Effectiveness Review CEPI Report & Recommendation.

[25] For example, CEPI launched an Oxford strategic partnership CfP in August 2022, which received five applications, of which three were deemed eligible; and as of July 2024, two contracts have been signed, with a combined value of $25 million.

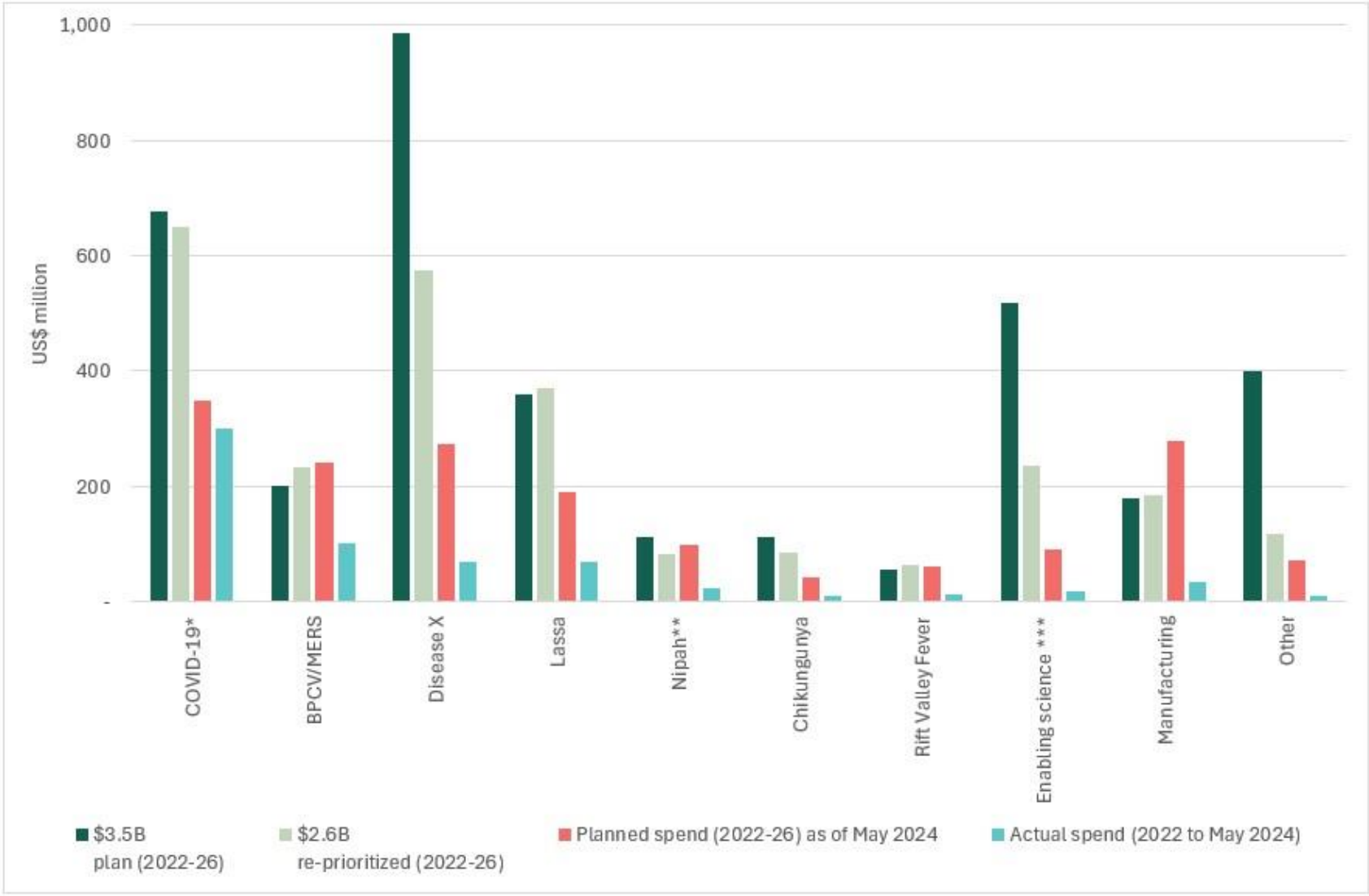
[26] This figure is artificially inflated by some CEPI 1.0 investment expenditures being carried over into the CEPI 2.0 strategic period.

Finding 36: A range of investment opportunities was presented to the Board in March 2024 for initial consideration, including a number of substantial new investments to take place within the CEPI 2.0 period. Selected by the Management Team based on where CEPI is best placed to act and contribute to the CEPI 2.0 mission within the 2.0 time frame, this included a mix of projects, both large and small and both within and outside of CEPI's current set of priority pathogens and SRAs. Some of these were enabled by scientific advances and evolution in the external environment which were not envisioned at the outset of CEPI 2.0 (e.g. in AI). Together, the set of investments was noted as having the potential to utilise between $350 million and $600 million by the end of the CEPI 2.0 strategic period. As such, a substantial underspend would still remain.

Two large proposals – totalling $100 million or more – were approved in ad hoc Board meetings following the March 2024 Board meeting. Other proposed investment opportunities were also supported in principle by the Board, albeit with a request for further justification and articulation, and on the understanding that a revised investment plan would be put forward to the Board for consideration at the August 2024 Board meeting alongside the Final Report from this MTR. Although the scope and scale of this investment planning justifies due analysis and consideration, it has taken substantial time and engagement between the Board and Management Team to agree, leaving little more than two years of implementation within the remainder of CEPI 2.0.

At the time of writing (the end of July 2024), the Management Team expect any unspent resources at the end of 2026 to be utilised in 2027. As such, this would allow for the new CEPI 3.0 strategy to be launched and for fundraising to take place in 2026, with guaranteed resources in place for 2027 and time for new resources to be in place for the remainder of the CEPI 3.0 strategic period.

Figure 5: CEPI 2.0 investment plan evolution and actual spending (cash outflows) to May 2024[27]



[27] * Included BP-SARS-CoV2 in $3.5 billion and $2.6 billion plans. Included in BPCV in planned spend at May 2024, and actual spent to May 2024.

** Nipah Mabs is not included in in $3.5 billion or $2.6 billion plans but is included in planned spend.

*** In $3.5 billion and $2.6 billion plans, enabling science activities pertaining to specific pathogens are included. In current plans, these are included in the respective lines for the pathogens.

EQ5: How effectively has CEPI's 2.0 Strategy been implemented?	
Headline findings	Analysis of the CEPI portfolio indicates that substantial progress has been made in implementing and achieving results against many areas of the CEPI 2.0 Strategy, albeit with evidence of mixed effectiveness by pathogen and SRA. CEPI's investments and wider role in responding to Covid-19 are widely considered to have been effective, as are its investments in R&D and enabling science for BPCV, Chikungunya, Lassa fever and RVF, which have all demonstrated strong programmatic progress. Evidence of effectiveness is less clear for investments related to MERS and Nipah, for which further programmatic progress is required. Newly introduced investment areas for CEPI 2.0, such as Disease X and Manufacturing and Supply Chain (MSC, detailed under EQ5.2), require more time to demonstrate results.
Evidence strength	**2:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings, although the absence of detailed project-level data limited the extent to which effectiveness could be analysed. Due to substantial constraints regarding time and resources, the team could not utilise the snowball approach to continue identifying new key informants until the point where no new data, categories or relationships seem to be emerging. Moreover, the team has been unable to interview several intended stakeholders representing industry, other R&D funders, multilaterals and civil society (although others from these categories have been interviewed), owing to scheduling difficulties. Nevertheless, the evidence collected and analysed is sufficient to formulate sound conclusions with the indicated strength of evidence rating. In addition, the MTR did not interview project-level staff due to resource scarcity. As such, a significant challenge was encountered in simply understanding whether planned activities had been implemented and were achieving outputs and results in line with plans. This limited the MTR's ability to systematically assess both the efficiency/fidelity of implementation and effectiveness of CEPI's portfolio investments. This assessment relied upon various portfolio-wide reports, notably the Annual Portfolio Reviews and Annual Progress Reports to discern implementation progress and results, which was triangulated against KPI reporting (where relevant) and spending patterns across the portfolio as a marker of progress. As such, areas of strong and less-strong programme progress were highlighted, rather than systematic assessments of efficiency and effectiveness by pathogen and SRA.

Finding 37: Analysis of the CEPI portfolio indicates that substantial progress has been made in implementing and achieving results against many areas of the CEPI 2.0 Strategy. An assessment of implementation progress and results is presented below, structured by Covid-19, priority pathogen and for Disease X, integrating other SRAs as relevant, with manufacturing dealt with below under EQ5.2.

Covid-19/SARS-CoV2

In response to the Covid-19 pandemic, CEPI reallocated its resources to focus efforts on the development of relevant vaccines and played a major role in supporting the wider ecosystem to advance equitable access to available vaccines through its role in designing and co-leading the implementation of COVAX.

For the entire CEPI 2.0 period, CEPI initially planned to spend $678 million on Covid-19, which was reprioritised in late 2022 to $650 million. Of this, CEPI has spent $301 million to date; barring any change in circumstances, CEPI's work in this area is being wound down, and spending is not expected to go beyond $348 million in the CEPI 2.0 period. By the end of 2023, CEPI support had facilitated the registration of seven vaccines, two of which were programmatically suitable for LMICs, with support ongoing for Phase I clinical development of a novel self-amplifying RNA vaccine (Gritstone). Some of CEPI's enabling science support began prior to the CEPI 2.0 period but includes development of 17 preclinical models, establishment of CoP, and expansion of the Centralized Laboratory Network to 17 partners (five of which are in LMICs), which enabled serum collection, assay testing and development of antibody standards.

As reported in the CEPI 1.0 evaluation, CEPI's investments were effective in helping to advance selected vaccine candidates. However, CEPI's investment in the supported vaccine that was most widely used in the early phases of the pandemic, when supply was constrained (Oxford/ AstraZeneca), was small and limited in scope, as it was for the Moderna mRNA vaccine, which became available to COVAX and most LMICs only in 2022, when supply was no longer constraining equitable access. The two vaccines for which CEPI investments were large – Novavax and Clover (almost $400 million each) – were significantly delayed in development, becoming available only from 2022 onwards. Nonetheless, CEPI was widely praised in its response to the Covid-19 pandemic and, through its R&D and enabling science work and its role in COVAX, is considered to have made a major contribution to the global Covid-19 response.

The related outcome KPIs are considered to have been accomplished, notably "acute phase of Covid-19 pandemic ended" and "risk of further coronavirus pandemics reduced". Nonetheless, the global response fell short of most stakeholders' expectations for equitable access and highlighted deep flaws in the ecosystem in which CEPI operates. Lessons learned from this experience exposed the need for a substantial shift in the ecosystem to ensure equitable access in a future pandemic, which was the basis for developing CEPI 2.0, and CEPI engaging to support the R&D of wider acute respiratory diseases, including SARS-CoV2, BPCV and MERS, as well as downstream issues and barriers to equitable access.

BPCV/MERS

BPCV/MERS R&D is closely linked to Covid-19/SARS R&D, and as such, as CEPI has progressed through CEPI 2.0 and the degree of emphasis placed on Covid-19 has subsided, resources have been concentrated towards more general BPBC R&D.

For the entire CEPI 2.0 period, CEPI initially planned to spend $201 million on BPCV/MERS, which was reprioritised in late 2022 to $232 million. Of this, CEPI has spent $103 million to date. Spending of $242 million is expected in the full CEPI 2.0 period to 2026. These figures indicate a relatively resource-intensive programme, with spending moving roughly at pace with plans.

With the aim to develop a BPCV candidate, CEPI entered into 12 agreements in 2022 (weighted toward inherently risky preclinical candidates) alongside a package of other support to advance BPBC research, including through collaboration with the National Institute of Allergy and

Infectious Diseases. Initial progress in the development of these vaccines has been faster than originally envisaged, and as of June 2024 10 vaccines have advanced to preclinical trials. By the end of 2024, CEPI aims to have up to two vaccines with approval to go to clinical trials. The scope of the BPBC programme has been narrowed to focus on sarbecovirus – a tactical shift that leverages scientific knowledge gained through Covid-19 and viral genetic relationships, which reduces product development risk (compared to a vaccine that would protect against an even broader range of pathogens) and maintains the potential for positive public health impact in the event of another outbreak of sarbecovirus disease. CEPI has made considerable progress in supporting enabling science for BPBC (e.g. standards and assays available to developers).

For MERS, learnings from prior vaccine development efforts were used to facilitate rapid response to the Covid-19 pandemic, linked to the phylogenetic relationships between the viruses and associated cross-learnings. CEPI supported the advancement of two vaccines to Phase I clinical trials in 2022, although subsequent progress has been limited in terms of more candidates reaching Phase I clinical trials (nine were targeted to be in Phase I by the end of 2023) and for one candidate to reach Phase IIa by the end of 2024. As such, the MERS portfolio remains small, relying on the use of a single platform. CEPI continues to advance work to support the enabling science, for instance through support for a suitable animal model with shared learning with BPBC, while also establishing manufacturing partnerships with Bio Farma and SK bioscience close to one of the historic locations of MERS outbreaks.

Disease X/100 Days Mission

CEPI's Disease X programme, supportive of the 100 Days Mission, aims to anticipate a range of threatening pathogens, develop related enabling science and vaccine constructs, and prepare for a response in the event of an outbreak by planning for manufacturing capacity.

For the entire CEPI 2.0 period, CEPI initially planned to spend $986 million on Disease X, which was reprioritised in late 2022 to $575 million. Of this, CEPI has spent $68 million to date. Spending of $274 million is expected in the full CEPI 2.0 period to 2026. As set out below, in part this is indicative of slow progress made in implementation and demonstration of results, but it also does not fully reflect the level of activity undertaken to date.

To date, CEPI has completed activities to identify and prioritise future Disease X candidates, develop CEPI-specific methodologies to respond to each which form part of a Disease X response plan, and engage in a number of strategic partnerships to support Disease X objectives. This includes partnership agreements to expand CEPI's manufacturing network. CEPI has been successful in establishing at least four viral family libraries, including Mpox (see Box 1), has advanced two vaccines to Phase I (BioNtech for Mpox and Lemonex as a delivery technology) against a target of two, and has 14 preclinical candidates on a range of platforms and antigen delivery technologies.

Further, CEPI continues to invest in enabling science, such as imaging and antigen design, and in 2023 it established a partnership with IQVIA to strengthen clinical trial capacity and outbreak response in LMICs. It has also worked to support the coordination of the vaccine R&D responses to Mpox and Ebola outbreaks, and has supported ecosystem strengthening for a coordinated global early warning system for high-priority pathogens in support of the 100 Days Mission, involving collaboration with WHO and others.

During the second half of CEPI 2.0, the cross-cutting issue of biosecurity has the potential to become increasingly relevant to the Disease X programme, given the diversity of pathogens, technologies and partners engaged. CEPI's agreement on biosecurity with Global Affairs Canada (September 2023) and forthcoming Biosecurity Strategy signals a start to this commitment.

The Mpox Programme is a new priority pathogen within CEPI 2.0. Two vaccines are licensed for Mpox by stringent regulatory authorities; however, no vaccine has obtained WHO prequalification. To enable access to currently available vaccines (Bavarian Nordic MVA-BN and KM Biologics LC16m8) to populations most in need, CEPI has made investments and will continue to support funding of priority research gaps and provide regulatory guidance to facilitate national approvals. Towards the end of Q4 2024, CEPI will accept proposals for development of a portfolio of additional pan-orthopox vaccine candidates with optimised characteristics for populations most at risk (to include the CEPI-funded BioNTech mRNA Mpox vaccine candidate).

At the CEPI Board meeting in December 2023, the decision was taken to "stand up" the Mpox programme beginning in 2024, indicating the possibility of accelerated progress in the second half of CEPI 2.0.

Box 1. The Mpox Programme

Lassa fever

The Lassa fever programme is a high-priority "flagship" programme with product licensure an expectation by many with the potential to be a landmark achievement for CEPI 2.0. This stems from the advanced nature of the lead candidate, progress in the enabling science, and CEPI having supported the first-ever Phase I vaccine for Lassa.

For the entire CEPI 2.0 period, CEPI initially planned to spend $360 million on Lassa, which was reprioritised in late 2022 to $371 million. Of this, CEPI has spent $69 million to date. Spending of $191 million is expected in the full CEPI 2.0 period to 2026. Spending is behind expectations mainly because of delays in implementation and slower progress in advancing the lead vaccine candidate to Phase III clinical trials.

The CEPI portfolio for Lassa fever vaccines consists of three viral vector vaccines – one in preclinical development (Oxford), one in Phase I (Emergent/PATH), and the most advanced (IAVI) in Phase IIa and with trials currently under way in Nigeria. The IAVI vaccine is built on a viral vector platform similar to that of the Merck Ebola vaccine, suggesting a reduced development risk compared to untested modalities and demonstrating the potential value accrued to this programme of previous innovative development work outside CEPI. To further reduce platform risk, CEPI is partnering with SK bioscience to evaluate the potential to employ an mRNA platform for Lassa.

CEPI has worked to enable R&D progress in a number of ways, including by identifying and filling knowledge gaps, developing pathogen roadmaps, and generating evidence to improve understanding of the Lassa pathogen. This was primarily through diagnostics assays to support clinical trials and a large-scale epidemiology study (the ENABLE Lassa programme) which, although one key informant pointed to issues in the study design, quickly started to generate data to support the design of a Phase III study and advanced clinical development. The ENABLE Lassa programme was subsequently provided a no-cost extension to complete activities, with the results analysed in 2023. It has also worked to support and strengthen serological standards,

the clinical research ecosystem, and West African regulatory systems, as well as exploring Chemistry, Manufacturing, and Controls (CMC) development plans and an integrated advanced vaccine strategy. In addition, starting in 2024, CEPI is funding a rapid diagnostic test for Lassa (with FIND) which includes equitable access provisions. However, one stakeholder noted that continued work is needed to build community engagement and partner relationships to ensure demand for the vaccine and to promote access.

Although the ambition to have one candidate in Phase IIb/III has not yet been achieved, CEPI's work has supported substantial progress in this area; and given the relatively advanced nature of the programme (with preparations under way for Phase IIb clinical trials to take place for the IAVI candidate in 2025), CEPI is now collaborating with African governments and regulators on licensing requirements. However, programme reviews suggest that licensing will not take place prior to the end of CEPI 2.0, owing to trial timelines. One key informant noted that CEPI's requirement for an R&D partner to use a specific manufacturing process (justified to ease regulatory requirements) had slowed clinical development and made it more expensive; this issue has not been triangulated and verified with CEPI. Nonetheless, CEPI is working to establish a market authorisation holder and is making plans for manufacturing. Owing to programme progress, expert scientific advisors (PRCM) have suggested integrating enabling science from the Lassa programme across other antigen programmes.

As with other programmes, biosecurity may be a cross-cutting issue for Lassa and will require attention by CEPI and partners on a forward basis, although notably the key partners engaged (e.g. Oxford, Emergent) are experienced developers.

Nipah

Nipah is a priority pathogen for which CEPI supported the very first human clinical trials of a vaccine candidate and has worked over time to increase awareness and knowledge.

For the entire CEPI 2.0 period, CEPI initially planned to spend $112 million on Nipah late-stage development of vaccine candidates, which was reprioritised in late 2022 to $82 million. Of this, CEPI has spent $24 million to date. Spending of $100 million is expected in the full CEPI 2.0 period to 2026. This is indicative of a programme that has made progress but has faced substantial challenges, notably with aligning expectations with CEPI 2.0 goals of licensing a Nipah vaccine for market access.

CEPI currently supports three vaccines, all of which have progressed to clinical trials. Two are currently in Phase I and one has completed Phase I and has approval to enter Phase II. One stakeholder perceived that advancing Nipah vaccines to clinical trials would not have happened in the absence of CEPI support. The most advanced of these (Auro/PATH) is ready to start Phase II and will receive CEPI funding of up to $25 million through this stage. The additional Phase I vaccine candidates are from Public Health Vaccines and the University of Oxford, with no preclinical candidates in the Nipah portfolio. Although CEPI did not provide funding to support Phase I development, it is initiating a project for a monoclonal antibody for Nipah, with plans to enter Phase I in 2024, the only biologic identified in the CEPI portfolio and the basis of a therapeutic/preventive bridging strategy for disease control.

CEPI continues to invest in enabling science related to animal model optimisation and a disease natural history study, critical for regulatory pathway for licensure, correlate of protection studies and epidemiology, the latter related to strain characterisation from previous, current and future Nipah outbreaks. CEPI is supporting the development of an adapted trial protocol for

evidence generation during an outbreak and is collaborating with FIND on initial work for a rapid diagnostic test. Planning activities are in process for licensure with the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Bangladesh Directorate General of Drug Administration and the Drugs Controller General of India, despite this licensure being some years away. As with other priority pathogens, Nipah may involve biosecurity as a cross-cutting issue; this is particularly important in light of the virulent nature of the virus.

Chikungunya

Chikungunya is a priority pathogen programme for which CEPI supported the advanced development of three vaccine developers. For the entire CEPI 2.0 period, CEPI initially planned to spend $112 million on Chikungunya, which was reprioritised in late 2022 to approximately $65 million. In collaboration with HERA, CEPI launched a CHIKV-focused CfP (CfP-3iii CHIKVACCINE) in June 2023 with a budget of $56.8 million. Four applications were received in total and each application was deemed eligible, with three ranked as a top priority for the programme and put through due diligence. As of July 2024, final negotiations are still under way to support licensure activity and post-licensure data needs to expand indications and enable access to licensed CHIKV vaccines to LMIC populations. The current CEPI Chikungunya programme consists of two candidates; one licensed (FDA, EMA, Health Canada) vaccine for travellers aged 18+ years (IXCHIQ, Valneva), which CEPI is supporting to enable access to LMICs and to expand indications to a broader age range in adolescent populations; and an inactivated two-dose vaccine in Phase II/III development by IVI/Bharat Biotech International Ltd.(BBV87). A third measles-vectored CHIKV candidate (MV-CHIK) was put on hold by the developer after Phase II development. Given the relatively advanced development status, the comparative development risk is lower than for other programmes.

Most critically, the licensure of the VLA1553 candidate (IXCHIQ), using an immune correlate of protection in lieu of Phase III efficacy, sets the precedent for following candidates to take a similar approach to licensure (and potentially WHO prequalification). Early enabling science investments have resulted in the successful development of an animal model and establishment of a correlate of protection for the VLA1553/IXCHIQ candidate. In addition, CEPI has funded technology transfer of VLA 1553 to Instituto Butantan and funded a Phase III adolescent trial (12–18 years) in Brazil, to enable local licensure, manufacturing and supply to LMICs. CEPI reports success of the tech transfer and is in discussion with an additional LMIC manufacturing partner to expand global supply capacity. However, because negotiations for new contracts are under way, some activities have been delayed, which explains part of the reported underspend. This includes, for example, commissioning effectiveness and long-term safety and durability (Phase IV) studies. To help inform governments and procurement agencies of licensed (and advanced) vaccines, CEPI has also undertaken work to understand the impact of various vaccine roll-out strategies for different epidemic scenarios, as well as work to simulate stockpiling needs to support both routine and emergency vaccinations. Much is also planned for 2024, including a burden of disease study in East Africa to inform vaccine development, deployment and use.

Rift Valley Fever

RVF is a priority pathogen supported by CEPI to reach preclinical stage development under CEPI 1.0. For the entire CEPI 2.0 period, CEPI initially planned to spend $57 million on RVF, which was reprioritised in late 2022 to $64 million. Of this, CEPI has spent $14 million to date. Spending of $61 million is still expected in the full CEPI 2.0 period to 2026.

CEPI currently supports two live attenuated vaccines for RVF, of which one has completed Phase I (Wageningen University & Research (WUR)) and one has completed preclinical development (Colorado State University (CSU)/University of California, Davis (UCD)); and a third, viral-vectored candidate (details to be announced shortly) is in Phase IIa development. A Phase I trial for the WUR vaccine candidate (funded by CEPI up to $25.9 million) was conducted in Belgium, with further clinical development (Phase IIa) planned in the RVF-endemic countries of Kenya and Uganda in 2025. The UCD candidate (funded up to $28.7 million) will directly enter Phase I clinical evaluation in Tanzania, another RVF-endemic country, in 2024. To further diversify the portfolio and ensure optimal positioning for both routine and outbreak use of RVF vaccines, CEPI is evaluating additional vaccine candidates, based on mRNA platforms.

With CEPI support, an international antibody standard for RVF has been developed and is currently in use by developers. CEPI has publicly recognised that there are other important areas of enabling science, namely epidemiology and modelling, that are important to the programme and advancing its RVF candidates. To this end, CEPI hosted a successful RVF epidemiology and modelling workshop in Nairobi in June 2024, with key subject matter experts and opinion leaders from major international organisations (WHO, Africa CDC, the US Centers for Disease Control and Prevention (CDC) and the Food and Agriculture Organization of the United Nations (FAO)) present. The purpose was to engage with the community and inform the RVF epidemiology and modelling call launched in July 2024, and this will support projects that are key to addressing the question of RVF vaccine efficacy study feasibility. CEPI is also currently working to expand trial site capacity to avoid regulatory delays in RVF-endemic countries, and the manufacturing team has identified the need to address scale-up risks associated with yield, stability and cost of production for an RVF vaccine.

RVF is both a climate-sensitive infectious disease and a priority livestock pathogen. Although there is no currently licensed human vaccine for RVF, multiple animal vaccines exist. As a result, One Health approaches are integral to successful RVF human vaccine development and use, and a One Health approach (animal and human vaccination) to disease control may be considered; if so, this would involve relevant partners in the global health space, some of which may be new to CEPI's sphere and may require a well-organised approach to partnership and coordination demands.

Other pathogens

Although not priority pathogens, CEPI has had some engagement with Ebola, filovirus and Zika, although only filovirus has budget specifically accorded to it as of the 2022 reprioritisation ($25 million for the 2.0 period, of which $8 million has been spent).

There are two registered vaccines for Ebola Zaire (Janssen and Merck), with a stockpile that is managed by WHO. CEPI continues to engage in the Ebola space by funding Integrum/UVRI to develop an antibody standard for the Sudan strain (there is currently no vaccine) in addition to sourcing serum for other haemorrhagic fevers, one of which (Marburg) is a filovirus. In addition, CEPI supports preclinical development of a second-generation candidate (Erbevo/Merck) and has announced funding of up to $54 million for a Phase I IAVI vaccine. CEPI documents indicate that it has invested in Zika candidates, although information on the amount, timing and nature of funding was not found through document review. Several organisations have reported Zika development programmes (mostly Phase I).

CEPI's aims for the remainder of CEPI 2.0 with Ebola, other filoviruses and Zika are not well defined at present and are subject to the Board's response to the revised investment plan, to be

presented and discussed at the August 2024 Board meeting. The MTR has found no evidence that investments in these pathogens have been a hindrance to the achievement of CEPI's priority goals, although it notes that CEPI's added value of engaging varies considerably by pathogen (e.g. with Ebola already having two licensed vaccines and a stockpile, whereas in the case of Zika, vaccine candidates are still early-stage).

EQ5.1: To what extent is CEPI making appropriate decisions to advance progress towards its strategic objectives and outputs as articulated in its 2.0 programme document and associated results framework?

Headline findings	CEPI is a technically astute organisation that is able to identify issues and areas where there is a significant need for intervention to achieve CEPI's strategic objectives. Robust governance procedures are also in place to ensure the technical quality of new investments. However, in such a dynamic ecosystem with so many gaps and barriers to achieving CEPI 2.0 strategic objectives, CEPI has struggled to sufficiently prioritise its efforts across the portfolio to optimise performance within the available resource envelope and given the limits of management's capacity.
Evidence strength	**2:** Evidence is largely reliant on KIIs and is perception-based, which is expected for a question such as this. As such, triangulation and development of findings has required some interpretation by the MTR Team. For instance, it may be that there are differences in the extent to which respondents felt enabled – through knowledge, trust or other constraints – to provide a full reflection on CEPI 2.0. Our approach to dealing with this is to acknowledge that it is likely to be an issue with the qualitative data collected and to be mindful of this when analysing data. In addition, by seeking to capture a mix of stakeholder perspectives, we have largely been able to triangulate evidence from multiple sources to develop findings.

Finding 38: CEPI is a technically astute organisation that is able to identify issues and areas where there is a significant need for intervention to achieve CEPI's strategic objectives. As highlighted above, this was demonstrated by CEPI's role in the Covid-19 pandemic as well as through the design of CEPI 2.0, which responds to the gaps in the ecosystem, laid bare by the pandemic, to bring new products to market and ensure equitable access to them. CEPI's ability to invest in the right areas is also demonstrated by the strong relevance of CEPI's existing portfolio (see EQ1), the progress being made towards programmatic results (see EQ5), and the unique role that CEPI often plays to facilitate these results (see EQ6). Furthermore, the rapid expansion of CEPI's portfolio of enabling science investments suggests that a proactive approach has been adopted internally to identifying interventions that support CEPI's R&D and strategic objectives. A proactive approach has also been adopted for a range of downstream issues, which will help to ensure equitable access in the longer term. As noted above, however, this is the source of some divergence of opinion as to where CEPI's role should start and stop, depending on CEPI's comparative advantages and the presence of partners.

Finding 39: Robust governance procedures are in place to ensure the technical quality of new investments. As noted by the CEPI 1.0 independent outcome evaluation and as set out in Findings 18 and 19, decision making at the Board and governance level is largely viewed as adequate. Many advances have since been made, broadly endorsed by the latest Board Effectiveness Review, as noted in findings in response to EQ2. This is supported by an increased focus on risk management, with risk reviews embedded in organisational planning and discussed consistently at governance committee meetings for investment decisions, for projects and portfolios, and with increased emphasis internally on portfolio management.

Finding 40: A significant issue relates to CEPI's ability to prioritise across the portfolio to optimise performance against its strategic objectives within the available resource envelope and

given the inevitable limits of management's capacity. As set out under EQ4, CEPI has been in a cycle of portfolio reprioritisation since the start of CEPI 2.0, which is still ongoing. This has been driven primarily by underspending against overly ambitious plans but has highlighted issues in the Management Team's capabilities, culture and practices (Finding 22 and Annex 5.6). CEPI staff, governance committee members and R&D partners referred to these challenges as impediments to efficient and effective decision making, for instance in how management systems bring the Board and teams together to consider strategic issues in a cross-functional manner.

EQ5.2: To what extent is CEPI, through its 2.0 Strategy, working to advance equity vis-à-vis access to vaccines and advancing manufacturing partnerships?	
Headline findings	CEPI demonstrated a strong commitment to ensuring equitable access to vaccines during the Covid-19 pandemic. The EAF builds on this experience by setting out a comprehensive approach to addressing equity across CEPI's scope of work. In practice, CEPI has sought to advance the objective of equitable access in a range of ways across the portfolio, both through the choice of vaccine candidates, with some candidates more appropriate for LMIC settings, and through arrangements for manufacturing and access to vaccines once they reach market. These arrangements include preparations for regulatory approval in LMICs, agreements for technology transfer to regional and/or low-cost manufacturers, and stockpiling for use in future outbreaks.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 41: CEPI demonstrated a strong commitment to ensuring equitable access to vaccines during the Covid-19 pandemic. As highlighted above, CEPI support helped to facilitate the registration of seven vaccines, two of which were programmatically suitable for LMICs, with support ongoing for Phase I clinical development of a novel self-amplifying RNA vaccine (Gritstone). An external review found that CEPI's strong commitments to equitable access had been translated into equitable access provisions in CEPI's Covid-19 vaccine development agreements.[28] Despite the challenge of negotiating agreements in a short time frame and a competitive environment, this included, for vaccine development agreements, a diverse set of mechanisms to address equitable access, including the Joint Management Advisory Group (JMAG), repayment requirements under specified circumstances, and robust, real-time information-sharing commitments. For outbreak response agreements, strong equitable access commitments were also in place. These commitments often utilise a broad "relational" approach (using language such as "reasonable", "best efforts" and "best endeavours") and, as such, require trust between both parties rather than invoking a firm contractual obligation. It is though unclear how such commitments could have been formalised more concretely. Nonetheless, this is an area for further learning and, in the view of the MTR Team, one where there is likely to be greater receptivity among developers prior to a future pandemic. The provisions put in place were most favourable for equitable access in agreements with smaller and newer developers.

[28] CEPI (2022) Enabling Equitable Access to COVID-19 vaccines: Summary of equitable access provisions in CEPI's COVID-19 vaccine development agreement.

Finding 42: The EAF sets out a comprehensive approach to addressing equity across CEPI's scope of work within CEPI 2.0, including in relation to access to vaccines and through manufacturing partnerships. The independent outcome evaluation of CEPI 1.0 (2017–21) found that CEPI's equitable access policy had evolved over time but that its implementation remained inconsistent across the portfolio and was often unclear, with a need for better communication and transparency on its application through CEPI's access provisions.[29]

The EAF was published in May 2023. A range of stakeholders commented that the EAF sets out a coherent vision for how CEPI will work to support structural change and improve connectivity between the different parts of the ecosystem, to enable both accelerated R&D&M and timely product availability. Such a policy shift was necessitated by CEPI 2.0's greater level of emphasis placed on Disease X and pandemic preparedness, for which other R&D funders are active and the set of issues around equitable access is fundamentally different and more complicated to address.

Considered in a continuum, the key objectives of the framework are to:[30]

1. Rapidly advance product development.
2. Secure the right to require timely production of that product for at-risk populations.
3. Make investments to increase utility of products for the Global South.
4. Support greater agility and resilience in regional R&D&M, supply chain and global health architecture to achieve the 100 Days Mission.

Critical enablers to the achievement of these objectives relate to the ways in which CEPI makes its investments in partners and technologies, incorporates equitable access provisions, and works indirectly through its policy and advocacy work to connect, collaborate and coordinate efforts with other public stakeholders to strengthen the health architecture for PPR.

Finding 43: In 2.0, CEPI has sought to advance the objective of equitable access in a range of ways across the portfolio. Many key informants reflected that a focus on the development of vaccines that primarily affect LMICs and on ensuring equitable access to vaccines was what made CEPI unique and guided CEPI's processes and ways of working, which was being supported by the EAF. There are several examples of decisions being taken to demonstrate this focus. These relate both to supporting vaccine candidates appropriate for LMIC settings and to making arrangements for manufacturing and access to vaccines once they reach market. These arrangements include preparations for regulatory approval in LMICs, agreements for technology transfer to regional and/or low-cost manufacturers, and stockpiling for use in future outbreaks.

Across the portfolio, CEPI's preparations for access include:

- **BPBC:** The portfolio of 12 R&D investments includes some with properties in favour of thermostability and low production costs, which would have greater utility in the Global South in support of equitable access objectives.
- **Disease X:** The Disease X programme includes a diversity of platforms, some of which are amenable to rapid deployment (e.g. mRNA) and have the potential for favourable thermostability and low production costs, in support of equitable access objectives.

[29] CEPA (2022) CEPI: Independent outcome evaluation of the first five-year business cycle 2017-21.

[30] CEPI (2023) Equitable Access Framework.

- **Lassa fever:** Phase II trials for the IAVI lead candidate are now under way in Nigeria, although vaccines built on a similar technical platform (e.g. Erbevo) require frozen storage and transport, which, if required for the IAVI candidate, may pose an access issue. Another product in the CEPI portfolio (Oxford) uses a ChAdOx-based modality, which has been shown to be thermostable and to have low production costs, and this may be more suitable. CEPI is also partnering with SK bioscience to evaluate the potential to employ an mRNA platform for Lassa, as well as collaborating with African governments and regulators on licensing requirements and addressing other downstream issues to address market authorisation and manufacturing issues. CEPI's support to FIND for a rapid diagnostic test for Lassa also includes equitable access provisions.
- **Nipah:** There is limited platform diversity among the existing candidates, and there are several challenges to R&D development and to ensuring equitable access. In particular, these relate to country-level regulatory and licensure standards and trials required, including agreement on the use of a monoclonal antibody and data needs to support this disease control strategy.
- **Chikungunya:** CEPI is working to transform the use of the only licensed vaccine for Chikungunya (Valneva) from an HIC travel product to a vaccine accessible to LMICs for a broader age range. Because of the advanced status of the vaccines, forward risk has shifted to downstream issues related to manufacturing, regulatory issues and demand. Although progress has been made in the technology transfer, KII input suggests that negotiations over manufacturing terms have created challenges and are complicated by lengthy decision and review processes at CEPI. Furthermore, concerns exist that little attention is being directed to downstream demand, with a fear that country-level interest in a vaccine is not well understood and may be limited.
- **RVF:** The RVF portfolio is small, with two early-stage candidates relying on one platform and making slower progress than expected. Preclinical and Phase I trials are being conducted in Uganda (for one of the candidates) and Kenya (for both), and work is planned to engage at the regional level to outline the regulatory pathway to licensure and stockpiling needs in support of equitable access.

Many CEPI staff commented on the critical importance of and deep focus on securing equitable access provisions in contracts and advocating to other relevant actors to do the same. Many R&D partners and other stakeholders interviewed reflected on such provisions being a fundamental part of CEPI's approach. CEPI has indicated that access arrangements for late-stage programmes, including Lassa, will be reviewed, although the date for this was not confirmed in this analysis. In addition to a thorough review of access agreements, CEPI may wish to consider an end-to-end readiness check, which would include demand estimation, manufacturing status and regulatory preparations to accommodate an immediate large-scale outbreak, especially given the status of some candidates in the portfolio. However, the success of any of these measures will become evident only when products are released to market and/or become in high demand in the event of an epidemic/pandemic. As the Chikungunya example shows, the prospect of developing a candidate with little demand further highlights the importance of end-to-end planning, including active engagement across teams within CEPI and with partner organisations, especially those closer to implementation (e.g. Gavi, UNICEF, WHO).

Finding 44: Equitable access is dependent on much more than provisions being put in place for CEPI's funding agreements, but CEPI's approach in this area appears to be appropriate. The Covid-19 experience showed very clearly that equitable access to vaccines against EIDs depends

on much more than simply the access conditions that are embedded within R&D funding agreements. It also depends on a wider set of functions, such as funding, manufacturing, procurement, supply and delivery, that are performed by other stakeholders outside of the control of CEPI but on whom equitable access depends. In response, through CEPI 2.0 and as set out in the EAF, CEPI situates the issue of equitable access within a wider 'systems equity' context. This considers a wider set of enabling factors, such as regulatory readiness, data and knowledge sharing, and geographical diversification of manufacturing. Many of these elements are outside of CEPI's direct control, and CEPI influencing and advocacy is required to deliver the strengthened architecture necessary.

The systems approach to equitable access informs the provisions that CEPI seeks to include in its R&D funding agreements, which add complexity to the negotiation process. Rather than the narrower approach to equitable access characterised by the traditional PDP approach as well as CEPI 1.0, which focused on ensuring availability of products developed, the systems approach generates a much wider menu of potential 'asks' that may be critical as manufacturing and supply are scaled up in the context of an outbreak response. These asks can include commitments to data sharing, stockpiles, affordable pricing, obligations (such as production scale-up) in the event of an outbreak, or step-in rights to ensure development continuity. What CEPI seeks to achieve will differ according to the nature of the investment, the vaccine or technology being advanced, the incentives CEPI is providing, and the partner.

For these reasons, increasingly CEPI is adopting a bespoke approach to including equitable access provisions in its R&D funding agreements, which the MTR Team, alongside general feedback from key informants, deem to be appropriate. This will be guided by principles and defined archetypes that set expectations, and it will be overseen by an Equitable Access Committee, although this has not yet been systematically embedded within CEPI's way of working. An extra layer of complexity has been caused by the addition, within CEPI 2.0, of support for disease and technology platforms where a larger universe of more commercially minded developers operate. This reinforces the need for a tailored approach to partnership.

Finding 45: A major emphasis of CEPI's work in MSC in 2.0 has been to advance the objective of equitable access in the event of a future pandemic. Alongside support for technical innovations in support of specific R&D product developments (e.g. one project with the California Institute of Technology with support from Ingenza is to develop a low-cost, thermostable BPBC candidate in lyophilised form), CEPI has sought to create a geodiversified network of vaccine manufacturers, which aims to substantially increase capacity and capability to produce vaccines against emerging outbreaks and pandemic threats in as short a period of time as 100 days.

Internal and external interviewees, notably those representing agencies with presence in the Global South, asserted that developing manufacturing capability in the Global South is a critical part of this approach. The network has expanded to at least four agreements across several regions in the Global South – Aspen (South Africa), Institut Pasteur de Dakar (Senegal), BioFarma (Indonesia), the Serum Institute of India (India) and BioNTech (Rwanda) – and a tech transfer being negotiated with Butantan (Brazil). The facility in Rwanda was mentioned by some interviewees as significant for supporting the Africa CDC-backed plan for Africa to manufacture 60% of its vaccine needs locally by 2040.

These initiatives exhibit potential for timely production and agility in R&D&M in support of equitable access in the event of a pandemic. There are, however, technical and partner challenges associated with realising innovations, negotiating and implementing successful manufacturing in the network and resolving CMC and other technical issues for each vaccine, for

which CEPI will need to define its role and determine if it or others should substantively engage and provide technical support. There are felt to be further opportunities to proactively engage organisations with important MSC capabilities, including MNCs. The scope of CEPI's efforts in this space may be linked to the AVMA, which has recently been launched as a multipartner model. Again, during the remainder of CEPI 2.0 it will be important for CEPI to articulate clearly the role it will play in this effort. At a high level, in line with CEPI's existing approach there is considerable support for an approach that works through existing manufacturers to increase their adaptability to respond to different threats than those in which they typically specialise. CEPI playing a role in this area is viewed especially positively where its support can be tied to its R&D investments. This is considered to have lower initial costs and higher chances for sustainability than establishing new facilities.

In the view of the MTR Team, investing in building the capacity of regional manufacturers – and facilitating current and future technology transfer to these manufacturers – can further the objective of equitable access in two related but distinct ways. First, for vaccines against pathogens that primarily pose a threat to specific regions and offer little promise of lucrative markets, such as Lassa or Nipah, regional manufacturers with a primarily regional mandate may provide a more sustainable solution to supply than manufacturers in the Global North, although some source of ongoing subsidy will almost certainly still be required. Second, for vaccines against pathogens with truly global pandemic potential, such as coronaviruses, rapid expansion of total supply in an outbreak is probably the best way to ensure that LMICs get access to vaccines as soon as possible in an environment in which they will be competing against far better-funded HICs. Regional manufacturers, together with established low-cost/high-volume suppliers in India and elsewhere, can contribute to this overall expansion of supply and regional supply security if the necessary capacity and technology transfer arrangements are in place. These two scenarios differ in important ways, and CEPI should differentiate clearly between them in its planning to support regional manufacturing to ensure its support is well designed.

Finding 46: CEPI's equitable access provisions are often cited as a barrier to engaging with R&D partners, notably MNCs, although this is only part of the issue. As introduced above, a number of CEPI staff, governance committee members and industry stakeholders interviewed raised the issue of IP and CEPI's equitable access provisions as being a significant barrier to R&D partners engaging with CEPI. This was often linked to some CfPs not being responded to by as many partners as had been hoped.

This view was not, however, shared by all, for instance with one R&D partner noting that *"[CEPI] contract terms strike a good balance between commercial interests and global health perspectives"*. Another strategic partner noted that *"back in 2018, certain terms and standard contracts were prohibitive for commercial entities to work with [CEPI]. However, I was pleased to see CEPI's attitude change, making the contracts more suitable for commercial partners. There's now flexibility in negotiations with CEPI, which I've found very reasonable. We receive funding from them, and in return we enter certain obligations for equitable access."*

Other stakeholders noted that this is, however, a more significant barrier to CEPI engaging with MNCs rather than smaller biotechs, which are less attracted by CEPI's offer of push funding for product development, especially if this funding comes with strings attached. One CEPI staff member noted that if CEPI were able to influence all R&D funders to adopt similar terms *"it would likely improve our chances of attracting larger partners who may currently be hesitant due to our insistence on equal access."* As above, we note CEPI's contribution to the Pandemic Treaty discussions, its engagement in global PPR forums such as the Global Pandemic

Preparedness Summit, and ongoing discussions with civil society and NIH in this area as positive developments. CEPI's role in this area is generally viewed positively. As one stakeholder noted, *"With support from CEPI and other funders, we can collectively enhance global preparedness."*

In the view of the MTR Team, and as reflected by a senior global health commentator interviewed, although CEPI's approach to equitable access provisions may be part of the problem, the wider issue is that CEPI may not be offering R&D partners a sufficiently large incentive to justify their engagement from a purely commercial perspective. In the absence of combined push and pull incentives at the right scale, it is unlikely that a sufficiently large market for MNC products can be assured at predetermined prices as and when scientific viability and relevance to the market have been proven. Here too, the issues may be quite different for vaccines for pathogens that are unlikely to result in a global pandemic than for those that are, where other well-resourced actors are engaged and markets are substantial. For the former class, with no markets in HICs, access provisions should not be an obstacle unless they potentially compromise control over technology platforms that can be used for other, more lucrative products. For the latter class of vaccines, product developers will be more likely to reject access provisions that might limit their ability to prioritise high-paying markets in HICs.

For products potentially needed in both HICs and LMICs, MNCs in particular may be more willing to engage in supply commitments than commitments to license IP and transfer technology, as shown by Pfizer's and Moderna's (belated) supply of their Covid-19 vaccines to COVAX and, outside the pandemic context, Pfizer's and GSK's willingness to supply pneumococcal vaccines to Gavi. A striking exception to this pattern was AstraZeneca's strategy of tech transfer for its Covid-19 vaccine. Nonetheless, CEPI may consider, in coordination with partners, integrating the use of coordinated push and pull financing mechanisms in select instances across the portfolio.

EQ5.3: What are the main drivers and barriers identified to advance towards strategic objectives? What mechanisms, if any, have been established to address barriers?

Headline findings

There is a range of well-understood barriers to the achievement of CEPI 2.0 strategic objectives. In many cases mechanisms are in place or being designed to address them, although finding comprehensive solutions remains out of reach. The most fundamental barrier which affects all pathogens relates to the lack of a ready market of sufficient size or predictability to justify significant R&D investment by the private sector. Although CEPI's R&D investments are part of the solution, and although it has increasingly focused on downstream issues, including ultimate product demand, this work is in its nascent stages, and there remain many unanswered questions across the portfolio as to how demand will be ensured for the achievement of strategic objectives.

Barriers also relate to the CEPI portfolio's breadth across pathogens but limited number of R&D investments per pathogen and technology platform, as well as the portfolio being comprised of mostly early-stage, low-value projects with small and medium-sized biotech companies, which are high-risk. Other barriers have provided justification for CEPI to engage in a substantive programme of enabling science, regulatory affairs, and MSC interventions. CEPI's challenges in finding partners to support these areas speaks to the wider state of the ecosystem.

Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

This section is based on a thematic analysis of all the data collected and analysed from across the MTR.

Finding 47: There are a range of drivers and barriers to the achievement of CEPI 2.0 strategic objectives. These barriers in many cases relate to assumptions underpinning the CEPI ToC and are often well understood. In many cases mechanisms are in place or are being designed to address them, although finding comprehensive solutions remains out of reach. The most fundamental barrier, which relates to why CEPI was established and which is common across all priority pathogens, relates to the lack of a ready market of sufficient size or predictability to justify significant R&D investment by the private sector (ToC assumption 6). Although CEPI's R&D investments to create vaccine products are part of the solution, and although it has increasingly focused on downstream issues to support a route to market, this work is in its nascent stages, and there remain many unanswered questions across the portfolio as to how demand will be ensured for the achievement of strategic objectives and what CEPI's role should be in stimulating this demand. These questions are more challenging and pressing for some products in later stages of development and which CEPI selected and supported under CEPI 1.0, when the organisation placed less emphasis on these issues.

Issues of market demand, like those related to access, vary by priority pathogen and SRA. For pathogens evolving into a global pandemic, the problem from a product developer perspective is demand uncertainty, because both the timing and the scale of outbreaks are highly unpredictable. As were widely used during the Covid-19 pandemic, one potential solution to this challenge is purchase commitments, but the Covid-19 experience suggests that CEPI (with partners) must consider carefully how and when to deploy this instrument in the face of better-funded competition from HIC agencies. In the view of the MTR Team, purchase commitments or other forms of pull mechanism may also be useful for vaccines primarily needed in LMICs, alongside efforts to build for preventive use, where this is appropriate. It is important to recognise, however, that for many of these products it is unlikely that an economically attractive market can be created. In some cases, perhaps including Lassa, a sustainable market might be possible with ongoing subsidy; in others, a stockpile rather than a sustainable market should be the objective. CEPI has started to advance partnerships and evolve its ways of working in a strategic way to cover these eventualities in a nuanced way across the portfolio.

Other barriers also vary by pathogen and SRA, although there are common themes across aspects of the portfolio. In terms of the CEPI portfolio, although this has evolved in a manner consistent with CEPI's plans, it remains broad but fairly limited in terms of the number of R&D investments made per pathogen and the number of platforms supported within the portfolio for some pathogens (ToC assumption 4). For instance, there are only two vaccine candidates in the portfolio that rely on a single technology platform for RVF and MERS. The Nipah portfolio is also small, with no preclinical candidates reported and with limited platform diversity among existing candidates. The portfolio is also mostly comprised of early-stage, low-value projects with small and medium-sized biotech companies. These projects are high-risk and have limited ability to scale up quickly, which in part explains the reported underspend in the early part of CEPI 2.0 and the organisation's inability to significantly increase spending without undergoing reprioritisation exercises (ToC assumption 5). Given that opportunities to expand the portfolio – both in number and for later-stage vaccine candidates – are limited, CEPI has employed a tactical approach to reduce development risks in a number of areas, such as by making R&D investments in products that share viral vector modalities with other existing products (e.g. for the IAVI Lassa fever vaccine candidate), through technology platform strengthening, and through exploring the potential to employ these platforms for priority pathogens (e.g. mRNA for Lassa fever). As and when CEPI's portfolio does shift towards later-stage development, the complexity of issues that it will need to deal with will increase exponentially.

Many regulatory issues challenge CEPI's ability to ensure that its R&D investments reach licensure, and CEPI's Regulatory Affairs Team engage across the CEPI portfolio to ensure that regulatory strategies are put into place and are communicated to regulators early on in the development pathway, to maximise the chances of success. CEPI's work in this area also extends to catalysing ecosystem strengthening through its work with regulators worldwide, identifying and helping to overcome regulatory challenges and supporting efforts to align regulatory requirements (ToC assumption 8). In particular, stakeholders commented on the need for regional regulatory development and harmonisation, notably across Africa, to reduce time-consuming and expensive registration processes in support of equitable access. A number of stakeholders referred to the substantial benefit regulatory harmonisation could have in the event of a future pandemic caused by a novel threat. CEPI's role in this area is highly valued: "The [CEPI] regulatory team has been instrumental in convening support for Chikungunya across regions like Brazil and Southeast Asia, ensuring alignment on regulatory pathways for vaccine licensure." It is though a work in progress, with further coordination among stakeholders at global, regional and national levels to address regulatory and trust aspects of vaccine development. The JCG and Regulatory Advisory Group established for COVAX are viewed as important mechanisms to do this. CEPI's recent MOU with PAHO includes a focus on collaboration on regulatory pathways.

Various challenges relate to the manufacturing of licensed products, including finding the right partners with appropriate capacities, addressing CMC and other technical issues for each vaccine (ToC assumptions 8 and 11), and working in a way that can build sustainable capacity that works to support equitable access objectives in the event of a future pandemic (ToC assumption 9). CEPI's approach is to simultaneously support manufacturing innovations and build a global manufacturing network to accelerate vaccine production in the event of an outbreak. Although partners have been selected, the work is at an early stage, and with many challenges related to realising the benefits of such a network.

Other barriers exist for each of CEPI's priority pathogens and individual vaccine candidates, and these often call for investments in enabling science. CEPI has usually adopted a flexible yet targeted approach to addressing these barriers as they have been identified, and increasingly even when the benefits of doing so may not be felt for some time (ToC assumption 3).[31] As noted elsewhere, this is the source of some difference of opinion in terms of whether and how far CEPI should engage to address issues beyond R&D development. CEPI's difficulty in structuring clear hand-offs to others within an end-to-end approach speaks to the state of the ecosystem, in terms of it constantly evolution and the considerable gaps that still remain, even with the emergence and strengthened presence of regional entities and other agencies.

As also noted elsewhere, there are also operational challenges that may constrain CEPI's ability to achieve the CEPI 2.0 strategic objectives related to the capability, culture and practices of the CEPI Management Team; a number of key informants indicated that these were a greater impediment to programme progress than the pace of science. Of particular importance are the implications that these challenges present for the agility of management, the speed of internal decision making on upstream scientific initiatives and downstream readiness and the ability for

[31] There is evidence of enabling science activities not being bound by stage gate reviews and being designed to tackle issues further along the development pathway, for instance in preparation for manufacturing and ensuring access to products that are still some way off licensure.

interdepartmental and multidisciplinary collaboration, which are critical to outbreak response and to achieve the 100 Days Mission (ToC assumptions 16 and 18).

3.3. Workstream C: Impact

3.3.1. Introduction

This workstream is focused on the DAC evaluation criterion of impact. The focus of this MTR is to evaluate the CEPI 2.0 results achieved thus far and assess the plausibility of the overall strategic objectives and other KPI targets being achieved by the end of the CEPI 2.0 period (2026). Progress is presented on a four-point scale, based on the likelihood that the target milestones will be achieved:

1. **high risk, not on track, no plausible expectation of course correction**
2. **medium risk, not on track, plausible expectation of course correction**
3. **low risk, on track, with risk mitigation plans in place**
4. **on track, low to no risk, high likelihood of attainment**

This workstream also explores CEPI's added value.

3.3.2. Findings

EQ6: What is the plausibility of CEPI meeting its strategic objective and outputs/targets for 2.0?	
Headline findings	There has been substantial programmatic progress across many areas of the CEPI 2.0 Strategy and towards the strategic objectives. However, many of the KPI targets are unlikely to be attained by 2026. This reflects both slow programmatic progress in some areas of the strategy and the fact that the KPIs themselves are poorly defined and with overly optimistic targets (see Finding 17).
Evidence strength	**2:** Evidence comprises multiple good-quality data sources, although the absence of detailed project-level data limited the extent to which efficiency and effectiveness could be analysed to triangulate with CEPI KPI and portfolio-wide reporting through Annual Portfolio Reviews. Limitations affected the strength of evidence such as the evaluators being provided with guided access to the internal Salesforce or Investor Management System (IMS) portals which limited the level of analysis that could take place. Screenshots were provided on request, but the team was not able to access any systematic reporting of project-level progress in relation to annual and CEPI 2.0 milestones and objectives. Due to substantial resource constraints (time and capacity within the team), project-level staff were not interviewed which is likely to have limited the depth of our understanding on project progress. However, the team is confident that the evidence collected and analysed is sufficient to formulate sound conclusions and actionable recommendations.

Finding 48: Most strategic objectives, if measured against the KPI targets established at the beginning of the 2.0 period, are unlikely to be attained by 2026, although substantial progress has been made towards them. Analysis of KPI achievement is structured by strategic objective; for additional detail on progress made against output KPIs, please see Annex 5.9.

Overall, much progress has been made against Strategic Objective 1, to prepare for known epidemic and pandemic threats. With the acute phase of the Covid-19 pandemic ending, CEPI's investments across its portfolio have promoted the development of priority pathogen vaccines and have contributed to reducing the risks of further coronavirus pandemics.

- **1.1: Acute phase of the Covid-19 pandemic ended.** The overall outcome has been attained, with WHO declaring the end of the international public health emergency in June 2023. The KPI is focused on at least two SARS-CoV-2 vaccines favourable for LMICs being available for use by the end of 2022. This was achieved, with CEPI playing a critical role in advancing seven vaccines, two of which were favourable for LMICs (the SK bioscience and Clover vaccines) and available to COVAX in 2022.
- **1.2: Development of vaccines and other biologic countermeasures against known high-risk pathogens accelerated.** As documented in Section 0, substantial progress has been made in the development of vaccines for CEPI's priority pathogens. However, this KPI targets priority pathogen vaccines ready for use by the end of 2026, which is highly ambitious:
  - **At least two vaccines reaching licensure for two or more priority pathogens, including at least one WHO pre-qualification.** Although development progress is being made for many vaccine candidates in the CEPI portfolio, none is expected to reach licensure by the end of 2026. This view is shared by both internal CEPI staff and R&D partners. Although licensure workshops for Lassa have been held, and Nipah is reportedly the closest pathogen to achieving this target, CEPI staff and R&D partners interviewed reported that Nipah licensure is unlikely to occur within the life cycle of CEPI 2.0.
  - **At least two monoclonal antibodies for two priority pathogens ready to use under outbreak conditions.** Currently, only one pathogen (Nipah) has initiated a monoclonal antibody to date, with plans to enter Phase I clinical trials in 2024. It is noted that the Board has not endorsed further investments for monoclonal antibodies.
- **1.3: Risk of further coronavirus pandemics reduced.** As highlighted throughout the report, CEPI has supported a range of work to enable the achievement of this objective. In relation to the KPI (two CEPI-funded BPBC vaccines, favourable for LMICs, assessed for clinical proof of concept), progress has not been as expected and CEPI has changed strategy. The portfolio is comprised of 11 candidates, with 10 in preclinical development and one in Phase I trials. However, this candidate has not met the milestone definition for "proof of concept", i.e. completion of Phase I clinical development. Although the initial focus was on broadly protective SARS-CoV-2 and betacoronavirus, CEPI's efforts in this area have now shifted to sarbecovirus, to reduce product development risk (as opposed to a broadly protective vaccine), because this approach allows CEPI to leverage scientific knowledge gained through Covid-19 and viral genetic relationships. This approach is still expected to maintain the potential for positive public health impact in the event of another outbreak of coronavirus disease. This decision was made following outcomes of the April 2023 SAC and August 2023 governance review.

Overall, some progress has been made against Strategic Objective 2 to transform the response to the next novel threat, albeit with work delayed in some areas and further progress required.

- **2.1: Vaccine prototype and platform innovations used to give a head start on novel threats.** As documented in Section 0, substantial progress has been made in the development of vaccine prototype and platform innovations. However, the targets (by the end of 2026) for the related KPI (focused on the number of CEPI-funded innovations that can be rapidly adapted against unknown pathogens) are highly ambitious:
    - **Two licensed vaccines against viable targets for LMICs using prototype and/or platform innovations.** Seven new platform technology innovation projects were onboarded in 2023, bringing the total to eight prototype vaccines in development. However, this work is in early stages, and according to CEPI's 2023 programmatic report it is unlikely that the KPI target will be achieved by the end of 2026. The most advanced candidate, for Lassa fever, has made substantial R&D progress and is currently in Phase IIa development trials, which is expected to proceed to Phase III trials after 2026.
    - **Clinical proof of concept for four virus family vaccine libraries.** As of the end of 2023, CEPI had three ongoing vaccine virus library candidates (Lassa, Junin and Mpox), with antigen design work complete or nearing completion. However, the target of having clinical proof of concept for these virus family vaccine libraries will be difficult to attain by 2026, partly because of delays to the start of the programme. With critical immunogen design partnerships now in place, CEPI expects this work to ramp up in 2024.
- **2.2: Enabling sciences scaled to further accelerate vaccine development.** CEPI is on track to meeting this target. Within the first two and a half years of the 2.0 Strategy, enabling science programmes and innovative tools are being actively used by CEPI-funded developers to further accelerate vaccine development. These include antibody standards and antigens for Lassa, MERS and SARS-CoV-2, and a growing central laboratory network (made up of more than 20 developers). Similarly, CEPI is filling significant gaps that previously existed in animal model development. Prevalence and incidence data from the ENABLE Lassa fever research programme (launched prior to 2.0) has captured burden of disease information for Lassa virus across five West African countries and is being directly utilised by Lassa vaccine developers to inform clinical trial design.
- **2.3: Vaccine manufacturing transformed.** The KPI aims to see "At least three innovations which demonstrate manufacturing cheaper, faster, or closer to an outbreak". Seven manufacturing innovation projects were signed as at the end of 2023, although this work is at an early stage and there is not yet evidence to demonstrate the desired results. However, reports of the MSC Division to the Board indicate that CEPI is on track to have at least three innovations demonstrating technical proof of concept for thermostability, speed, scale and access by 2026.

Progress has also been made against Strategic Objective 3 to connect stakeholders and experts in EIDs to enable rapid countermeasure development, effective response and equitable access for those in need.

- **3.1: Financing for epidemic preparedness and response secured.** The KPI targets in this area relate to the implementation of new financing mechanisms, including funding for vaccines and other biologic countermeasures, preparedness and response R&D by 2023. This has been achieved through CEPI's work to support the G20 Joint Finance and Health Taskforce and with the establishment of the Pandemic Fund. Second, CEPI aims to have dedicated funding for vaccine and other biologic countermeasures, preparedness and

response R&D by the end of 2025. As of December 2023, CEPI had received $2.6 billion in commitment towards CEPI 2.0, although this remains well below the target of $3.5 billion, and several stakeholders have commented on the global deprioritisation of PPR in recent years. As such, this KPI target is considered to be off track at the midpoint of CEPI 2.0 but with risk mitigation plans in place.

- **3.2: Coordination among key stakeholders enables system readiness.** [32] The KPI is focused on alignment of key elements of a targeted ecosystem to accelerate development and promote equitable access of EID countermeasures. As highlighted above, CEPI has played an active coordination role in much of its work with key stakeholders to ensure equitable access and support system readiness, including through the JCG and various other forums. However, the ecosystem in which CEPI operates remains highly dynamic and fragile, and CEPI still faces substantial challenges in identifying and putting in place appropriate hand-offs to partners as part of a strong end-to-end approach for its supported products.
- **3.3: Equitable access principles as the foundation of any effective response.** As documented in Section 0, CEPI has considerably advanced its approach towards ensuring equitable access. The KPI targets are focused on:
    - **Removing at least one key systemic obstacle (such as pricing, thermostability and right of first refusal) to access for LMICs.** CEPI is one of the few organisations with a role in explicitly pursuing this objective. Work in this area has included: sharing information and data during health emergencies; contributing to the Pandemic Treaty; influencing access policies in the wider ecosystem, such as via advocacy for the inclusion of equitable access provisions in out licensing agreements for IP, including with NIH; and global governance dialogues (e.g. G7 and G20). CEPI is also supporting globally diversified manufacturing capabilities through partnerships and hosting the Secretariat of the RVMC. No evidence was found to conclude that a systematic obstacle to LMIC equitable access has been completely removed; but a rating of on track, with risk mitigation plans in place, is felt to be appropriate.
    - **Guidance available to address potential injuries caused by vaccines/to establish a no-fault compensation mechanism.** By end-2022, CEPI had reviewed the COVAX No Fault Compensation Programme. In consultation with WHO, CEPI began developing a similar scheme to cover other vaccines and diseases, incorporating lessons learned from COVAX. With additional effort prior to the end of 2026, it is likely that CEPI will have developed relevant and appropriate guidance on this issue.
    - **Three G20 countries making new funding and/or procurement commitment for vaccines development include reference to access provisions.** CEPI has continued to broaden the G20 Joint Finance and Health Taskforce to ensure that adequate surge financing mechanisms are in place, in addition to including greater representation from Global South participants. In 2023, CEPI secured additional funding, including

[32] The 2023 milestones for this KPI relate to (a) articulation of key elements of the future target ecosystem and (b) clarification of CEPI's role through partnership agreements. The 2026 target relates to RACI(s) for 80% of key elements in place. The target measures for this KPI are widely considered to be meaningless and impossible to measure. As such, our assessment of progress and plausibility is based on a qualitative assessment of the extent which there is adequate alignment on key elements of a target ecosystem to accelerate development and promote equitable access.

CAD 80 million from Canada and $100 million from the US, in addition to the conversion of a €35 million pledge by the European Commission to a contribution agreement. However, collated evidence does not indicate the extent to which any of these commitments included references to access provisions. CEPI's work to advocate for the inclusion of equitable access provisions in out licensing agreements for IP is, however, showing promise.

Finding 49: CEPI adds considerable value to the R&D&M ecosystem in a range of ways. Almost all stakeholders interviewed shared this view but provided different justifications for it that related to CEPI's role as a funder as well as its role in advocacy and catalysing the actions of others within the ecosystem (which one senior global health stakeholder engaged in CEPI's governance considered to be more functional owing to CEPI's active engagement in it).

A majority of interviewees noted that CEPI's added value stems from its unique focus on R&D and equitable access for vaccines against EIDs and from having a strong portfolio of investments to make demonstrable product development progress in a short time frame. Its focus and successes to date on Lassa fever, Nipah and Chikungunya were viewed by donors, civil society and R&D partners to represent a unique and important value-add. Multiple R&D partners suggested that CEPI's value-add extended, beyond just the R&D progress, to their business growth, or even in some cases to their survival. A range of stakeholders outside of the CEPI Management Team reflected that R&D is CEPI's niche and is where CEPI's expertise and efforts should be concentrated, rather than pursuing a broad agenda to address downstream issues that may detract from this role. The focus on Disease X and platform technology development was, however, considered to be an area of very high potential value being pursued through CEPI 2.0.

However, a range of other stakeholders, including CEPI staff, governance committee members and external stakeholders, pointed to a host of examples of CEPI adding value in the R&D&M ecosystem in working to address issues beyond those related directly to its R&D portfolio. This included examples from CEPI's active engagement at the United Nations General Assembly (UNGA), the World Vaccine Congress and technical summits, its positioning and soft power to leverage other countries and agencies to create an entrepreneurial environment to stimulate innovation in the sector, and its promotion of and support for Global South manufacturing capacity development.

A common thread among these examples relates to the sector experience and deep technical expertise of CEPI staff, which several stakeholders (internal and external to CEPI) reflected was much stronger than for other agencies working in this space. This had enabled, for instance, substantial progress to be made in addressing regulatory barriers to vaccine introduction and in progressing conversations towards regulatory harmonisation, which other agencies would not have been able to advance, as highlighted by several key informants representing CEPI's management and Board. CEPI's work in MSC, particularly its support for innovation, was also felt to be adding significant value. Work to establish a manufacturing network is nascent and is an area of divergent opinion on what CEPI's role should be.

Despite these divergent viewpoints, all stakeholders agreed that CEPI had played an important and value-adding role during the Covid-19 pandemic, in which CEPI worked well beyond its core R&D focus under CEPI 1.0 to address a wide range of downstream issues to ensure equitable access. In the view of the MTR Team, and as suggested by a few key informants, there is a credible argument that suggests that CEPI's continued role in these areas under CEPI 2.0 will better position the organisation to deal with the next pandemic as and when it arises.

3.4. Workstream D: Learning

3.4.1. Introduction

The achievement of CEPI 2.0 strategic objectives requires CEPI to prioritise the identification and sharing of learning as part of its ways of working. This workstream is focused on understanding the extent to which a strong learning culture exists within CEPI and the key learnings that have been identified to date.

3.4.2. Findings

EQ7: What lessons can be drawn with respect to design, implementation and interim results that should or could lead to refining CEPI's Theory of Change, results framework, indicators or operations moving forward?

Headline findings	There is mixed evidence on the extent to which CEPI has a strong learning culture. Although a range of monitoring and review processes takes place, there appears to be a lack of critical analysis and learning generated. It is also unclear whether adequate systems and processes are in place to support cross-team collaboration and learning, which many stakeholders described as weak. The key learnings from CEPI 2.0 identified by the MTR fundamentally relate to the challenges associated with adopting and implementing a new strategy, especially one that represents such a radical strategic shift as CEPI 2.0 and that requires enhanced operational capacities to deliver.
Evidence strength	**1:** Evidence comprises multiple good-quality data sources which have been triangulated to derive the findings.

Finding 50: There is mixed evidence on the extent to which CEPI has a strong learning culture. As highlighted above, many monitoring and review processes take place internally, often to inform governance requirements and to facilitate reflection on progress and issues encountered, but these largely lack critical analysis of why identified issues have arisen, what CEPI has done well and less well, what CEPI can and cannot do differently, and what the trade-offs would be if CEPI were to engage in a different manner. Several CEPI staff noted that this does happen within the organisation but to varying extents across teams, with one noting that it is stronger for PPR, where after-action review processes are common. It is also unclear whether discontinued projects are systematically reviewed and learnings generated. Other staff noted that it can be challenging to focus on reflective activities alongside a busy day job. There are some positive examples in R&D, for instance in relation to MERS, where learnings from earlier investments were used to speed up Covid-19 vaccine development and are now being applied to BPCV.

However, several emerging issues across the portfolio call for a high level of cross-team collaboration and learning, and it is unclear whether adequate systems and processes are in place to support this. For example, as CEPI continues to learn about how to engage partners and make progress towards results across the strategy, much can be learned from the previous experiences of CEPI and other funders of biological countermeasures. There are many other areas of work that also warrant focused learning, for instance to integrate the learnings from the Lassa experience of engaging with regulators and the application of the Lassa enabling science programme across other antigen programmes, and also with regard to biosecurity,

which will be a cross-cutting issue across the portfolio. Multiple staff referred to cross-functional wash-up sessions as being an appropriate forum to capture learning but suggested the need to improve them for this purpose.

The key learnings from CEPI 2.0 identified by the MTR are as follows:

Learning 1: Within a high-level strategy setting out a grand vision, such as CEPI 2.0, there is a need for clear objectives by programmatic area (e.g. pathogen/SRA) and well-defined roles and hand-offs to other agencies required to contribute as part of an end-to-end approach. Evidence collected for this MTR suggests that the grand vision set out by CEPI 2.0 and the 100 Days Mission was effective as a tool to gain political support and financial resources for the organisation and for PPR. However, the lack of robust planning to underpin CEPI 2.0 at its outset caused delays while the details of how to operationalise the strategy were formalised. Many stakeholders interviewed also referred to challenges stemming from a lack of clarity as to how CEPI's investments in different areas, responding to different areas of CEPI 2.0, aligned to each other and built towards a common, holistic objective. Stakeholders also referred to a lack of clarity on where CEPI's role started and finished, referencing uncertainty over how CEPI should engage with partners to assume responsibility for certain issues as part of an end-to-end approach. It is acknowledged that not all of these issues were fully understood and that they could not have been addressed in 2021 as CEPI 2.0 was developed.

Learning 2: The uncertainty associated with fundraising within the strategic period is not conducive to planning and strategy operationalisation. The main fundraising activity for CEPI 2.0 took place at, and in the run-up to, the Global Pandemic Preparedness Summit, which was held in March 2022 – already three months into the CEPI 2.0 implementation period. Although an interim budget for the first half of 2022 had been agreed in late 2021, this created uncertainty over the programme of work for CEPI 2.0 from the outset. Had the full $3.5 billion requested been successfully raised, this timing may not have presented an issue. However, given that only $1.5 billion was initially raised (a little more than $2 billion had been raised by July 2024 against a revised target of $2.6 billion), this triggered the first of a series of portfolio reprioritisation processes, which are still ongoing. Had the fundraising activity happened sooner, this would in all likelihood have enabled portfolio prioritisation to have taken place prior to the CEPI 2.0 implementation period starting.

Learning 3: A new strategy that involves a substantial expansion in the organisation's role takes time to operationalise. Expectations for CEPI 2.0, especially in the short term, were unrealistic. Expectations for CEPI 2.0 were set very high, with high-level operational plans based on projects with unrealistic timelines and frontloaded budgets. Initiating CEPI 2.0 in the middle of the Covid-19 pandemic also meant that the timelines, programmatic ambitions and financial spending forecasts were unrealistic and fed the ongoing need for portfolio reprioritisation.

Learning 4: Monitoring progress towards strategic objectives, including through KPIs, can usefully inform decision making, but there is a need to focus on what is important. There is increasing recognition of the need to adopt an end-to-end approach to ensure that upstream vaccine development investments lead to equitable access and the achievement of strategic objectives. Some of the investments made in CEPI 1.0, for instance in the Lassa programme, have encountered issues in late-stage development that could have been identified and remedied earlier and in a more systematic manner. This also speaks to the importance of measuring what is important, both in terms of R&D development and also along the roadmap towards equitable access. The latter may enable CEPI to better demonstrate where and how its investments in enabling science, CMC, manufacturing, regulatory work, and ensuring vaccine

demand contribute to the overall objective, even where this is unlikely to be achieved for some time.

Learning 5: As CEPI's Management Team expands and necessarily seeks to standardise and systematise processes and ways of working, it is challenging to retain the organisation's DNA, notably its agility and ability to rapidly respond to issues as they emerge. As noted above, CEPI is recognised externally as an agile organisation, based on its response to the Covid-19 pandemic. But CEPI has grown dramatically, making an informal, consensus-based decision-making model less effective, and necessitating more structured systems, processes and ways of working. Evidence suggests that the organisation is on the right track towards strengthening internal operations, but some raised a concern as to whether CEPI could do this while maintaining its agility and responsiveness. Others noted the importance of avoiding policies and processes that are overly sophisticated or rigid, which may stifle decision making and flexibility. This may be an area where a well-designed monitoring and KPI framework, with business owners responsible for the achievement of specific targets, can be used to embed a culture of performance accountability that also links to decision-making authorities to enable agility in the manner desired.

4. Conclusions

In the midst of the Covid-19 pandemic, CEPI 2.0 and, later, the 100 Days Mission helped to galvanise global commitment to CEPI's mission: 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. However, Covid-19 and CEPI 2.0 pose a range of very challenging issues for CEPI to deal with. This fundamentally relates to an expansion of CEPI's role and scope beyond R&D development to Phase II to include licensure and the full suite of downstream issues that affect equitable access, including manufacturing and ecosystem strengthening. It also critically relates to the increased level of emphasis placed on Disease X and pandemic preparedness, for which other R&D funders, including agencies of HIC governments, are active and where the issues surrounding product development and equitable access are very different than for CEPI's priority pathogens. CEPI has made good progress in addressing the implications of this strategic shift, notably through the EAF and its evolving work to define pathogen and partner archetypes to guide ways of working across the portfolio. However, this has taken time, and there remain divergent opinions as to what CEPI's role should be and how it should engage with other partners as part of an end-to-end approach. It is also evident that some issues still need to be worked through, for instance in relation to how manufacturing capacity is built sustainably and how this can be deployed for outbreak response.

The process tracing methodology employed to assess causal inference has not been able to confidently validate the contribution claim that CEPI's actions and activities are being implemented as intended and that the assumptions underpinning the ToC are working as intended to achieve the desired outcomes and strategic objectives. To do so would, notably, require further evidence of timely investments being made and progress towards outputs, outcomes and strategic objectives. The evidence collected and analysed through the MTR suggests that much programmatic progress has been made, providing an encouraging signal that the contribution claim could be validated at a later date, but potentially after the CEPI 2.0 period. The justification for this statement and the primary reasons for a lack of progress to date are articulated below.

Planning for CEPI 2.0 was inadequate, in part due to taking place during a pandemic and also because fundraising took place within the implementation period; this has contributed to a disconnect between the technical progress that CEPI is making, which is not always well understood, and the level of ambition that stakeholders expect of CEPI in terms of both spending and programmatic progress. For instance, with Lassa fever strong programmatic progress has been made but product licensure within the CEPI 2.0 period is expected by some stakeholders, despite this being unattainable. The context has also evolved substantially since CEPI 2.0 was developed, as have CEPI's ways of working in response to its expanded role, which is not fully captured in the strategy.

Alongside this, and given that many programmatic targets were not technically evaluated for feasibility, which was challenging to do given the novelty of CEPI 2.0 and that it was designed in the middle of a pandemic response, it suggests the need for a comprehensive clarification of:

- CEPI's strategy to clarify CEPI objectives by pathogen and SRA, as well as CEPI's role vis-à-vis others across the portfolio
- CEPI's ToC to accurately reflect its current portfolio of work, realistic outcomes, structure and ways of working

- spending expectations
- programmatic KPIs and targets
- how CEPI 2.0 will lead into a new strategic period with surplus resources and an unfinished agenda from CEPI 2.0 and the 100 Days Mission.

Strategy operationalisation has been severely challenged for a range of reasons linked to Covid-19, the timing of fundraising, the need to radically shift approach, and an almost constant cycle of reprioritisation which ensued after a slow start to the CEPI 2.0 period. These issues relate fundamentally, although not exclusively, to the operational capacity within the Management Team, which has been strained by the effort required to implement CEPI 2.0. There are high expectations for the reorganisation and plans to recruit additional senior leaders to the Management Team, although it remains to be seen whether this will be sufficient to strengthen capacity for the effective execution of CEPI 2.0 in the remainder of 2024–26.

Strategy operationalisation has also been challenged by a difficult operating environment, notably linked to Covid-19 (both its acute phase and as the emergency response was wound down), ongoing electoral political uncertainty which may substantially change global policy priorities, fiscal constraints, and a rapidly evolving multilateral and regional landscape for PPR.

Although spending and implementation progress has been slower than anticipated in some areas, notably when measured against the CEPI 2.0 budget, substantial programmatic progress has been made in the CEPI 2.0 period. This progress has built effectively on the R&D advances made under CEPI 1.0, with further R&D progress and advances within an end-to-end approach for the achievement of equitable access. Notable achievements include:

- the registration of seven Covid-19/SARS-CoV2 vaccines supported by CEPI, two of which were programmatically suitable for LMICs
- the rapid advancement of a broad set of BPCV candidates, including one to Phase II development
- learnings from prior MERS investments being used to speed up vaccine development for Covid-19 vaccine development, although further vaccine development has been slow
- initiation of Phase II trials for Lassa fever, although progress has been slower than hoped for, and efforts to reduce development risk, including by evaluating the potential to employ an mRNA platform for Lassa
- the conclusion of Phase I trials for two Nipah vaccine candidates, with one of these ready to start Phase II, as well as initiation of a project for a monoclonal antibody for Nipah, with plans to enter Phase I in 2024 (the basis of a therapeutic/preventive bridging strategy for disease control)
- advancement of plans to adapt a licensed Chikungunya vaccine to ensure it is accessible to LMICs and for a broader age range
- development of two vaccine candidates for RVF, one of which is now in Phase I
- expansion of the manufacturing network and initiation of several innovation projects
- establishment of other laboratory, clinical and regulatory networks to strengthen global preparedness and response.

These achievements demonstrate CEPI's ability to select and support strong R&D partners, subject to some attrition and with a commitment to keep learning in this area, and to advance

vaccine candidates for priority pathogens and manufacturing where there is significant unmet need. CEPI's work on rapid response technologies and under the Disease X programme continues to show promise, but progress has not been as quick as expected.

In line with the scope of CEPI 2.0, CEPI has also embarked upon, and in many cases has made significant progress in, advancing its agenda for enabling science. Although it has done so without a complete and coherent understanding of where CEPI can and is best placed to fit into the wider ecosystem of actors active in this space – and, as outlined above, CEPI's role in this area is the source of some debate – in many instances its investments have been critical to making both R&D progress and overcoming other hurdles to ensuring equitable access.

CEPI has reaffirmed its commitment to equitable access through development decisions, publication of the EAF, and implementation efforts during CEPI 2.0. For example, the BPBC programme engages the California Institute of Technology and other partners to develop a low-cost thermostable vaccine; the agreement with FIND to develop a diagnostic test for Lassa fever includes equitable access provisions; and there is the CEPI manufacturing network with partners located in the Global South. These achievements constitute notable progress. However, CEPI is yet to complete a comprehensive review of the access provisions for late-stage programmes. In the event of another pandemic, access agreements will need to withstand the formidable economic and political forces that manifested during the Covid-19 pandemic.

A key strength of the CEPI portfolio is its focus on preventive vaccines for multiple pathogens and the opportunity that this provides for technologies and related science to be applied across programmes and for Disease X in support of the 100 Days Mission. There is good evidence that CEPI has capitalised on these commonalities, for example mRNA and ChAdOx viral vector platform technologies were rapidly brought to commercial stage during the Covid-19 pandemic, the latter in large part due to CEPI's support, and these platforms are now being used to develop vaccines for Disease X and Lassa. Enabling science from MERS has also been useful in the Covid-19 and BPBC programmes. However, ensuring technological alignment across a diverse portfolio that is formed iteratively and that promotes innovation affecting other parts of the portfolio will remain a challenge. Regular reviews and end-to-end planning to promote such alignment and ensure a 'line of sight' between early stage and downstream activities for each programme may be beneficial. It should though be noted that although many further opportunities for shared benefit exist across programmes, ultimately much of the progress on an individual programme relies on efforts specific to that vaccine or pathogen. Another challenge of the portfolio is its sheer complexity, which is further magnified by access commitments and cross-cutting issues such as biosecurity, which, albeit important, place a substantial burden on internal staff and partners. This complexity will increase substantially as the portfolio matures and CEPI engages more substantively in activities related to late-stage development, licensure and vaccine deployment. CEPI's ability to structure clear 'hand-offs' to partners will become especially important at this juncture.

CEPI's work to coordinate and collaborate with industry, R&D funders, regional partners, country governments and regulatory bodies, as well as through its participation in all manner of global forums (e.g. G7, G20, UNGA), demonstrates the high esteem in which the organisation is held, and the significant soft power it has cultivated within the global health architecture. This has been used to good effect in a number of areas to promote global and regional models for regulatory alignment and PPR and to promote the need for and benefits of CEPI-supported vaccines when they reach the market (e.g. for Lassa fever). There is also emerging evidence that CEPI's work in support of the Pandemic Treaty, global PPR forums such as the Global Pandemic Preparedness

Summit, and work with individual partners such as NIH to promote equitable access principles as the foundation for a future global response, linked to the presence of a manufacturing network. Such work is important to CEPI clarifying its role in such a global response vis-à-vis other actors, notably HIC agencies with far greater resources.

CEPI faces several fundamental challenges to achieving its 2.0 strategic objectives. First, as noted above, its vastly expanded role has strained its capacities and resources and, despite ongoing efforts to prioritise its many programmes, it is not clear that it has yet managed to define a feasible set of core activities.

Second, and related to this, it has not yet fully clarified its role relative to other actors in PPR. In order to fulfil its LMIC-focused mission, there is a need for more explicit differentiation of CEPI's role across pathogens, which involve a mix of early and late stage R&D investments, pose outbreak threats of different types and different levels of market demand and demand certainty, and have quite different sets of active partners which CEPI can work alongside as part of an end-to-end approach (which the pathogen and partner archetypes works acknowledges). This should include clarifying its approach to ensuring LMIC access in the event of a global pandemic in which LMICs and agencies acting on their behalf find themselves competing for vaccine doses with better funded HIC buyers and in which CEPI may have more limited leverage over manufacturers of leading vaccines.

Third, although its overall R&D portfolio is broad, it has relatively few investments and candidates in each of its vaccine programmes, leading to high development risk. CEPI is seeking to address this by reducing reliance on single technology platforms and leveraging R&D developments for other products to the extent possible.

Fourth, its vaccine development programmes continue to rely primarily on small and medium-sized biotechs, which may not have the expertise or capacity needed for later-stage R&D, regulatory approval, and manufacturing at scale. CEPI has struggled to date to engage with the MNCs who have this expertise, notably as the interests of these companies (which are highly variable) and the terms on which they may be willing to engage with CEPI are, in general, quite different from those of the smaller biotechs on which CEPI has primarily relied to date. This constraint can be addressed in part, but probably not through CEPI's partnerships with manufacturers in the Global South.

Finally, for some of its programmes addressing pathogens primarily posing a threat to specific regions, demand and its implications for vaccine use and sustainable supply are not yet well understood. CEPI and its partners have expanded their efforts to address this challenge as part of its strengthened end-to-end approach, although such work will require considerable continued effort for the remainder of CEPI 2.0.

At the midpoint in the CEPI 2.0 strategic period, and in a challenging operating environment, there are now some difficult choices to be made by the CEPI Management Team and the Board in relation to the breadth and scope of CEPI's activity and how to scale up CEPI's level of spending and programmatic activity to address the above-noted challenges and meet stakeholder expectations and the CEPI 2.0 strategic objectives.

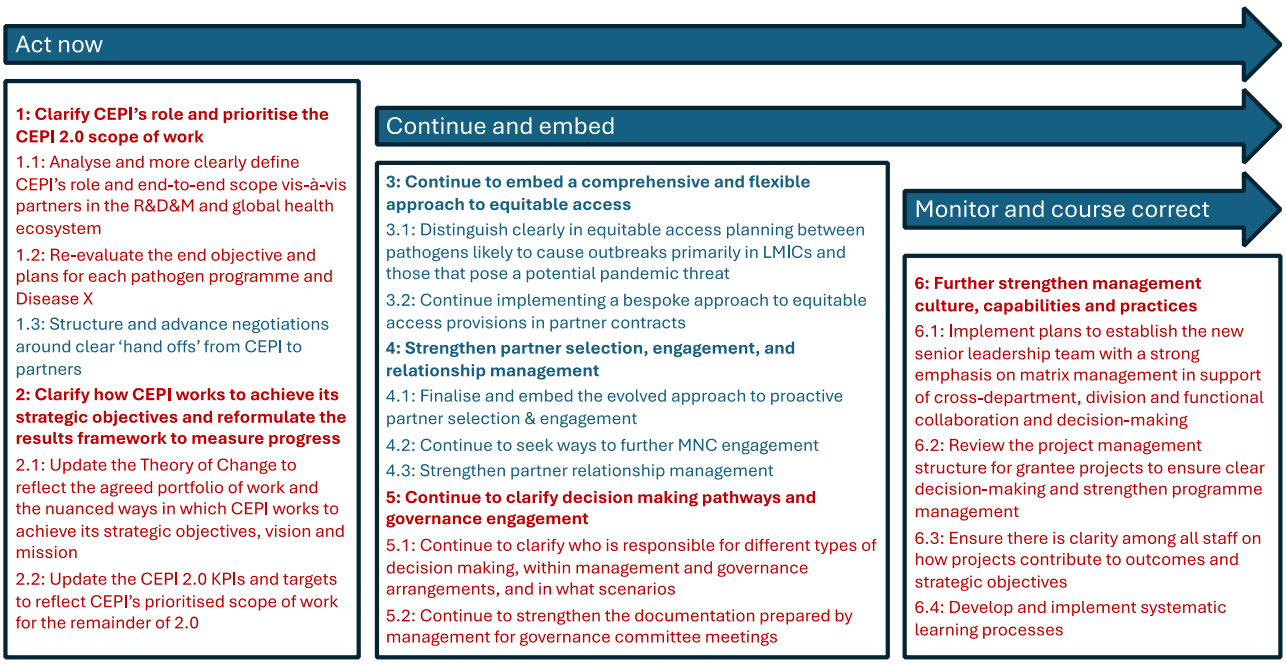
5. Recommendations

This section presents the MTR recommendations, which have been developed by the MTR Team based on the findings and conclusions, with input from the CEPI Management Team. Specifically, following submission of the Final Report, the MTR Team facilitated a workshop with senior

members of the CEPI Management Team to discuss the priority MTR findings and conclusions, the general areas for recommendations as well as specific high-level recommendations developed by the MTR Team. The CEPI Management Team provided inputs to ensure that recommendations were fit-for-purpose, feasible and actionable. This input has been used by the MTR Team to frame the recommendations presented below. As such, while the recommendations are those of the MTR Team, it is intended that they also reflect the inputs of the primary MTR users.

Recommendations under the first four areas are mutually supportive of each other and structured to provide a suggested chronological sequence of actions. Recommendations in areas five and six are designed to enable actions in response to other recommendations and wider CEPI 2.0 Strategy operationalisation.

The recommendations can be grouped into three categories, as summarized in the diagram below. The red recommendations are, in the view of the MTR Team, the most time critical recommendations to address to advance CEPI 2.0 Strategy operationalisation.



Recommendations area 1: Clarify CEPI's role and prioritise the CEPI 2.0 scope of work

Recommendation 1.1 (Act now): Analyse and more clearly define CEPI's role and end-to-end scope vis-à-vis partners in the R&D&M and global health ecosystem to enable a clear view of the areas of overlap, gaps, strengths, and commitment to equitable access. The primary objective of this analysis is to facilitate strategic decisions about where and how CEPI should act within an end-to-end approach to most efficiently and effectively achieve its strategic objectives, delineating between an active funding role, a catalytic role, and an advocacy role.

Secondarily, this recommendation is intended to inform decisions about strengthening the partner model (explored further under recommendations area 4). Although respective roles in the ecosystem have historically been understood in a general way, and work to advance this in more detail (e.g. through xVAX) has been challenging, the global health ecosystem has been affected by the demands of the pandemic while strategic cycles and leadership changes have

also had an impact on partner priorities. This recommendation is aimed at creating a fresh view of the current partner landscape and enable a forward view of their priorities, to inform CEPI's.

This analysis should be conducted in a comprehensive way and summarised for strategic decision-making purposes by CEPI Executive Leadership and the Board. For example, the end-to-end continuum can be depicted as upstream R&D, clinical trials, and downstream activities (e.g. registration, manufacturing, demand estimation) and portrayed over a multi-year horizon for the end-to-end approach, with caveats to express the dynamic ecosystem in which it operates. This analysis should include an assessment of strengths and weakness of CEPI and of partners against activities on the continuum, an evaluation of commitment to equitable access for each partner, and an assessment of the ability to structure clear 'hand offs' to partners, in part based on historical experiences of partner engagement.

This work would likely be best led by the new Deputy CEO and the three Executive Directors that report directly to that post (Strategy, Governance and Portfolio Management; Access and Business Development; and Preparedness and Response).

Recommendation 1.2 (Act now): Based on the analysis and decisions taken in response to recommendation 1.1, re-evaluate the end objective and plans for each pathogen programme and Disease X, considering the possibility that objectives for the programmes may be significantly different from one another and in many cases will not involve end-to-end development by CEPI.

This approach should build on the work the Management Team has already advanced to develop pathogen archetypes, which should be refined to consider the likelihood of a pandemic or local/regional outbreak, potential outbreak frequency, expected volumes of demand for a vaccine and other factors, and considering CEPI's role for each pathogen category both before and during an outbreak. The objective of this analysis is to facilitate strategic decisions on CEPI's role for each programme and will incorporate information on partner priorities and capabilities. For example, for pandemic-threat pathogens, CEPI may choose, in addition to developing vaccines, to make upstream technology available (for instance virus family libraries) to enable rapid response by other partners who are equipped and have an incentive to advance prompt clinical trials, registration, and manufacturing. For regional outbreaks in LMICs, where partner engagement may be limited, CEPI may consider development through registration or a pre-registration stockpile that can be accessed if needed, depending on outbreak frequency, and expected engagement by other players in the ecosystem.

Decisions on CEPI's role should also be based on, or at least made in full knowledge of, the willingness of partners to engage. In particular, if partners are not willing or able to engage, whether and how CEPI decides to assume a role that is perhaps outside of its core area of comparative advantage should be decided by the Executive Leadership and Board *a priori* and clarified with stakeholders.

The associated planning process should consider the full range of activities associated with each programme, including upstream and downstream activities, and CEPI's intended funding, catalytic and/or advocacy role at each stage, linked to a well-defined allocation of resources required to deliver on this, to determine precisely what CEPI does and how it does it. Particular areas where CEPI should carefully consider its role, where stakeholders interviewed often expressed concern at CEPI's current approach, relate to manufacturing efforts that support rapid scale up in production in response to an epidemic or pandemic scenario (as opposed to technology innovation, which was widely supported); CEPI playing an active role in ensuring a market and stimulating country demand for vaccine products; and broad based enabling science

and ecosystem strengthening activities that are not specifically tied to programme objectives. At this mid-point in the CEPI 2.0 strategic period, the Executive Leadership will need to decide how to act quickly while encouraging staff ownership and engagement in such a process.

This work will require engagement across the Executive Leadership, notably the Executive Directors for Vaccine R&D and Manufacturing and Supply Chain, as well as the Executive Directors for Access and Business Development, and Preparedness and Response. This would ideally be led by the CEO and/or Deputy CEO to ensure cross departmental collaboration.

Recommendation 1.3 (Act now): Based on a clear understanding of CEPI and partner roles and responsibilities derived from the analyses conducted for recommendations 1.1 and 1.2, structure and advance negotiations around clear 'hand offs' from CEPI to partners for both upstream and downstream activities and for ecosystem strengthening. These 'hand offs' should form the basis of high-level agreements/memorandums of understanding between CEPI and partners, with an intent to structure more detailed and operational agreements over time and where appropriate.

It is expected that this work would be led by the Executive Directors for Access and Business Development and Preparedness and Response, working across the Executive Leadership.

Recommendations area 2: Clarify how CEPI works to achieve its strategic objectives and reformulate the results framework to measure progress

Recommendation 2.1 (Act now): Alongside and based on the actions to respond to recommendations area 1, update the ToC to reflect the agreed portfolio of work and its contribution to the 100 Days Mission, realistic outcomes, structure, and the nuanced ways in which CEPI works and interacts within the broader global R&D ecosystem to achieve its mission. Specifically:

- Articulate the different ways in which CEPI works across pathogens and for Disease X in both preparedness and response, and in relation to partners for each, showing where there is overlap and differentiation.
- Design the ToC in a way that can communicate how CEPI works to achieve the strategic objectives. Consider using a systems-based approach to communicate the complexity of CEPI's work, how this work relates to the 100 Days Mission, and the contextual influences upon CEPI and its contribution to the broader R&D&M ecosystem.
- Document key assumptions that underpin the causal pathways that comprise the ToC.
- Following best practice, review the ToC on an annual basis to ensure it continues to accurately reflect what CEPI does, how it works and its role within the dynamic R&D&M ecosystem.

This work should be led by the Executive Director for Strategy, Governance and Portfolio Management, with inputs from across the organisation and with Executive Leadership sign off.

Recommendation 2.2 (Act now): Using decisions taken on CEPI's role under recommendations area 1 and the updated ToC as a guiding framework, update the CEPI 2.0 KPIs and targets to reflect CEPI's prioritised scope of work for the remainder of 2.0, including the use of interim milestones and process indicators. It is recommended to:

- Structure KPIs along the end-to-end continuum by priority pathogen and for Disease X according CEPI's planned activity and the nature of its role vis-à-vis partners. This

provides an opportunity to help clarify expectations on what can be achieved within the remainder of CEPI 2.0 and to clearly demonstrate results for the 2022-2026 period.

- Consider including targets beyond 2026 where this relates to longer-term results that CEPI 2.0 activities will contribute towards and that relate to the CEPI 2.0 strategic objectives, 100 Days Mission, and CEPI vision and mission. These can be carried over to the design of a future phase of activity.
- Following best practice, review the Results Framework on an annual basis to ensure it continues to accurately reflect what CEPI does, how it works, and its contribution to the dynamic R&D&M ecosystem.

This work should be led by the Executive Director for Strategy, Governance and Portfolio Management, with inputs from across the organisation and with Executive Leadership sign off.

Recommendations area 3: Continue to embed a comprehensive and flexible approach to equitable access

Recommendation 3.1 (Continue and embed): Distinguish clearly in equitable access planning between pathogens likely to cause outbreaks primarily in LMICs, for which the primary access challenges may be to find a manufacturing partner and ensure downstream systems for distribution and delivery, and those that pose a potential pandemic threat, for which the greatest challenge may be to secure supply for LMICs in the face of HIC competition. This should utilise the work advanced in response to recommendation 1.2, building on CEPI's work to develop pathogen archetypes, and be implemented alongside CEPI's ongoing review of access agreements for priority pathogens and Disease X.

For pathogens with pandemic potential, consider what leverage CEPI can deploy to promote access, especially through tech transfer, to vaccines in which CEPI has not been a major investor, while acknowledging that this leverage may be primarily restricted to advocacy and policy promotion.

For pathogens posing a threat primarily to LMICs and specific regions, distinguish between those for which a sustainable if modest market sufficient to attract commercial suppliers might be created, perhaps with ongoing subsidy, and those for which a stockpile is more appropriate.

This work should continue to be led by the Executive Director for Access and Business Development, working across the Executive Leadership.

Recommendation 3.2 (Continue and embed): Continue implementing a bespoke approach to equitable access provisions in partner contracts, guided by the EAF, the nature of the partnership, and the mutual objectives sought. Such an approach should seek to reduce instances where such provisions act as a barrier to partner engagement, including for MNCs. Separately, while the specific commercial details of contracts may be confidential, as per CEPI's Transparency and Confidentiality Policy and with Transparency as an underpinning principle of the EAF, CEPI should seek to publish the broad intent of the provisions included for PPR and covering different types of outbreaks.

This work should continue to be led by the Executive Director for Access and Business Development, working across the Executive Leadership.

Recommendations area 4: Finalise and embed an evolved approach to partner selection and engagement, and strengthen the relationship management function

Recommendation 4.1 (Continue and embed): Finalise and embed the evolved approach to proactive partner selection and engagement based on technical capability and organisational mandates, guided by the finalised and agreed partner archetypes, to ensure partnerships are structured to fill identified gaps in the end-to-end approach for each pathogen and for PPR, in support of CEPI strategic objectives and equitable access. Further:

- *For R&D&M partners,* partnership agreements should be established with incentives aligned to the mutual objectives sought, clearly defining how investments and capabilities built in a preparedness phase are expected to be utilised in a future outbreak (e.g. for technology transfer and utilisation of manufacturing capacity). CEPI should also seek to identify barriers to R&D partners submitting proposals for CEPI funding and where feasible, look to address them; and more clearly communicate to partners CEPI's priorities and decision-making processes.
- *For other partners (e.g. countries, regional organisations, other R&D funders, DFIs, multilateral and global health partners, networks)* partnership agreements should be established with clear hand-offs in place and well-defined expectations, from both perspectives, on what respective roles should be. This may vary for instance by region and country, even with the same partner based on organisational priorities and funding, and depending on the presence of partners across different geographies. Such an approach must also differentiate expectations in a preparedness phase from an emergency footing to maximise synergies and reduce duplication of efforts, and potentially in the situation of a global pandemic, seek ways to avoid destructive competition for doses, from which LMICs would likely again emerge the losers.

This work should continue to be led by the Executive Director for Access and Business Development, working across the Executive Leadership.

Recommendation 4.2 (Continue and embed): Continue to seek ways to further engagement with MNCs (a current gap in CEPI's partnership arrangements) to advance R&D&M objectives for priority pathogens and in support of Disease X and PPR objectives. Specifically, it is recommended for the Executive Directors for Access and Business Development and Preparedness and Response to lead work to:

- Advance work to understand MNC motives and barriers to engaging with CEPI.
- Continue to look at entry points for engaging MNCs, including through R&D&M and PPR projects, flexibly employing equitable access provisions so as not to deter engagement (see recommendation 3.2).
- Consider what CEPI can offer developers (e.g. access to the vaccine library in the event of a pandemic) as an incentive to engage.
- Continue engagement with industry representatives (e.g. IFPMA and DCVMN via the JCG) and expand direct MNC engagement where possible (e.g. by inviting select stakeholders to join portfolio review meetings and via ongoing communication between CEPI and MNC leadership).

Recommendation 4.3 (Continue and embed): Strengthen CEPI's partner relationship management function. For R&D&M partners, whose relationships are usually managed at the project level, there is a need to consider how to most efficiently engage with partners across CEPI's different teams and matrix management system. It is also recommended, however, to engage with partners on a strategic level with senior level ownership within CEPI of relationships with

partners that can foster mutual trust and leverage CEPI's soft power in pursuit of its objectives. Such relationships will be increasingly important as CEPI furthers its strategic partnerships which relate to multiple areas of the CEPI portfolio.

Responsibility for addressing this recommendation should rest with the Executive Leadership, notably the Executive Directors for Vaccine R&D and Manufacturing and Supply Chain, as well as the Project Management Office.

Recommendations area 5: Continue to clarify decision making pathways and engagement of governance committees

Recommendation 5.1 (Continue and embed): Continue to clarify who is responsible for different types of decision making, within management and governance arrangements, and in what scenarios, and (a) further streamline decision making; and/or (b) consider decentralising decision-making responsibility from the Board/Committees to management where appropriate. Specifically, it is recommended for the Executive Director for Strategy, Governance and Portfolio Management, in communication with the Board, to:

- Continue to clarify and differentiate the functions and scope of decision-making between the Board and the Investors Council, as well as the Portfolio Strategy and Management Board and Vaccine Research and Development and Manufacturing Committee.
- Clarify and evolve the functions of the Equitable Access Committee and External Relations Committee.
- Clarify how decisions should be taken that involve CEPI engagement in issues beyond the strategy (e.g. for therapeutics, biosecurity) or involving two or more divisions or departments.

Recommendation 5.2 (Continue and embed): Continue to strengthen the documentation prepared by management for governance committee meetings. This should include succinct information on the background context of issues, point in time financial and operational progress status, and clear decision points for the meetings.

A general principle should be to use language to be inclusive of all members while ensuring key issues as well as the risks and implications of potential options are clearly articulated. Ensure all relevant documents are structured to support strategic decision making.

Responsibility for addressing this recommendation should rest with the Executive Director for Strategy, Governance and Portfolio Management and across the Executive Leadership, with all Executive Directors working to ensure that materials provided by their teams meet this brief.

Recommendations area 6: Further strengthen management culture, capabilities and practices

In addressing the recommendations for this area, CEPI should seek to balance the need to retain agility while working to systematise processes and ways of working commensurate with the size of CEPI's management team and the scale of its activities.

Recommendation 6.1 (Monitor and course correct): Implement plans to establish the new Executive Leadership team with a strong emphasis on cross-department, division and functional collaboration and decision-making in support of CEPI's role. This will help to enable end-to-end line of sight for vaccine candidates including proactive identification and management of opportunities and barriers for R&D&M and bringing products to market. Responsibility for this lies with the CEO and Executive Leadership.

Recommendation 6.2 (Monitor and course correct): Review the project management structure for grantee projects to ensure clear lines of decision-making between CEPI and the grantees; and further strengthen the programme management function with the new risk framework, IMS and other systems fully embedded. Responsibility should rest with the Chief Operating Officer and Project Management Office in concert with other departments. It is further recommended to:

- Develop consistent and timely processes and templates for communication and feedback with grant applicants during the CfP process.
- Improve matrix management and collaboration within and between programme teams by engendering a stronger organisational culture of multidisciplinary work and the modelling of cross-divisional work by Executive Leadership (see recommendation 6.1).

Recommendation 6.3 (Monitor and course correct): Ensure there is clarity among all staff on how projects are expected to report on and deliver project-level results and contribute to wider outcomes of relevance to the portfolio and strategic objectives. It is recommended that the Executive Leadership:

- Engage staff early in modifications to the end objective and plans for each pathogen programme and Disease X, the ToC and Results Framework so that there is organisation-wide support for their adoption and reporting.
- Ensure that management decisions impacting projects or teams, as well as their rationale, are clearly communicated back to relevant staff. Identify, embed and communicate the channels available to staff to input into decision-making processes and/or to question or provide feedback on decisions.

Recommendation 6.4 (Monitor and course correct): Develop and implement systematic learning processes at a project, department, cross-department and organisational level focused on both technical delivery and ways of working to improve implementation of CEPI 2.0, and to inform a next phase of activity. Developing such processes should be the responsibility of the Evaluation and Learning Manager and Executive Director for Strategy, Governance and Portfolio Management, although responsibility for implementing it should rest across the organisation with the Executive Leadership accountable.

We provide expert monitoring, evaluation, learning and strategy services to help build a more equitable and sustainable world for all.

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CEPI 2.0 Midterm Review Final Report

Annexes

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Date: 20 January 2025

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Annex 1. Stakeholder groups and key informants interviewed (all)

No.	Organisation	Name	Position
1	BioNTech	Holger Kissel	Senior Vice President Scientific Relations & Liaison
2	Valneva	Olivier Jankowitsch	VP Governmental Affairs
3	VIDO (BPCV and AMN)	Volker Gerts	CEO
4	Uganda Virus Research Institute (Centralized Laboratory Network)	Jennifer Serwanga	Assistant Director of Research in Immunology
5	Institut Pasteur de Dakar	Joe Fitchett	Senior Adviser for Biotechnology
6	Serum Institute of India	Umesh Shaligram	Director of R&D
7	Bio Farma	Indra Rudiansyah	Project Leader for mRNA and viral vector vaccines programme
8	Biovac Institute/DCVMN	Morena Makhoana	CEO
9	IFPMA (Switzerland)	Thomas Cueni	Member of JCG and former Director General IFPMA
10	Wellcome and IC, Philanthropy	Charlie Weller	Investors Council chair, Head of Infectious Disease Prevention at Wellcome
11	Finland , IC	Outi Kuivasneimi	IC cochair
12	Ethiopia, IC	Professor Afework Kussu	Ethiopia, primary IC rep (M)
13	WHO	Chikwe Ihekweazu	Assistant Director, leading WHO Hub for Pandemic and Epidemic Intelligence
14	UNICEF Supply Division	Andrew Jones	Head of Vaccines Centre
15	IFP	Farid Fezoua	Global Director, Health and Education
16	ex-Wellcome – WHO	Jeremy Farrar	WHO Chief Scientist, former Director at Wellcome
17	Africa Centres for Disease Control and Prevention (Africa CDC)	Jean Kaseya	Director General
18	PAHO	Sylvain Aldighier	Director
19	Australia, CEPI Board Chair	Jane Halton	Board Chair
20	IFPMA	Dr David Reddy	IFPMA DG and process Biopharmaceutical CEO Roundtable Secretary
21	Amref Health Africa (Kenya)	Githinji Gitahi	CEO

22	German Federal Ministry of Education and Research	Prof Dr Veronika Von Messling	Directorate-General of the Life Science Division
23	Ministry of Foreign Affairs of Mexico	H.E. Ulises Canchola Gutiérrez	Ambassador
24	Japan Government	Mr Itani Mr Takahashi Mr Iijima	Ministry of Foreign Affairs of Japan Director of the Global Health Cooperation Ministry Japan International Affairs division
25	GSK Vaccine R&D	Dr Emmanuel Hanon	SAC Chair, Former Head of GSK Vaccine R&D
26	EMA	Marco Cavaleri	JCG member, Head of Anti-infectives and Vaccines at EMA
27	BMGF	Peter Dull	SAAC and PSMB
28	GAVI	Derrick Sim	Managing Director, Vaccine Markets and Health Security
29	International Vaccine Institute (IVI)	Jerome Kim	Director General
30	PATH	Jessica Milman	Global Head for Vaccine Innovation and Access
31	SCARDA	Minoru Tobiume	
32	University of Chicago/ J-PAL	Rachel Glennerster	Executive Director at Jameel Action Lab
33	PAN	Eloise Todd	Executive Director, Co-founder
34	CEPI	Luc Debruyne	Strategic Advisor to the CEO
35	CEPI	Kristine Rose	Chief of Staff R&D
36	CEPI	Frederik Kristensen	Former Deputy CEO at CEPI, now Managing Director at the Regionalized Vaccine Manufacturing Collaborative (RVMC) Secretariat (since February 2024)
37	CEPI	Emma Wheatley	Director of Access and Private Partnerships
38	CEPI	Sally Suzanne Girgis-Hjoberg	Head of Investor Relations, Resource Mobilisation and Investor Relations
39	CEPI	Nicole Lurie	Executive Director Preparedness and Response
40	CEPI	Ranna Eardley-Patel	Interim External Stakeholder and Project Lead, Manufacturing and Supply Chain

41	CEPI	Tom Mooney	Executive Director of Communications and Advocacy
42	CEPI	Joseph Simmonds-Issler	Chief of Staff, Strategy and Portfolio Management, Governance Strategy and Portfolio
43	CEPI	Saul Walker	Interim Executive Director, Policy Partnerships and Access
44	CEPI	Timothy Endy	Programme Lead
45	CEPI	Richard Jarman	Programme Lead
46	CEPI	Katrin Ramsauer	Programme Lead
47	CEPI	Adam Hacker	Director and Global Head of Regulatory Affairs and Quality, Research and Development
48	CEPI	Andrew Hebbeler	Biosecurity
49	CEPI	Fernando Pons	COO
50	CEPI	Richard Hatchett	CEO
51	CEPI	Jodie Rogers	Senior Communications and Advocacy Manager, Communications and Advocacy
52	CEPI	Ingrid Kromman	Executive Director Manufacturing and Supply Chain
53	CEPI	In-Kyu Yoon	Acting Executive Director of Research and Development
54	CEPI	Nina Schwalbe	Advisor
55	CEPI	Mark Lucera	Head of Strategy
56	CEPI	Samia Saad	Director of Resource Mobilisation and Investor Relations
57	CEPI	Sabrina Kriegner	(former) Senior Manager Learning, Strategic Planning, Results
58	CEPI	Freya Hopper	Senior Strategy Manager
59	CEPI	Thomas Collin-Lefebvre	Strategic Planning and Monitoring Manager
60	Clover Biopharmaceuticals	Nicolas Burdin	Clover COVID-19 -C1 (PRJ-6052[1])
61	SK bioScience	Jins Park	Senior Vice President
62	Oxford Lassa	Sarah Gilbert	
63	Aspen Pharmacare Holdings. Vaccine development and manufacturing (PRJ-6936)	Lorraine Hill	

64	KU Leuven R&D project for supply chain modelling	Nico Vandaele	

Annex 2. List of documents reviewed during data collection phase

Group	Name
Strategies	20211126-CEPI-2.0-Results-Framework-v1.0-jan-21 - Copy.pdf
Strategies	20211126-CEPI-2.0-Results-Framework-v1.0-jan-21.pdf
Strategies	CEPI_Equitable-Access-Framework_May-2023_2.pdf
Strategies	CEPI's 2022-2026 Strategy - CEPI.pdf
Strategies	CEPI-Equitable-Access-Dashboard.pdf
Strategies	EA REVIEW of -COVID-19-VACCINE-DEVELOPMENT-AGREEMENTS_Final_April-2022.pdf
Old evaluations	Equitable Access Review Of CEPIs Covid-19 Vaccine Development Agreements.pdf
Old evaluations	Independent Outcome Evaluation – Management Response.pdf
Old evaluations	Independent outcome evaluation of the first five-year business cycle 2017-21.pdf
Strategy progress & Annual Reports	Board of Directors' Report, Annual Accounts, 2022.pdf
Strategy progress & Annual Reports	CEPI 2020 Annual Progress Report.pdf
Strategy progress & Annual Reports	100DM 3rd implementation report proforma - Sustainable Financing.Final.docx
Strategy progress & Annual Reports	CEPI-100-Days-Report-Digital-Version_29-11-22.pdf
Strategy progress & Annual Reports	1. CEPI Portfolio Review Meeting 2024 - Briefing Materials 26 Jan.pdf
Strategy progress & Annual Reports	CEPI Portfolio Review Meeting 2024 - Meeting Report (1).docx
Strategy progress & Annual Reports	Day 1 Plenary Final - APR 2024.pptx
Strategy progress & Annual Reports	Day 2 Parallel ENABLING Final - APR 2024.pptx
CEPI 2.0 Strategy development	2020 08 24 Andrew Witty on CEPI 2.0 - Notes
Strategy progress & Annual Reports	Day 2_Manufacturing session_pre-read materials.pptx
Strategy progress & Annual Reports	Day 2_Platforms session_pre-read materials.pptx
Strategy progress & Annual Reports	Day 3_CHK session_pre-read materials.pptx
Strategy progress & Annual Reports	Day 3_JCG session_pre-read materials vShared (Cherry).pptx
Strategy progress & Annual Reports	Day 3_JCG session_pre-read materials.pptx
Strategy progress & Annual Reports	Day 3_Nipah session_pre-read materials.pptx
Strategy progress & Annual Reports	Day 3_RVF session_pre-read materials.pptx
Strategy progress & Annual Reports	APR 2024 Day 2 and 3 Playback summaries.pptx
Strategy progress & Annual Reports	Notes - CHK (Hyde) - Day 3.docx
Strategy progress & Annual Reports	Notes - Enabling Science (Regents) - Day 2.docx
CEPI 2.0 Strategy development	2020 08 27 AMHR on CEPI2.0 - Notes
Strategy progress & Annual Reports	Notes - Platforms (Nobel) - Day 2.docx

Strategy progress & Annual Reports	Notes - Plenary (Nobel) - Day 1.docx
CEPI 2.0 Strategy development	2020 09 02_Senegal_Papa Seck CEPI2.0
CEPI 2.0 Strategy development	2020 08 27 Arnaud Bernault CEPI2.0 - Notes
Board meetings	SLIDE DECK _Board meeting #12_FINAL Strategy.pdf
Board meetings	SUMMARY FROM BOARD PROCEEDINGS, February 2017.pdf
Board meetings	SUMMARY FROM BOARD PROCEEDINGS, January 12, 2017.pdf
Board meetings	SUMMARY FROM BOARD PROCEEDINGS, July 2017.pdf
Board meetings	SUMMARY FROM BOARD PROCEEDINGS, November 2017.pdf
Board meetings	SUMMARY FROM BOARD PROCEEDINGS, September 2017.pdf
Board meetings	Summary of Minutes of Board meeting #13.pdf
Board meetings	Summary of Minutes of Board meeting #15.pdf
Board meetings	Summary of Minutes of Board meeting #16.pdf
Board meetings	Summary of Minutes of Board meeting #17.pdf
Board meetings	Summary of Minutes of Board meeting #19.pdf
Board meetings	Summary of Minutes of Board meeting #20.pdf
Board meetings	Summary of Minutes of Board meeting #21.pdf
Board meetings	Summary of Minutes of Board meeting #22.pdf
Board meetings	Summary of Minutes of Board meeting #5.pdf
Board meetings	Summary of Minutes of Board meeting #7.pdf
Board meetings	Summary of Minutes of Board meeting #9.pdf
Board meetings	Summary of the minutes of Board meeting #18.pdf
Board meetings	CEPI B25 05.00 20240218 Board paper_Ecosystem.pdf
Board meetings	CEPI Portfolio Review Meeting 2024 - Briefing Materials 26 Jan.pdf
Board meetings	March #25 Boardbook for EDs (002)
Board meetings	CEPI_B19_04.00 R&D&M Priorities
FCDO annual reports for investments to CEPI	Investors Overview 2023 - CEPI.pdf
Other donor reports on CEPI	1OO DAYS MISSION (2021).pdf
Other donor reports on CEPI	Market Shaping and Market Access in the Global Vaccines Market - Approaches for the Future (2021).pdf
Other donor reports on CEPI	Wellcome Trust – Improving global pandemic preparedness by 2025 (2021).pdf
Other donor reports on CEPI	Wellcome Trust – Towards a reformed R&D ecosystem for infectious disease (2023).pdf
PSMB	20220905 PSMB ToR v2.6Final.pdf
PSMB Effectiveness Review	20230612 PSMB effectiveness review follow-up.pptx
CEPI 2.0 Strategy development	2020 09 02 Trevor Mundel on CEPI2.0 _notes
COVID lessons learned	Internal COVID-19 lessons learned exercise findings.pdf

CEPI Business Plans	CEPI Annual Plan 2024 Final.pdf
Board effectiveness review	CEPI B24 05.00 Board Effectiveness and Management Response combined.pdf
2022 GSSP	CEPI Replenishment & Pandemic Preparedness Summit Internal Lessons Learned_v1
Manufacturing and Supply	Mfg Network - Lessons Learned_Oct23_Report.pptx
R&D	VRDMC Decisions.pptx
R&D	VRDMC_Final recommendations to PSMB_updated Feb 2024.pptx
Governance	CEPI Governance.pdf
Governance	CEPI-JCG-Terms-of-Reference-January-2023.pdf
Governance	CEPI-SAC-Terms-of-Reference-January-2023 (1).pdf
Governance	CEPI-JCG-meeting-summary-August-2023.pdf
Governance	JCG-Meeting-Summary-23-Feb-2021.pdf
Governance	PUBLIC_Summary_JCG 31 Jan 2024.pdf
Connect Objective documents	CEPI B25 05.00 20240218 Board paper_Ecosystem
Operating Model	20220630 Operating Model End of Project Summary v0.2cd.pptx
Reputation Report	CEPI reputation research report_18092019_Final version
Governance	SAC-meeting-summary-1-Nov-2023.pdf
CEPI 2.0 Strategy development	2020 09 03_Marco Cavalieri on CEPI2.0
CEPI 2.0 KPIs	CEPI 2.0 KPIs 2023.xlsx
Operating Model	Summary-of-listening-sessions-and-progress-on-Operating-Model.pdf
IMS	DTB Strategic roadmap project-level financials_data_Mfg Network.csv
IMS	DTB Strategic roadmap project-level financials_data_PandR.csv
IMS	DTB Strategic roadmap project-level financials_data_Regulatory.csv
IMS	IMS Screenshots 20240410.pptx
Board meetings	Addressing CEPI's investment gap in the short and medium term.pptx
Board meetings	March 2023 Board meeting B21 actions.pdf
Board meetings	March 2023 Board meeting FWD look .pdf
Board meetings	March 2023 Board meeting MSC Division .pdf
Board meetings	March 2023 Board meeting Portfolio update.pdf
Board meetings	September 2023 Board meeting CEO Update.pdf
Board meetings	September 2023 Board meeting Committees report.pdf
Board meetings	September 2023 Board meeting Global South.pdf
Board meetings	September 2023 Board meeting Lassa.pdf
Board meetings	September 2023 Board meeting Portfolio overview.pdf
Board meetings	September 2023 Board meeting Risk update.pdf

Board meetings	September 2023 Board meeting Update on actions from CEPI 1.0 evaluation.pdf
Capacity development	05-04-2023 Position Paper - CEPI's approach to training v0.1_Condensed_repositioned
Committees	Equitable Access Committee Terms of Reference.pdf
Committees	Executive and Investment Committee Terms of Reference.pdf
Committees	Investors Council Terms of Reference (IC).pdf
CEPI portfolio	CEPI active portfolio overview website_Last Updated 4 Apr 2024 (1)
CEPI portfolio	Projects funded by CEPI-2024-04-24-12-31-26
Learning processes	CEPI 2.0 Monitoring & Evaluation Framework
Strategies	CEPI 2.0 Equitable Access
Commentary on CEPI	The Science of Investing in CEPI (2023).pdf
Connect Objective documents	20230123 Unicef-CEPI Partnership Priorities
PSMB Effectiveness Review	20231114 PSMB ToR analysis.pptx
Strategy progress & Annual Reports	3rd-100DM-Implementation-Report-IPPS-WEB.pdf
Risk framework	ARC_March 24_ Risk Report_FINAL.pdf
Strategy progress & Annual Reports	SAC April 2023 Stiklestad day 1 - mfng network and sustainability
Strategy progress & Annual Reports	SAC April 2023 Nordkapp day 2 - H5, BPCV, filo, mabs
Committees	CEPI JCG Terms of Reference January 2023.pdf
Committees	JCG-meeting-summary-18Oct22-published.pdf
Committees	Meeting-Summary_JCG-17-June-2022.pdf
Committees	PUBLIC_Summary_JCG 31 Jan 2024.pdf
CEPI portfolio	CEPI Portfolio Review Meeting 2024 - Meeting Report
CEPI 2.0 Strategy development	200617_Lessons learned workshop v27_Short.pptx
Committees	CEPI-JCG-meeting-summary-August-2023.pdf
Strategy progress & Annual Reports	CEPI 2022 Annual Progress Report.pdf
Strategic Partner MOUs	FINAL_CEPI_UniversityOfOxford_StrategicPartnership230823.docx
Strategy progress & Annual Reports	Day 1_Plenary sessions_pre-read materials.pptx
Strategy progress & Annual Reports	Day 2_Enabling science session_pre-read materials.pptx
Committees	JCG-meeting-summary-6_7Feb23-published.pdf
Strategy progress & Annual Reports	Notes - M&SC (Hyde) - Day 2.docx
Strategy progress & Annual Reports	Notes - Plenary (Nobel) - Day 2.docx
Strategy progress & Annual Reports	Notes - Plenary (Nobel) - Day 3.docx
Strategy progress & Annual Reports	Notes - RVF (Nobel) - Day 3.docx
PSMB Effectiveness Review	PSMB Effectiveness Review 2023 findings v1_draft.pptx
CEPI 2.0 Strategy development	SAC_08_20_Slidedeck_Final_1808
CEPI 2.0 Strategy development	Strategy Overview - SAC preread_vshared

CEPI 2.0 Strategy development	20200820 - SAC Meeting - Notes_vSent
CEPI 2.0 KPIs	Annexed full KPI table from v2
CEPI 2.0 Strategy development	5 - CEPI 2.0 - Cost Assumptions_vHandover
CEPI 2.0 Strategy development	7 - CEPI 2.0 - Ecosystem Mapping_vHandover
CEPI 2.0 Strategy development	8 - CEPI 2.0 - Collision Workshop_vHandover
CEPI 2.0 Strategy development	1 - CEPI 2.0 - Preread presentation for March Board meeting - vHandoverFinal
CEPI 2.0 Strategy development	20200819 - CEPI 2.0 - Scenario planning_v01.pptx
CEPI 2.0 Strategy development	20200826_CEPI 2.0 - Board pre-read_v2.pptx
CEPI 2.0 Strategy development	Board pre-read exhibits_v4.pptx
CEPI 2.0 Strategy development	R&D Leaders - Preread (Manufacturing).pptx
CEPI 2.0 Strategy development	R&D Leaders - Preread.pptx
CEPI 2.0 Strategy development	Update to Portfolio Team (shared 20 Jul 2020).pptx
CEPI 2.0 Strategy development	R&D Leaders - Preread (Epidemiology).pdf
CEPI 2.0 Strategy development	R&D Leaders - Preread (Regulatory).pdf
CEPI 2.0 Strategy development	R&D Leaders - Preread (Sent to Paul Kristiansen 16 Jul 2020).pdf
CEPI 2.0 Strategy development	R&D Leaders - Preread (Therapeutics).pdf
CEPI portfolio	CEPI Portfolio Review Meeting 2024 - Meeting Report
Biosecurity	IM for RJH_BSG Opening Remarks_final 04282024 to RLM
Biosecurity	Appendix 1_Agenda_BSG Meeting 04302024 to BSG updated to RLM
Biosecurity	Appendix 3_Summary table of biosecurity vulnerabilities_ priorities and activities_04242024 to BSG to RLM
Biosecurity	Appendix 2_For BSG Discussion_CEPI Biosecurity strategy Discussion Paper__04242024 to BSG to RLM
Biosecurity	2024 04 30 BSG meeting slides_v3 04282024
PSMB	20220824 PSMB Final Minutes v1.0.pdf
PSMB	20220824 PSMB Pre-read and Presentation material v1.0.pdf
PSMB	EIC and IC Investment Paper - SPEAC 2.0 Final - September Revised Final_300822.pdf
PSMB	PSMB Portfolio Status Dashboards_August 2022.pdf
PSMB	20221216 PSMB Final Minutes v1.0.pdf
PSMB	20221216 PSMB Pre-read and Presentation material v1.0.pdf
PSMB	20221216 PSMB Supplementary Material 2 v1.0.pdf
PSMB	PSMB Portfolio Status Dashboards_December 2022 v1.0.pdf
PSMB	20220725 Response to PSMB re SPEAC investment.pdf
PSMB	20220623 PSMB Final Minutes v0.1.pdf
PSMB	CEPI_Equitable-Access-Framework_May-2023.pdf
VRDMC	04102023_VRDMC_vPRE READ.pdf

2023 APR near final version	CEPI APR 2023 v1
Operating Model	20220422-Internal-Governance-for-Publication-v-0.1cd.pdf
Biosecurity	ANNEX_DRAFT CEPI Biosecurity strategy__v1.4 to RLM
Biosecurity	CEPI and Global Affairs Canada deepen collaboration to strengthen international biosecurity and advance the 100 Days Mission _ CEPI
Business plans	01.08.2022 - Progress Update - 2022 Priorities (July).pptx
Business plans	05.12.2022 - Progress Update - 2022 Priorities.pptx
Business plans	20.04.2022 - Progress Update - 2022 Priorities.pptx
Business plans	23.05.2022 - Progress Update - 2022 Priorities.pptx
Business plans	23.08.2022 - Progress Update - 2022 Priorities.pptx
Business plans	24.10.2022 - Progress Update - 2022 Priorities.pptx
Business plans	27.06.2022 - Progress Update - 2022 Priorities.pptx
Business plans	28.09.2022 - Progress Update - 2022 Priorities.pptx
Business plans	CEPI Annual Plan 2022 (1).pdf
Business plans	Progress Update - 2022.pdf
Business plans	CEPI Annual Plan 2023 (1).pdf
Business plans	Progress Update - All Staff - H1.pdf
Business plans	Progress Update - All Staff - H1.pptx
Business plans	Progress Update - All Staff - Q2 - Workplace.pptx
Business plans	Progress Update - All Staff - Q2.pdf
Business plans	Progress Update - All Staff - Q2.pptx
Business plans	Progress Update - All Staff - Q3 - Workplace.pptx
Business plans	Progress Update - All Staff - Q3.pdf
Business plans	Progress Update - All Staff - Q3.pptx
Business plans	Progress Updates - All Staff - Q1 - Final.pdf
Business plans	Progress Updates - All Staff - Q1 - Final.pptx
Business plans	Progress Updates - All Staff - Q1.pptx
Business plans	ProgressUpdateQ1.mp4
Business plans	CEPI Annual Plan 2024 Final 2.pdf
Business plans	ED Memo_CEPI's Monitoring Framework & Q1 Must Wins Reporting.docx
Business plans	ED Memo_Q2 Must Wins Reporting.pdf
Business plans	Presentation - Annual Plan - Lessons Learned.pptx
Business plans	Summary - Annual Planning Lessons Learned.docx
CEPI 2.0 Strategy documents	20201111_CEPI 2.0_costing board exhibits (1).pptx
CEPI 2.0 Strategy documents	20211203 CEPI 2.0 Financial Scenarios_playback.pptx
CEPI 2.0 Strategy documents	CEPI investment case.docx
CEPI 2.0 Strategy documents	CEPI_B18_01.01 Programming.pdf

CEPI 2.0 Strategy documents	CEPI_B19_04.00 R&D&M Priorities.docx
CEPI 2.0 Strategy documents	Compare 2020-2022-2024.docx
Committees & Board approval	20220905-PSMB-ToR_05092022.pdf
Committees & Board approval	Board and Committee paper - non-investment - template.docx
Committees & Board approval	Board and Committee presentation template.pptx
Committees & Board approval	Board and EIC paper - Investment - template.docx
Committees & Board approval	RE MTR interviews with CEPI Committees governance.msg
Deep Dives	20220905-PSMB-ToR_05092022.pdf
Deep Dives	Board and Committee paper - non-investment - template.docx
Deep Dives	Board and Committee presentation template.pptx
Deep Dives	AV Nipah Change Log.pdf
Deep Dives	CEPI-Emergent-Aurobindo-Profectus Novation Jan 2020.docx.pdf
Deep Dives	Profectus Emergent (Nipah) PA signed.pdf
Deep Dives	Amendment01-MA-Step2- Clover-SCB2019.pdf
Deep Dives	Change management log_Log_pdf.pdf
Deep Dives	MA-Step1-Clover-SCB2019.pdf
Deep Dives	MA-Step2-Clover-SCB2019.pdf
Deep Dives	CEPI CMC Framework external_V03_Sep2023.xlsx
Deep Dives	CMC Platform meeting Minutes Kick-off 01-Nov-2023.docx
Deep Dives	070622_CEPI_CPI Framework Agreement_Execution Version - Signed.pdf
Deep Dives	Change Log - CPI.pdf
Deep Dives	17.05.18.pdf
Deep Dives	Change Log - IAVI Lassa.pdf
Deep Dives	FINAL - CEPI - IAVI Signed Agreement.pdf
Deep Dives	Password to open IAVI agreement.docx
Deep Dives	IPD_CR log.pdf
Deep Dives	IPD-CEPI_-_Partnering_Agreement_-_Execution_Version (1).pdf
Deep Dives	CEPI & KULEUVEN agreement signed.pdf
Deep Dives	KUL_-_CEPI_FIRST_AMENDMENT_TO_RESEARCH_AGREEMENT_Execution_06_Nov_2019.pdf
Deep Dives	KUL_CR change_APRIL 2024_signed.pdf
Deep Dives	KUL-CEPI_agreement-_VAX-MAN_22Sept2021_-_Execution_copy.pdf
Deep Dives	OJ - 28.09.18 - (signed pages collated).pdf
Deep Dives	Oxford-Lassa Change request history.pdf
Deep Dives	PADOVAX Quarterly Progress Report Mar2024 LASSA_final.docx
Deep Dives	Argentys_Change_Request_Form_CR2_20200206.pdf

Deep Dives	BioDist_Study_Change_Request 03_fully executed.pdf
Deep Dives	Complete_with_DocuSign_PHV02_CR14_Ph1_Extens (1).pdf
Deep Dives	CR history PHV.pptx
Deep Dives	Crozet_Change_Request_Form_20200330 CR04_fully executed.pdf
Deep Dives	DocuSign_CR5_UTMB_NeV_Change_Request_Form_CR5.pdf
Deep Dives	MA-PHV-Nipah.pdf
Deep Dives	PHV_CR10_approved_fully executed Docusign.pdf
Deep Dives	please docusign, CR13 PHV, signed (1).pdf
Deep Dives	Please_DocuSign_CEPI-PHV_rVSV-NiV_CR09_Chang.pdf
Deep Dives	Please_DocuSign_CR08_Change_Request_Form_MNV.pdf
Deep Dives	Please_DocuSign_CR11_PHV_Nipah_HeV_Challenge.pdf
Deep Dives	Please_DocuSign_CR12-CEPI-PHV_rVSV-NiV_CR12_.pdf
Deep Dives	Please_DocuSign_CRF_6_MNVT_Change_Request_Fo.pdf
Deep Dives	UTMB Change Request Form 20190121 signed by PHV.pdf
Deep Dives	20240213-Deliverable 1B Ph2b site assessment and CBP.docx
Deep Dives	Change request and other decision history.pdf
Deep Dives	Complete_with_DocuSign_CEPI_IVI_West_Africa_.pdf
Deep Dives	Deliverable 1A Concept Paper Ph3 Assessment.pdf
Deep Dives	BF_CR log.pdf
Deep Dives	CEPI_-_Bio_Farma_Funding_Agreement_(Fully Signed) (25_August_2023).pdf
Deep Dives	SII_CEPI_FUNDING_AGREEMENT_17JAN2024_SIGNED (1).pdf
Deep Dives	SII_CR log.pdf
Deep Dives	231207_GBP511 SG1_CR2_Part B - CEPI team presentation_Final (1).pptx
Deep Dives	CEPI 2.0_VRDMC_PSMB_Change Request_June2023_final (1).pptx
Deep Dives	Change request historyBPCV (1).pdf
Deep Dives	Please_DocuSign_SK_BIOSCIENCE_-_COVID_19_fin (1) (2).pdf
Deep Dives	Please_DocuSign_SK_Bioscience_Final_signatur (1).pdf
Deep Dives	Change request history.pdf
Deep Dives	Please_DocuSign_SK_BIOSCIENCE_-_COVID_19_fin (1).pdf
Deep Dives	Complete_with_DocuSign_EXECUTION_VERSION_2_-
Deep Dives	28May2021_CEPI_Valneva_-_Amendment_No.1.pdf
Deep Dives	FINAL_CEPI_Valneva_Funding_Agreement_24.07.19.pdf
Deep Dives	Valneva CR#6_signed_14Nov2022.pdf
June 2024 Board papers	CEPI Board #26 June Boardbook - for EDs.pdf
June 2024 Board papers	June 2024 Board Meeting Summary.pdf
Lessons learned	20240223- Plan learning org 12Feb2024_draft.docx

Lessons learned	CEPI Org learning key findings 31 May 2024_draft2.pptx
Lessons learned	Learning org review summary 31May2024_draft2.docx
Lessons learned	CEPI LL Overview.xlsx
Lessons learned	Lessons Learned training_2024.pptx
Lessons learned	Nipah India Outbreak 2023 Lessons Learned.xlsx
Lessons learned	SUDV Response Lessons Learned Tracker.xlsx
Partner selection	CEPI_B19_04.01 Strategic Partnerships
PMO procedures	Disease Programme Teams_June 2024.pptx
PMO procedures	Disease Programme Teams_May 2024.pptx
PMO procedures	image.png
PMO procedures	Jan24_Ways of Working Manual.CLEAN.pptx
PMO procedures	xxx Disease Program Team Terms of Reference_version 1.docx
Segmentation	Segmentation MTR Deck_FINAL
Staff Surveys	Email publishing Results Jun 2024.pdf
Staff Surveys	Health_and_Wellbeing_Survey_March_2024 ALL Questions.pdf
Staff Surveys	Health_and_Wellbeing_Survey_March_2024.pdf
Staff Surveys	June-2023-Staff-survey-commitments-from-the-Executive-Directors.docx
Staff Surveys	Staff_survey_March_2023 All rated questions.pdf
Staff Surveys	Staff_survey_March_2023 Factors.pdf
Voice of customer report	Final report - CEPI VoCP cleaned
2023 APR near final version	CEPI APR 2023 v1.pdf
2023 APR near final version	v8 APR 2023_KPI overview table_FINAL.docx
Leadership	CEPI Executive Leadership Configuration
Leadership	CEPI Executive Leadership Configuration – Current Status
Leadership	OAI Final Memo

Annex 3. Theory of change (ToC)

During the inception phase we undertook a review of CEPI's ToC with key stakeholders. This review was organised around KIIs and a facilitated participatory workshop run by the evaluation team and key stakeholders from within CEPI. There were three objectives for this review. The first objective was to sense-check the ToC and establish if there have been any shifts in thinking or approach since it was conceived. The second objective was to understand if the ToC was still fit for purpose, given significant changes to the operating context since it was designed. The third objective was to unpack in more detail the specific pathways (i.e. under the three strategic objectives around Prepare, Transform and Connect) that are articulated in the ToC and to capture the key assumptions that sit across the ToC in order to provide a thorough understanding of the way in which CEPI intends to achieve its objectives.

The review solicited a great deal of stakeholder feedback on the ToC, which resulted in a range of updates to it. These changes seek to better capture the breadth of activity and set out the causal pathways more comprehensively for each strategic pillar and the assumptions that underpin them. Our understanding of most of the feedback provided is reflected in the ToC presented in this report – the Draft MTR ToC (Figure 1).[1]

The review highlighted some substantial shifts in thinking and approach since the 2.0 Strategy was conceived, notably in relation to: the level of emphasis placed on Covid-19, which has reduced over time; how CEPI's different investments build on each other; how the three strategic pillars – Prepare, Transform and Connect – relate to and interlink with each other; and how CEPI orients itself to influence the ecosystem within which it operates. We understand that 'fund, catalyse and advocate' framing has been used by CEPI internally to refer to the organisation's varied roles and functions across its scope of work. This framing would likely be helpful for structuring a further revised ToC to reflect how CEPI works at the present time, but it is unclear how this framing relates to the three strategic pillars, and it could represent quite a departure from the framing of the 2.0 Strategy. As such, it has not been integrated into the Draft MTR ToC. It may, however, feature in the MTR recommendations for further revisiting the ToC, and it has informed how the evaluation approach has been designed, for instance in structuring the process tracing exercise.[2]

The Draft MTR ToC presented below does, in our view, reflect reasonably well how the 2.0 Strategy was *initially* envisaged to work, and as such it provides a good basis from which to evaluate how and whether strategy implementation has played out as intended, while acknowledging that much has changed since 2019/20. The Draft MTR ToC, along with a description of its structure, is presented in full below, including nested ToCs for each of the three strategic pillars and the main assumptions that underpin the ToCs. As noted above, however, a further ToC revision is likely required to reflect the latest shifts in thinking and approach since the 2.0 Strategy was conceived.

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[1] Some points of feedback provided in the ToC workshop were noted but not fully understood by the evaluation team, or time did not permit the research required to address the comments. As such, these points have not been integrated. This will be addressed shortly. These feedback points related to: additional activities in Prepare, reflecting engagement/advocacy work in Transform; additional activities on pharmacoviligence and vaccine safety; the framing of Connect activities in line with the EAF; and CEPI's role in catalysing funding and action of others, including by providing a demonstration effect through innovation and disruption. They also reflect the nature of working relationships between different types of partners and how these work to enable the achievement of results.

[2] We note that this framing has not been universally adopted or holistically applied, but it is featured in the Equitable Access Framework and Enablers Roadmap, which the evaluation team will review in detail.

Figure 1. Overarching Draft MTR ToC for the CEPI 2.0 Strategy

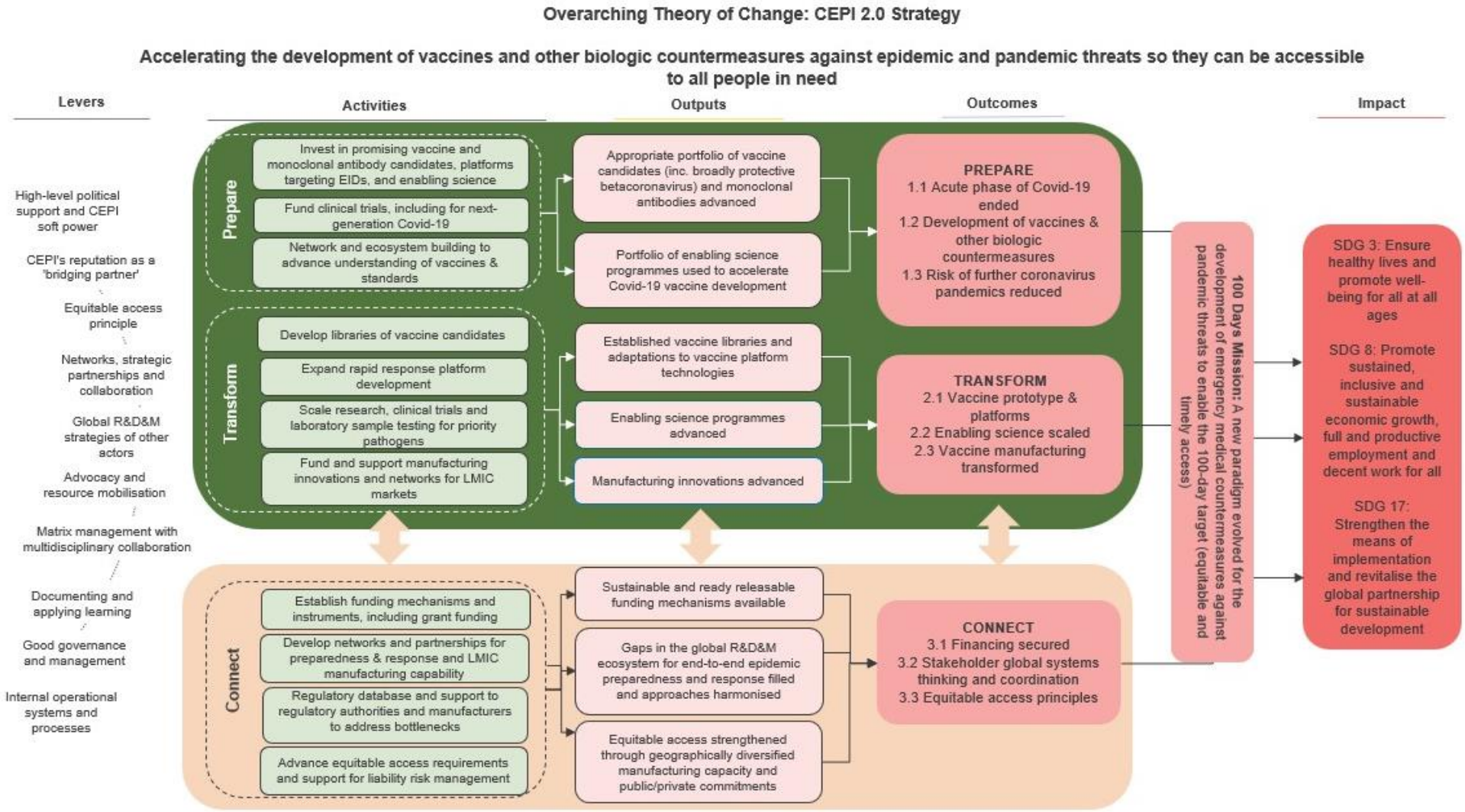


Figure 2. Nested Draft MTR ToC for Strategic Objective 1 (Prepare)

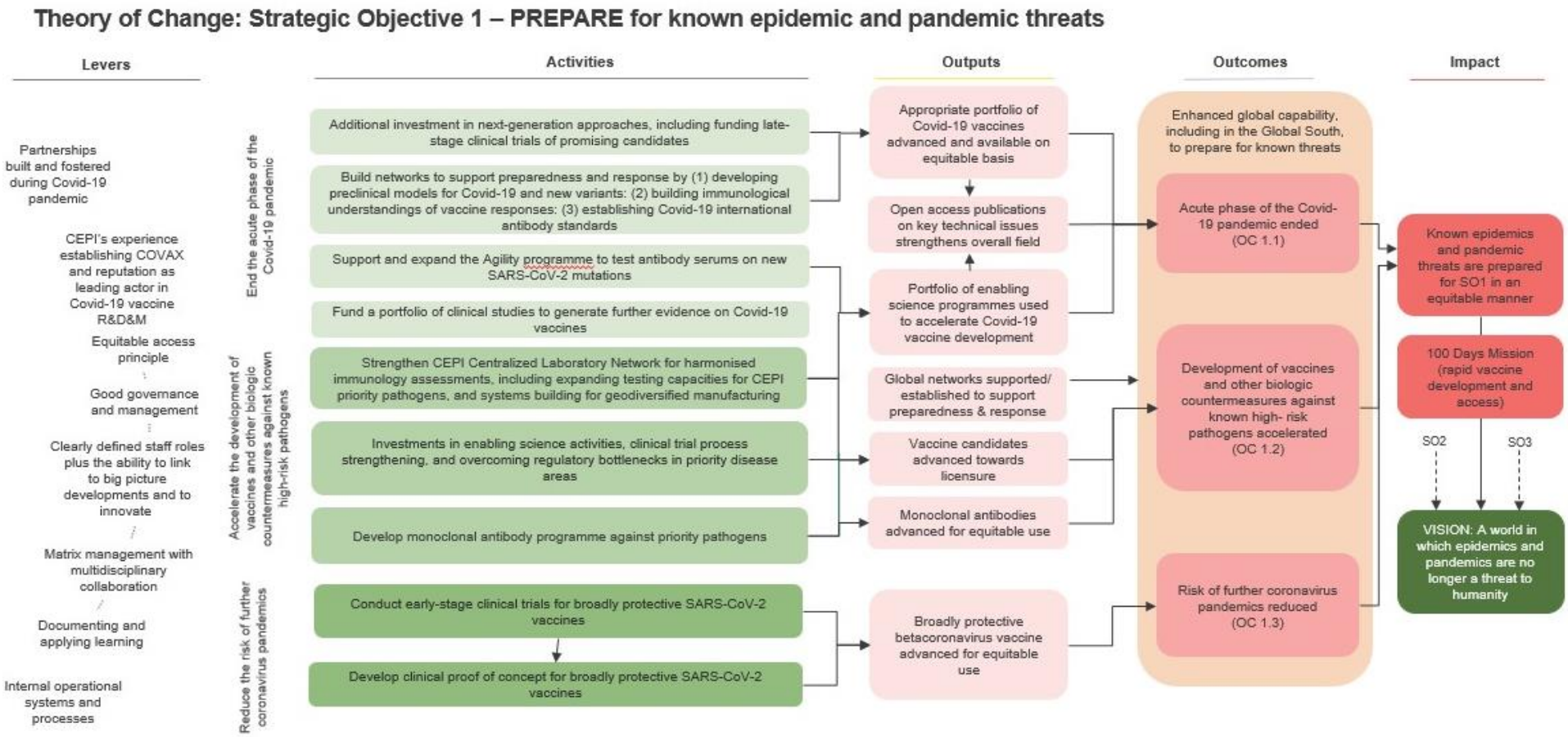


Figure 3. Nested Draft MTR ToC for Strategic Objective 2 (Transform)

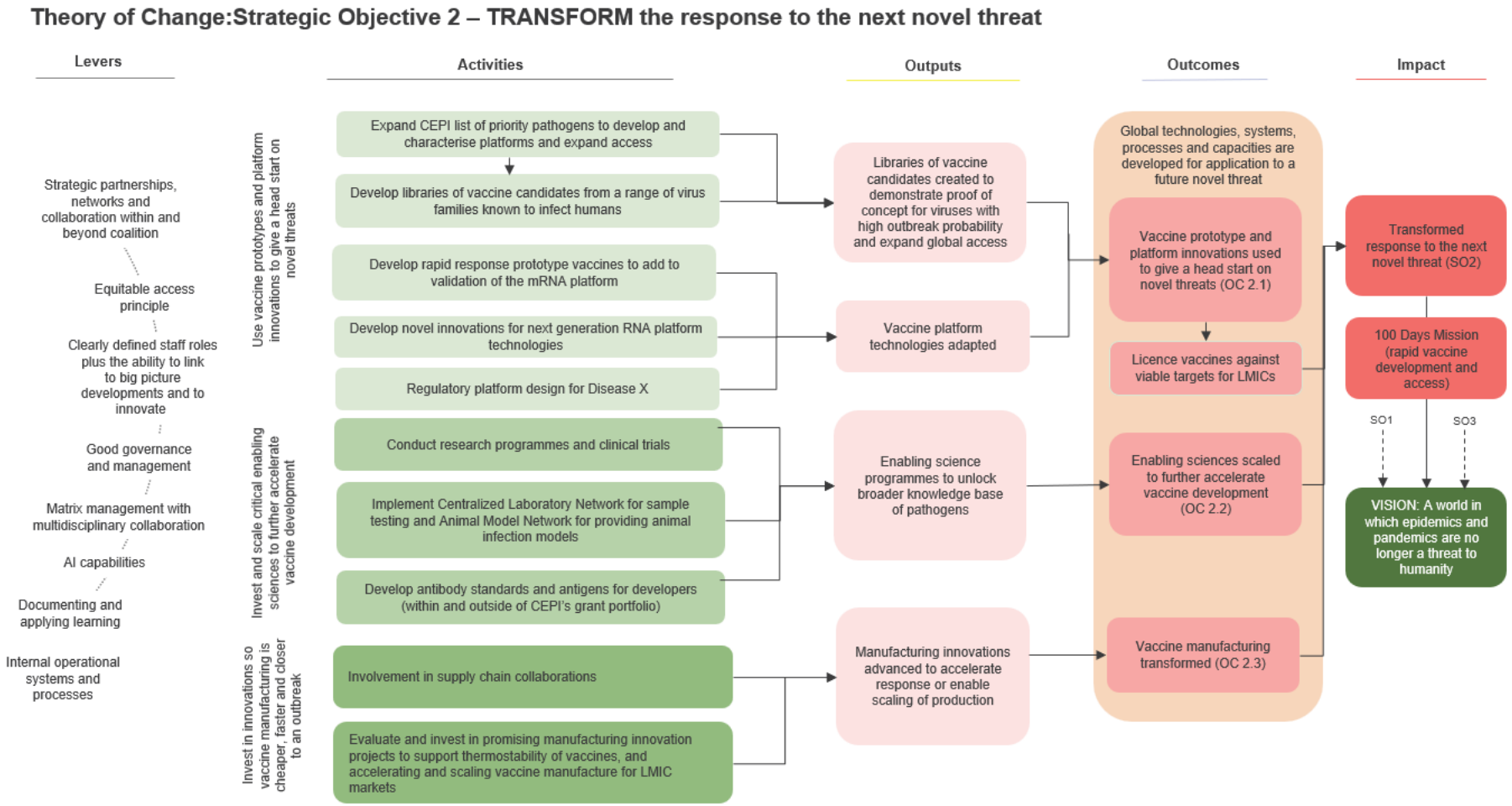


Figure 4. Nested Draft MTR ToC for Strategic Objective 3 (Connect)

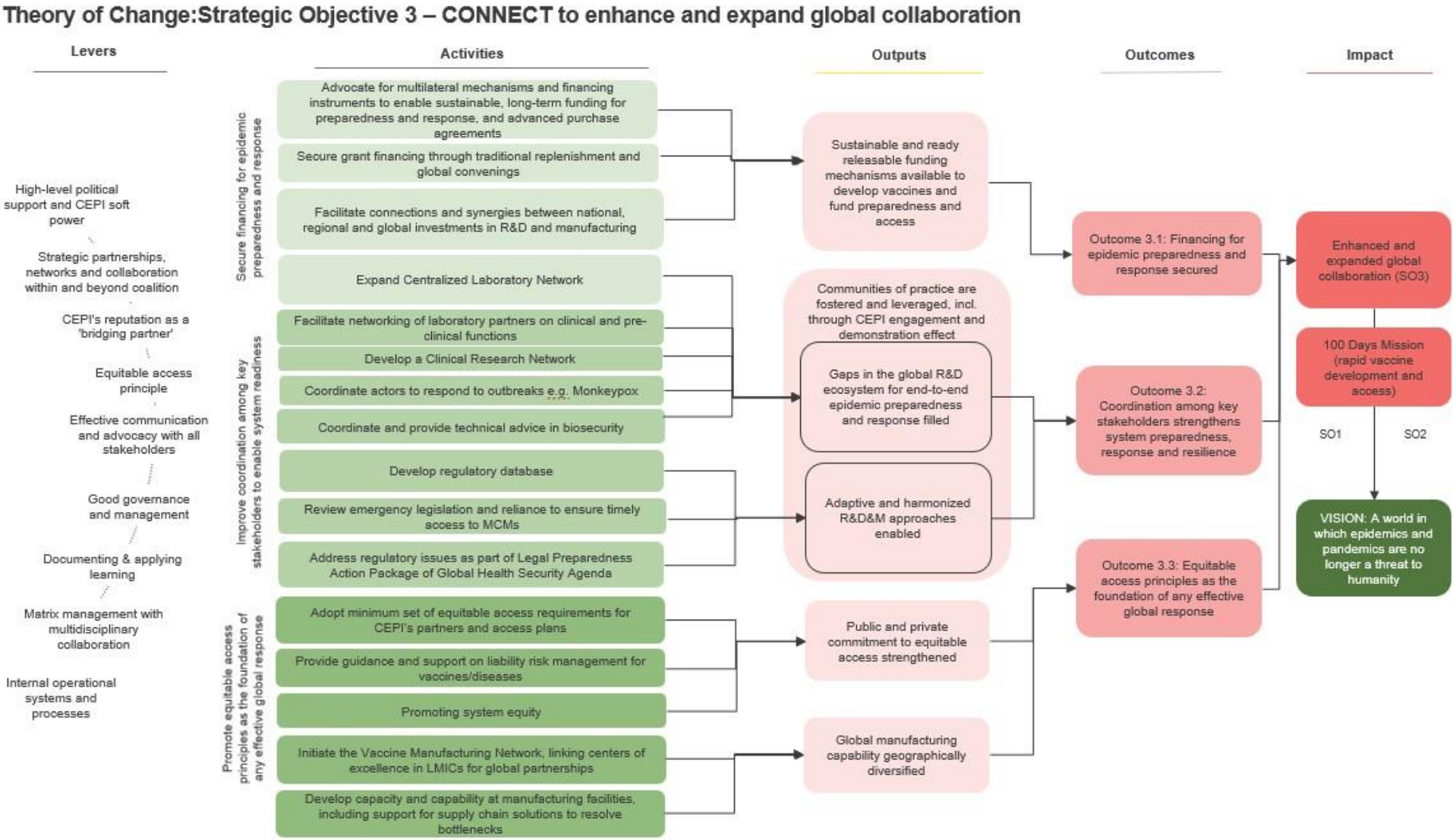
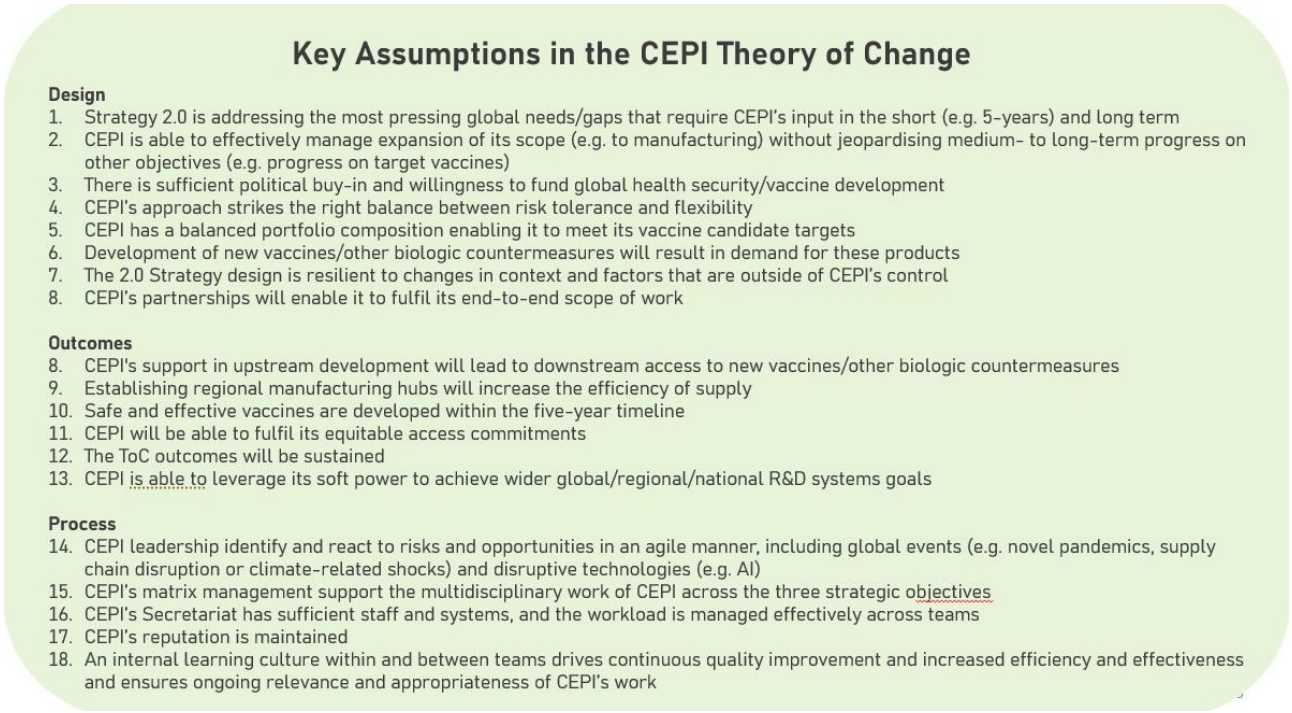


Figure 5. Assumptions underpinning the Draft MTR ToC for the CEPI 2.0 Strategy



Annex 4. Evaluation framework

This evaluation framework maps each EQ and subquestion to the analytical methods proposed to be used to respond to the question, the judgement criteria which will be used to assess the question, and the detailed data sources. This evaluation framework is a fundamental part of the evaluation plan, because it guides the development of tools for data collection. Also delineated are the preliminary types of data and information that will be sought from each workstream.

Workstream A: To what extent is CEPI focusing on the right things?		Evaluative method	Analytical tools	Data collection approaches	Criteria for judging performance
Relevance, including equity					
EQ1	**To what extent is CEPI focusing on the right things?**	• Answered through the sub-EQs			
EQ1.1	**To what extent is the CEPI 2.0 Strategy appropriate for achieving its mission and objectives?**	• Strategy analysis – internal and external validity	• Analysing whether strategic decisions on activities in the 2.0 Strategy have contributed/are likely to contribute to the mission and objectives	• KIIs • Document review	• The right activities are being implemented that have led/will lead to the stated outputs, outcomes, strategic objectives and mission in the 2.0 Strategy, and ToC assumptions underlying the ToC hold true
EQ1.1.1	**To what extent is the CEPI 2.0 Strategy responding appropriately to relevant country, global and partner/institutions' needs and priorities?**	• Strategy analysis – external validity • Mapping to stakeholder needs	• Mapping of the 2.0 Strategy against stakeholder needs/ priorities • Qualitative analysis of interview data, including strategy intent and views of appropriate balance • Analysis of CEPI and other needs gap analyses	• KIIs • Document and literature review • Stakeholder and landscape analyses (use of existing analyses where possible, supplemented with Itad's analysis) • Context analysis	• CEPI's planned activities and 2.0 Strategy align with needs and priorities identified by country, global and partner institutions and other stakeholders
EQ1.1.2	**To what extent is the CEPI 2.0 Strategy engaging in appropriate activities to achieve its objectives?**				
EQ1.1.3	**To what extent is the CEPI 2.0 Strategy engaging in appropriate partnerships to achieve its objectives?**	• Strategy analysis – external validity	• Analysing the plausibility that the 2.0 Strategy's activities and outputs will contribute to the mission and objectives	• KIIs • Document review	• The right activities are being implemented that lead to the stated outputs, outcomes and strategic objectives in the 2.0 Strategy and ToC, and ToC assumptions underlying the ToC hold true

EQ1.2	**To what extent does the evidence support CEPI's 2.0 Theory of Change (ToC)?**	• Strategy analysis – external validity • Benchmarking to partnership typology • Stakeholder analysis	• Analysis against a tailored partnership typology	• KIIs • Document review	• Clear and stated definition by CEPI of what partnership is and how its partnership strategic planning will be employed to meet objectives • CEPI is working with the right partners to achieve its objectives
EQ1.2.1	**To what extent [does the ToC] identify appropriate indicators, outcomes and assumptions?**	• Process tracing	• Evidence gathered through process tracing to test if ToC causal chains/ assumptions hold true • Cross-case analysis from deep dives		• CEPI's activities and the outputs and outcomes achieved to date align with the ToC • The assumptions underlying the ToC hold true • Process tracing gives confidence in the causal pathways
EQ1.2.2	**To what extent [does the ToC] provide a pathway for CEPI to achieve its mission?**	• ToC analysis • Process tracing	• ToC assessment tool (Innovation Network)		• The causal pathways in the ToC from the outputs to the mission are still relevant and appropriate in the current context • The causal pathways hold true
Governance and management					
EQ2	**To what extent are CEPI's management and governance systems fit for purpose vis-à-vis implementation of the programme of work?**	• Benchmarking to best practice against the capability, culture and practice framework	• Capability, culture and practice mapping and assessment	• KIIs • Document and literature review	• The right capabilities are in place to enable and support implementation (e.g. roles and responsibilities are well defined, representation is appropriate) • The right culture is in place (e.g. stakeholders adhere to their roles and responsibilities) • The right practices are in place • The net effect of the driving and restraining forces on governance and management mechanisms is that both can operate effectively and efficiently

Workstream B: How well is CEPI 2.0 being operationalised and how can this be strengthened?		Evaluative method	Analytical tools	Data collection approaches	Criteria for judging performance
Coherence					
EQ3	**Is CEPI's work coherent with, and does it add value to the work of, other institutions/organisations working on vaccine-preventable diseases?**	• Mapping to other organisations' mandates, priorities and specialisms	• Stakeholder and landscape analysis (other agencies, what they do in relation to CEPI 2.0) • Soft power analysis	• KIIs • Document and literature review	• Processes to align objectives and actions are in place • Activities are aligned and linked to others
EQ3.1	**To what extent is CEPI 2.0's work synergistic with other institutions/organisations working on vaccine-preventable diseases?**				
EQ3.2	**To what extent is CEPI's 2.0 work adding value to and avoiding duplication of efforts with partners?**				
Fidelity and effectiveness					
EQ4	**To what extent has 2.0 implementation proceeded as intended?**	• Process tracing	• Context and timeline analysis • Quantitative data analysis (including KPI data)	• KIIs • Document and data review • Literature review	• Evidence of workplan progress (activities, outputs) and strategic goals (outcomes, impact) being met on time • Resource utilisation • Evidence of achievement of outputs across all areas of the workplan • Evidence of causal connections between outputs and intermediate outcomes • Evidence of decision making on strategy implementation which is appropriate to achieve articulated outcomes/outputs
EQ5	**How effectively has CEPI's 2.0 Strategy been implemented?**				
EQ5.1	**To what extent is CEPI making appropriate decisions to advance progress towards its strategic outcomes and outputs as articulated in its 2.0 programme document and associated results framework?**				

EQ5.2	**To what extent is CEPI, through its 2.0 Strategy, working to advance equity vis-à-vis access to vaccines and advancing manufacturing partnerships?**		• Context and timeline analysis • Equity analysis (vis-à-vis Equitable Access Framework)		• The degree to which considerations of equitable access are integrated into critical decisions points as CEPI develops products and pathways • The effectiveness of CEPI's efforts to build LMIC capacity for vaccine production, research and development • The presence of mechanisms to ensure equitable access principles and commitments are upheld
EQ5.3	**What are the main drivers and barriers identified to advance towards strategic outcomes? What mechanisms, if any, have been established to address barriers?**		• Context and timeline analysis • Quantitative data analysis (including KPI data)		• Evidence of success/constraining factors, drivers and barriers

Workstream C: Is CEPI on course to achieve the 'right results'?	**Evaluative method**	**Analytical tools**	**Data collection approaches**	**Criteria for judging performance**
Impact				
EQ6	**What is the plausibility of CEPI meeting its strategic outcome and outputs/targets for 2.0?**	• Process tracing to establish confidence in causal connections between activities	• What is the plausibility of CEPI meeting its strategic outcome and outputs/targets for 2.0?	• Process tracing to establish confidence in causal connections between activities	• What is the plausibility of CEPI meeting its strategic outcome and outputs/targets for 2.0?

Annex 5. Evaluation methods and analytical tools

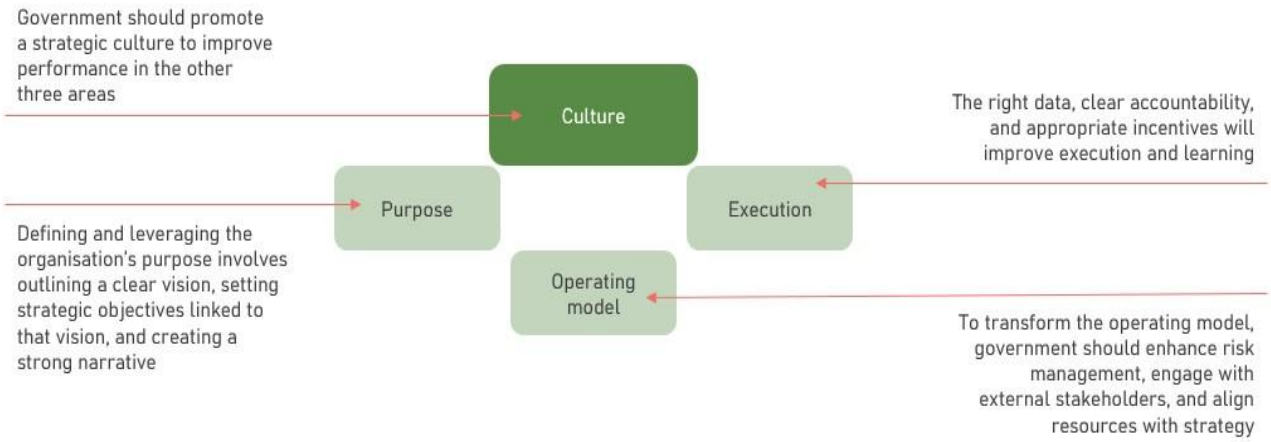
5.1. Benchmarking to best practice in strategy development

This relates to EQ1.1 (To what extent is the CEPI 2.0 Strategy appropriate for achieving its mission and objectives?) and EQ1.1.2 (To what extent is the CEPI 2.0 Strategy engaging in appropriate activities to achieve its objectives?).

Key components of the 2.0 Strategy and how it was developed were mapped to good practice as outlined in the literature on high-impact strategic planning.[3] This included looking at the following:

- **purpose** – alignment of the strategic objectives to the mission, accompanied by a strong narrative on how the mission will be achieved
- **operating model** – governance and management, risk management, stakeholder engagement and resourcing of the strategy
- **execution** – including collection, analysis and learning with the right data, clear accountability and incentives (motivational drivers) for implementation
- **culture** – involving embedding a strategic culture within the organisation to underpin the other three areas.

Figure 6. Four steps to high-impact strategic planning



This mapping against good practice supported, in combination with other methods, analysis of the likelihood that the strategy will achieve its mission and strategic objectives. This analysis included examination of the design of the ToC and whether the structures and processes supporting its implementation are adequate to achieve the desired outcomes. This work was informed by the KIIs and document and literature reviews to determine whether the strategy includes the right activities to meet its strategic objectives.

[3] Boland, M., Thomas, T. and Werfel, D. (2018) *Four Steps to High-Impact Strategic Planning in Government*. Boston Consulting Group.

5.2. Stakeholder and landscape analysis

This relates to EQ1.1.1 (To what extent is the CEPI 2.0 Strategy responding appropriately to relevant country, global and partner/institutions' needs and priorities?), and, to a lesser extent, to EQ1.1.3 (To what extent is the CEPI 2.0 Strategy engaging in appropriate partnerships to achieve its objectives?).

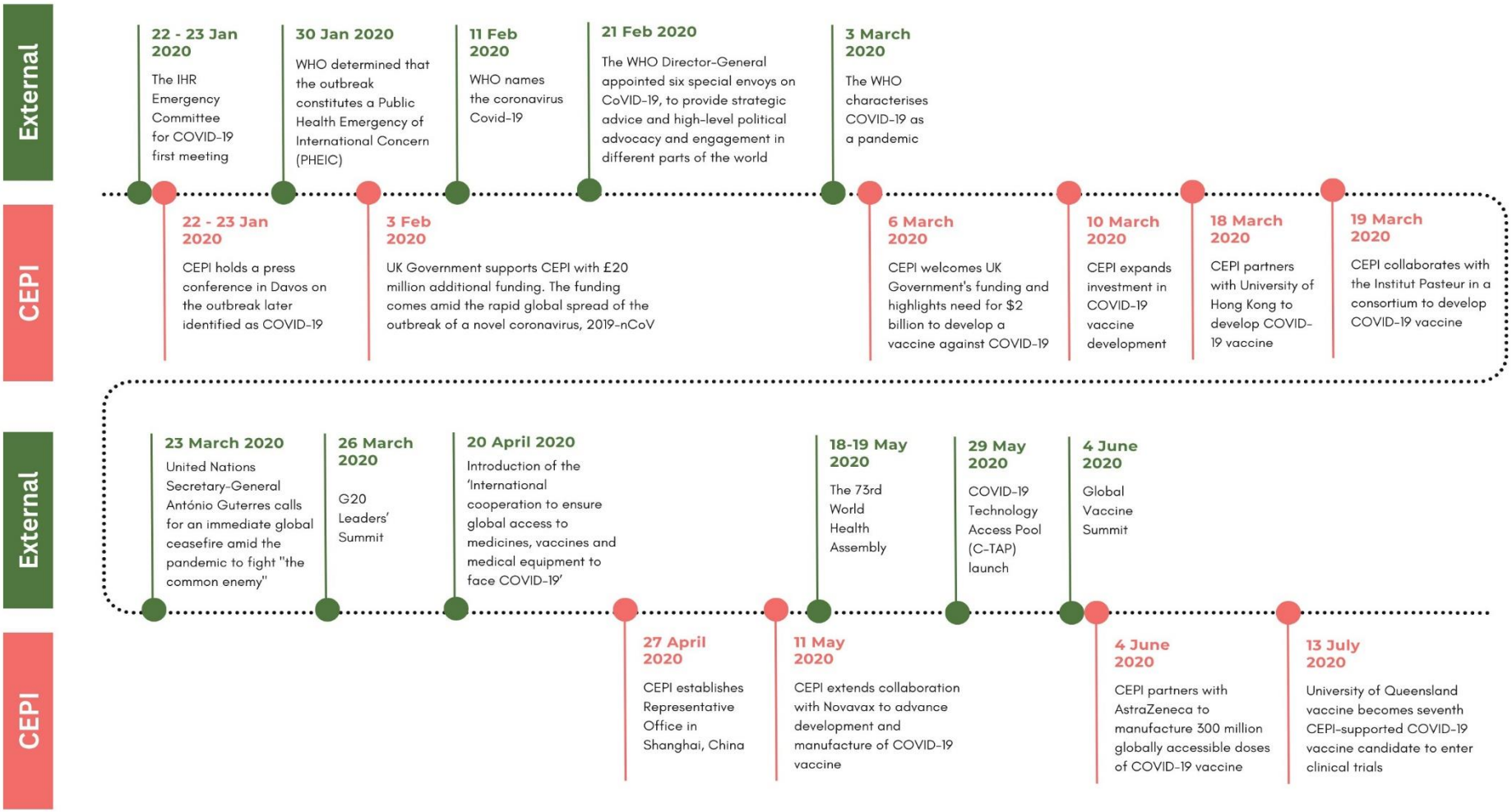
This drew upon and analysed existing mapping and analyses of the specific actors working in the global R&D landscape, including CEPI's current partners (stakeholder analyses), as well as trends in global R&D, including emerging new actors such as the Health Emergency Preparedness and Response Authority (HERA) and SCARDA, changing needs and priorities (landscape analyses), in order to determine whether CEPI is working with the right partners and responding to these needs to achieve the 2.0 strategic objectives. To inform this assessment we reviewed the prioritisation within the strategy, the mix of priorities, CEPI's decision-making processes and feedback from the KIIs, to determine whether the strategy is balancing these competing needs appropriately.

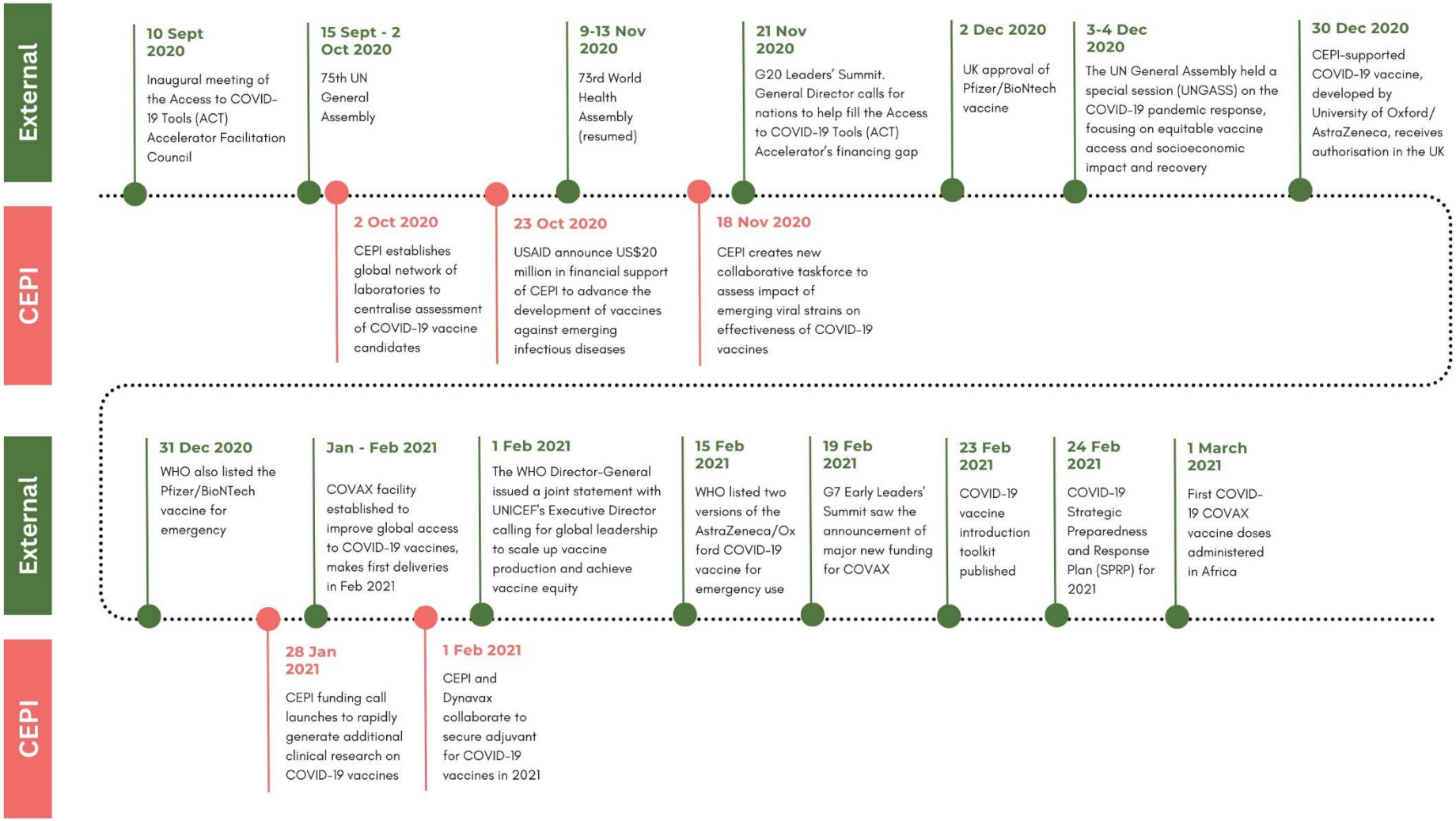
5.3. Context and timeline analysis

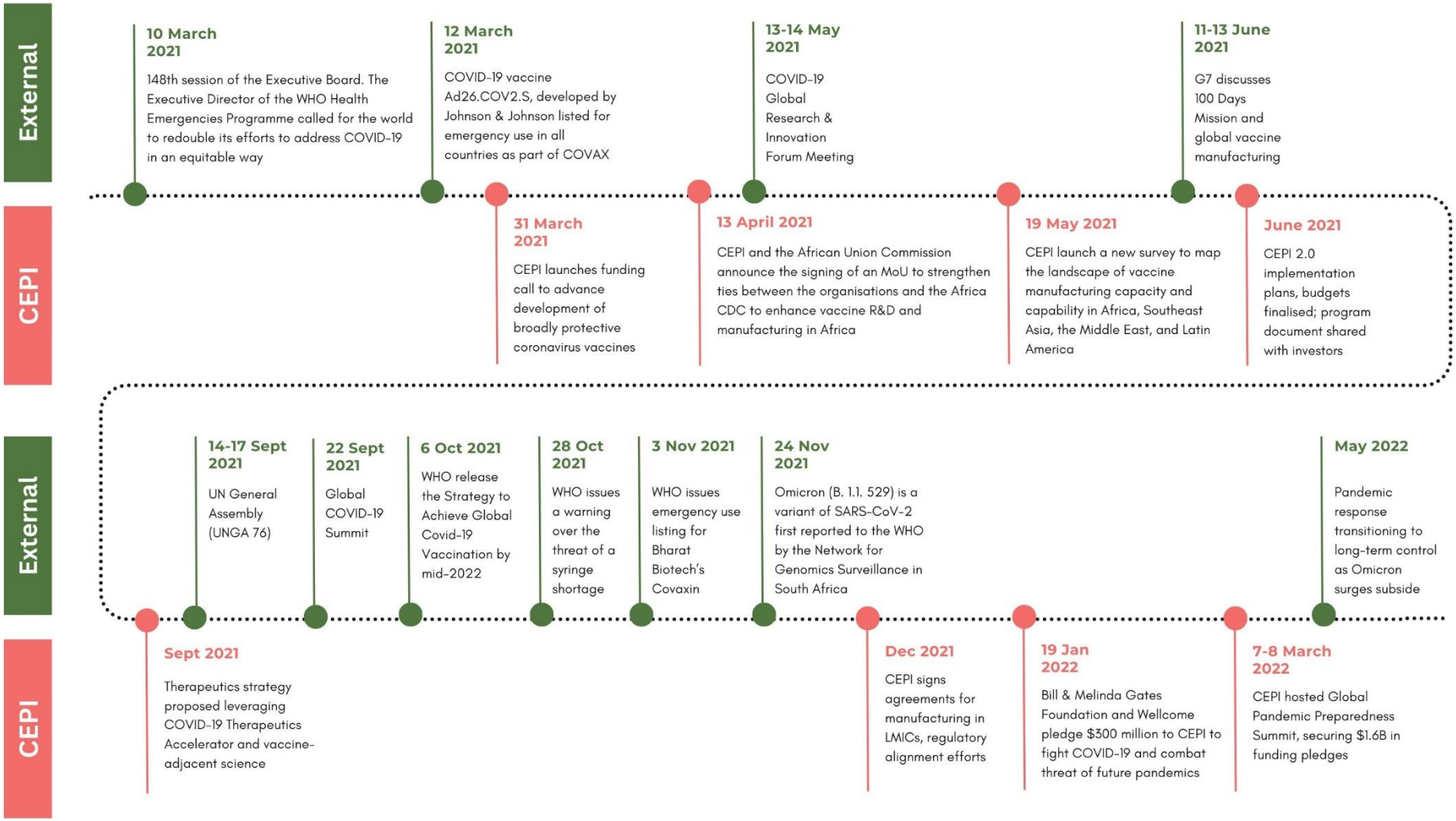
We conducted a context and timeline analysis to underpin our understanding of the context in which CEPI 2.0 was designed and operationalised.

First, we reviewed CEPI documents and data to create a coherent timeline and generate descriptions related to these timeline events. The analysis covered the time period 2021–24, i.e. from when 2.0 was first being designed up to the present date. We also included internal and external events against the backdrop of which the design and implementation of CEPI 2.0 took place.

Finally, we created the visual timeline (below), with the objective of situating the evaluation in the wider context, which is of particular importance because of the shifting environment and landscapes in which CEPI 2.0 operationalises.


External
22 - 23 Jan 2020
The IHR Emergency Committee for COVID-19 first meeting
30 Jan 2020
WHO determined that the outbreak constitutes a Public Health Emergency of International Concern (PHEIC)
11 Feb 2020
WHO names the coronavirus Covid-19
21 Feb 2020
The WHO Director-General appointed six special envoys on CoVID-19, to provide strategic advice and high-level political advocacy and engagement in different parts of the world
3 March 2020
The WHO characterises COVID-19 as a pandemic
CEPI
22 - 23 Jan 2020
CEPI holds a press conference in Davos on the outbreak later identified as COVID-19
3 Feb 2020
UK Government supports CEPI with £20 million additional funding. The funding comes amid the rapid global spread of the outbreak of a novel coronavirus, 2019-nCoV
6 March 2020
CEPI welcomes UK Government's funding and highlights need for $2 billion to develop a vaccine against COVID-19
10 March 2020
CEPI expands investment in COVID-19 vaccine development
18 March 2020
CEPI partners with University of Hong Kong to develop COVID-19 vaccine
19 March 2020
CEPI collaborates with the Institut Pasteur in a consortium to develop COVID-19 vaccine
External
23 March 2020
United Nations Secretary-General António Guterres calls for an immediate global ceasefire amid the pandemic to fight "the common enemy"
26 March 2020
G20 Leaders' Summit
20 April 2020
Introduction of the 'International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19'
18-19 May 2020
The 73rd World Health Assembly
29 May 2020
COVID-19 Technology Access Pool (C-TAP) launch
4 June 2020
Global Vaccine Summit
CEPI
27 April 2020
CEPI establishes Representative Office in Shanghai, China
11 May 2020
CEPI extends collaboration with Novavax to advance development and manufacture of COVID-19 vaccine
4 June 2020
CEPI partners with AstraZeneca to manufacture 300 million globally accessible doses of COVID-19 vaccine
13 July 2020
University of Queensland vaccine becomes seventh CEPI-supported COVID-19 vaccine candidate to enter clinical trials


External
10 Sept 2020
Inaugural meeting of the Access to COVID-19 Tools (ACT) Accelerator Facilitation Council
15 Sept - 2 Oct 2020
75th UN General Assembly
9-13 Nov 2020
73rd World Health Assembly (resumed)
21 Nov 2020
G20 Leaders' Summit. General Director calls for nations to help fill the Access to COVID-19 Tools (ACT) Accelerator's financing gap
2 Dec 2020
UK approval of Pfizer/BioNtech vaccine
3-4 Dec 2020
The UN General Assembly held a special session (UNGASS) on the COVID-19 pandemic response, focusing on equitable vaccine access and socioeconomic impact and recovery
30 Dec 2020
CEPI-supported COVID-19 vaccine, developed by University of Oxford/ AstraZeneca, receives authorisation in the UK
CEPI
2 Oct 2020
CEPI establishes global network of laboratories to centralise assessment of COVID-19 vaccine candidates
23 Oct 2020
USAID announce US$20 million in financial support of CEPI to advance the development of vaccines against emerging infectious diseases
18 Nov 2020
CEPI creates new collaborative taskforce to assess impact of emerging viral strains on effectiveness of COVID-19 vaccines
External
31 Dec 2020
WHO also listed the Pfizer/BioNTech vaccine for emergency
Jan - Feb 2021
COVAX facility established to improve global access to COVID-19 vaccines, makes first deliveries in Feb 2021
1 Feb 2021
The WHO Director-General issued a joint statement with UNICEF's Executive Director calling for global leadership to scale up vaccine production and achieve vaccine equity
15 Feb 2021
WHO listed two versions of the AstraZeneca/Oxford COVID-19 vaccine for emergency use
19 Feb 2021
G7 Early Leaders' Summit saw the announcement of major new funding for COVAX
23 Feb 2021
COVID-19 vaccine introduction toolkit published
24 Feb 2021
COVID-19 Strategic Preparedness and Response Plan (SPRP) for 2021
1 March 2021
First COVID-19 COVAX vaccine doses administered in Africa
CEPI
28 Jan 2021
CEPI funding call launches to rapidly generate additional clinical research on COVID-19 vaccines
1 Feb 2021
CEPI and Dynavax collaborate to secure adjuvant for COVID-19 vaccines in 2021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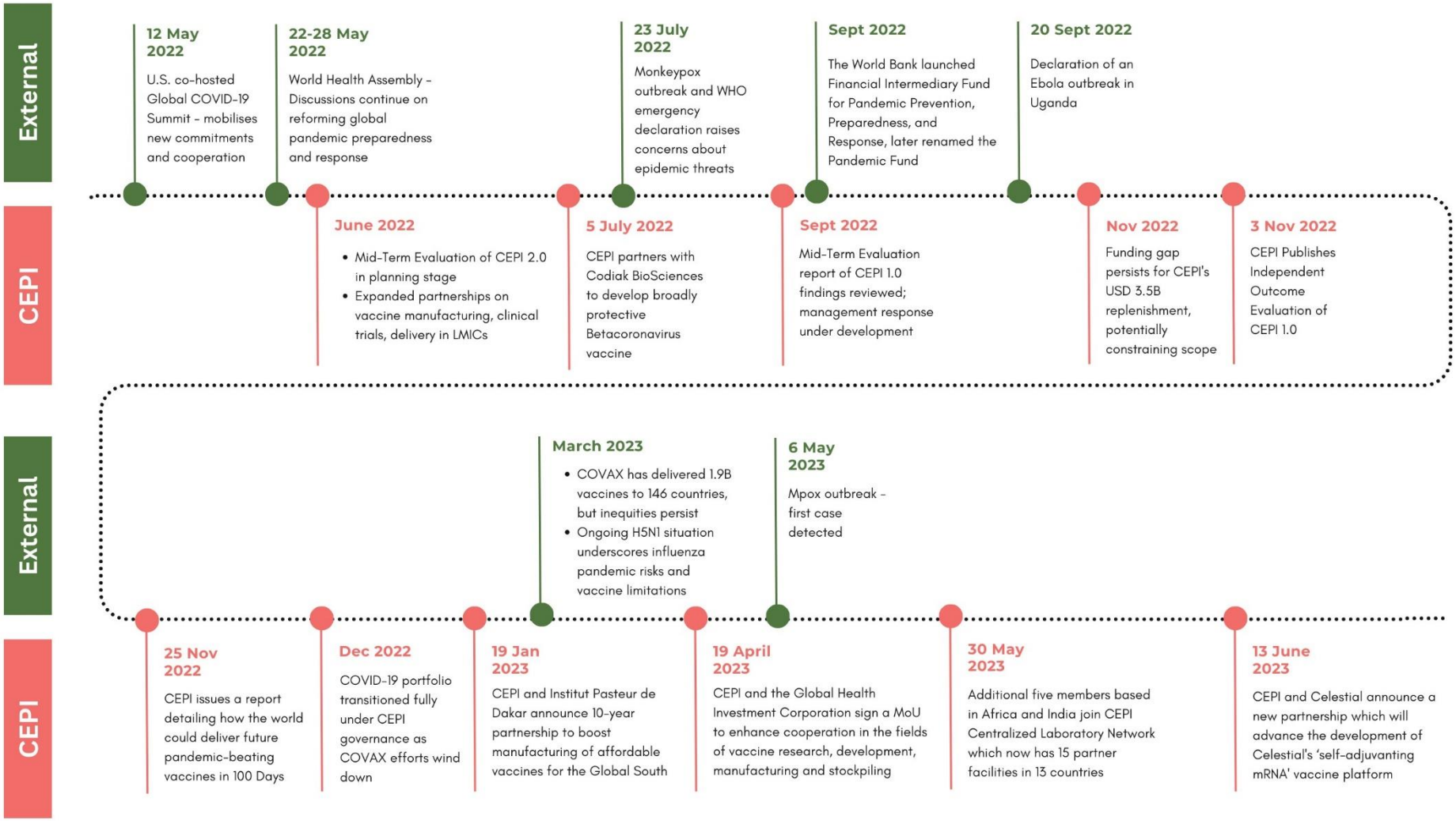
10 March 2021
148th session of the Executive Board. The Executive Director of the WHO Health Emergencies Programme called for the world to redouble its efforts to address COVID-19 in an equitable way
12 March 2021
COVID-19 vaccine Ad26.COV2.S, developed by Johnson & Johnson listed for emergency use in all countries as part of COVAX
13-14 May 2021
COVID-19 Global Research & Innovation Forum Meeting
11-13 June 2021
G7 discusses 100 Days Mission and global vaccine manufacturing
31 March 2021
CEPI launches funding call to advance development of broadly protective coronavirus vaccines
13 April 2021
CEPI and the African Union Commission announce the signing of an MoU to strengthen ties between the organisations and the Africa CDC to enhance vaccine R&D and manufacturing in Africa
19 May 2021
CEPI launch a new survey to map the landscape of vaccine manufacturing capacity and capability in Africa, Southeast Asia, the Middle East, and Latin America
June 2021
CEPI 2.0 implementation plans, budgets finalised; program document shared with investors
14-17 Sept 2021
UN General Assembly (UNGA 76)
22 Sept 2021
Global COVID-19 Summit
6 Oct 2021
WHO release the Strategy to Achieve Global Covid-19 Vaccination by mid-2022
28 Oct 2021
WHO issues a warning over the threat of a syringe shortage
3 Nov 2021
WHO issues emergency use listing for Bharat Biotech's Covaxin
24 Nov 2021
Omicron (B. 1.1. 529) is a variant of SARS-CoV-2 first reported to the WHO by the Network for Genomics Surveillance in South Africa
May 2022
Pandemic response transitioning to long-term control as Omicron surges subside
Sept 2021
Therapeutics strategy proposed leveraging COVID-19 Therapeutics Accelerator and vaccine-adjacent science
Dec 2021
CEPI signs agreements for manufacturing in LMICs, regulatory alignment efforts
19 Jan 2022
Bill & Melinda Gates Foundation and Wellcome pledge $300 million to CEPI to fight COVID-19 and combat threat of future pandemics
7-8 March 2022
CEPI hosted Global Pandemic Preparedness Summit, securing $1.6B in funding pledges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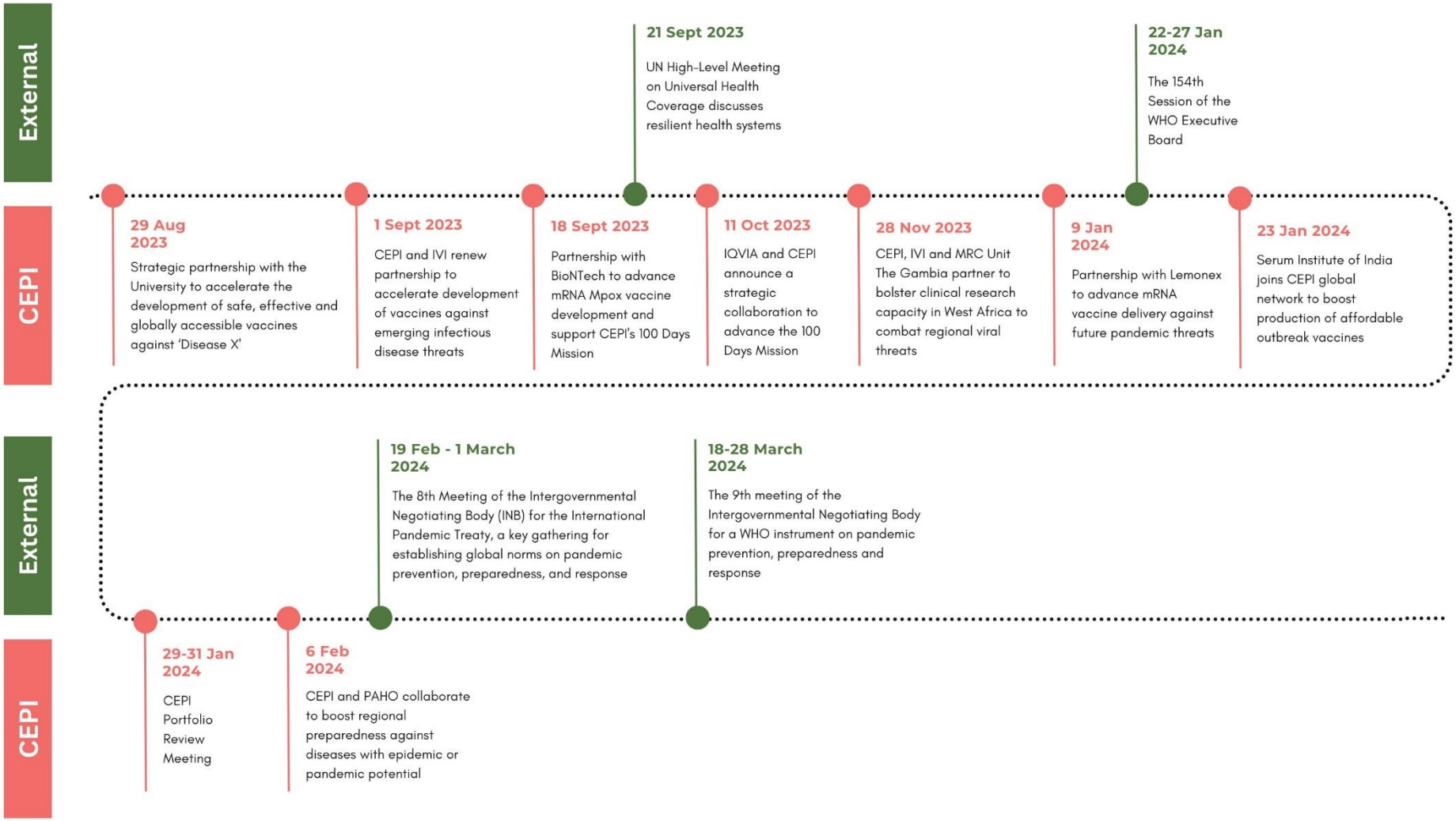
12 May 2022
U.S. co-hosted Global COVID-19 Summit – mobilises new commitments and cooperation
22-28 May 2022
World Health Assembly – Discussions continue on reforming global pandemic preparedness and response
23 July 2022
Monkeypox outbreak and WHO emergency declaration raises concerns about epidemic threats
Sept 2022
The World Bank launched Financial Intermediary Fund for Pandemic Prevention, Preparedness, and Response, later renamed the Pandemic Fund
20 Sept 2022
Declaration of an Ebola outbreak in Uganda
CEPI
June 2022
• Mid-Term Evaluation of CEPI 2.0 in planning stage
• Expanded partnerships on vaccine manufacturing, clinical trials, delivery in LMICs
5 July 2022
CEPI partners with Codiak BioSciences to develop broadly protective Betacoronavirus vaccine
Sept 2022
Mid-Term Evaluation report of CEPI 1.0 findings reviewed; management response under development
Nov 2022
Funding gap persists for CEPI's USD 3.5B replenishment, potentially constraining scope
3 Nov 2022
CEPI Publishes Independent Outcome Evaluation of CEPI 1.0
External
March 2023
• COVAX has delivered 1.9B vaccines to 146 countries, but inequities persist
• Ongoing H5N1 situation underscores influenza pandemic risks and vaccine limitations
6 May 2023
Mpox outbreak – first case detected
CEPI
25 Nov 2022
CEPI issues a report detailing how the world could deliver future pandemic-beating vaccines in 100 Days
Dec 2022
COVID-19 portfolio transitioned fully under CEPI governance as COVAX efforts wind down
19 Jan 2023
CEPI and Institut Pasteur de Dakar announce 10-year partnership to boost manufacturing of affordable vaccines for the Global South
19 April 2023
CEPI and the Global Health Investment Corporation sign a MoU to enhance cooperation in the fields of vaccine research, development, manufacturing and stockpiling
30 May 2023
Additional five members based in Africa and India join CEPI Centralized Laboratory Network which now has 15 partner facilities in 13 countries
13 June 2023
CEPI and Celestial announce a new partnership which will advance the development of Celestial's 'self-adjuvanting mRNA' vaccine platform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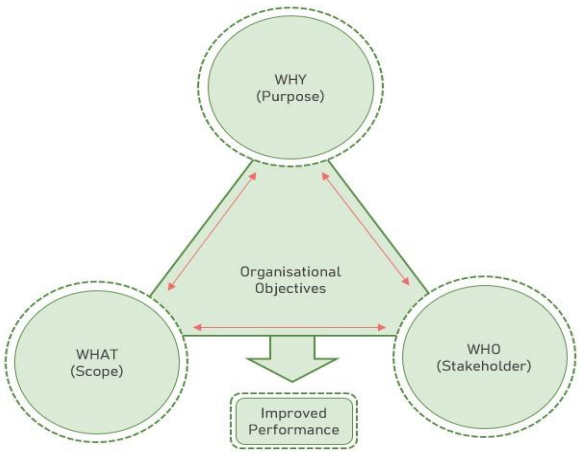
29 Aug 2023
Strategic partnership with the University to accelerate the development of safe, effective and globally accessible vaccines against 'Disease X'
1 Sept 2023
CEPI and IVI renew partnership to accelerate development of vaccines against emerging infectious disease threats
18 Sept 2023
Partnership with BioNTech to advance mRNA Mpox vaccine development and support CEPI's 100 Days Mission
21 Sept 2023
UN High-Level Meeting on Universal Health Coverage discusses resilient health systems
11 Oct 2023
IQVIA and CEPI announce a strategic collaboration to advance the 100 Days Mission
28 Nov 2023
CEPI, IVI and MRC Unit The Gambia partner to bolster clinical research capacity in West Africa to combat regional viral threats
9 Jan 2024
Partnership with Lemonex to advance mRNA vaccine delivery against future pandemic threats
22-27 Jan 2024
The 154th Session of the WHO Executive Board
23 Jan 2024
Serum Institute of India joins CEPI global network to boost production of affordable outbreak vaccines
29-31 Jan 2024
CEPI Portfolio Review Meeting
6 Feb 2024
CEPI and PAHO collaborate to boost regional preparedness against diseases with epidemic or pandemic potential
19 Feb - 1 March 2024
The 8th Meeting of the Intergovernmental Negotiating Body (INB) for the International Pandemic Treaty, a key gathering for establishing global norms on pandemic prevention, preparedness, and response
18-28 March 2024
The 9th meeting of the Intergovernmental Negotiating Body for a WHO instrument on pandemic prevention, preparedness and response

5.4. Partnership typology

This relates to EQ1.1.3 (To what extent is the CEPI 2.0 Strategy engaging in appropriate partnerships to achieve its objectives?) and, to a lesser extent, to EQ1.1.1 (To what extent is the CEPI 2.0 Strategy responding appropriately to relevant country, global and partner/institutions' needs and priorities?).

For the MTR, we define *partnership* as a formalised collaborative relationship between CEPI and another entity that involves pooling resources, expertise and efforts to implement activities under Strategy 2.0.[4] For the MTR, we started work on these EQs by drawing on the document review and the literature to map the purpose and scope of existing CEPI partners in relation to the 2.0 Strategy strategic objectives. To do this, we drew upon tools in the AA1000 Stakeholder Engagement Standard (see Figure 7).

Figure 7. Purpose, scope and stakeholders



The results from this mapping exercise were used as a starting point for analysis of both EQs. For EQ1.1.3 we then used the results to develop a partner typology of CEPI's partners, using the stakeholder identification tool in the AA1000 Stakeholder Engagement Standard to further understand the types and proportions of partnerships CEPI currently has in place. This typology has five dimensions:

- **dependency** – entities that are dependent on CEPI's activities and associated performance or on whom CEPI is dependent in order to operate
- **responsibility** – entities to whom CEPI has, or in the future may have, legal, commercial, operational or ethical/moral responsibilities
- **tension** – entities who need immediate attention from CEPI with regard to financial or wider economic, social or environmental issues
- **influence** – entities who have an impact on CEPI's strategic or operational decision making
- **diverse perspectives** – entities whose diverse views can lead to a new understanding of an issue and the identification of opportunities for action that may otherwise not occur.

[4] OECD (2008) *The Challenge of Capacity Development: Working Towards Good Practice*. OECD Publishing. doi:10.1787/journal_dev-v8-art40-en.

This typology included a cross-section of CEPI's partners based upon the information that was readily available, and as such was not representative of CEPI's partners as a whole. Although the AA1000 Standard helped us to analyse CEPI's partners through different lenses, the quantitative results from the typology provided indicative findings only that were used only to triangulate results.

We then drew upon the findings from the stakeholder analysis to compare CEPI's current partners with the broader global R&D stakeholder landscape, to determine whether CEPI has the right mix of partners to achieve its objectives and, if it does not, what needs to change.

5.5. ToC analysis

This relates to EQ1.2.1 (To what extent [does the ToC] identify appropriate indicators, outcomes and assumptions?) and EQ1.2.2 (To what extent [does the ToC] provide a pathway for CEPI to achieve its mission?).

In order to address these EQs, we benchmarked the ToC that is included in the CEPI 2.0 Monitoring and Evaluation Framework (2021) against good practice in ToC development, adding a few additional relevant questions.[5] In doing so, we tested the appropriateness of the activities, outputs, outcomes and mission, as well as the causal pathways between them, with a checklist of questions, including:

- **activities & outputs** – do all the outputs have activities (and resources) associated with them (and vice versa)?
- **outcomes** – are the outcomes measurable? Are they realistic? Are the outcomes phrased in terms of change? Do the outcomes clearly identify who or what will experience the intended change?
- **impacts** – will it be possible to demonstrate how activities and outcomes contribute to longer-term change?
- **indicators** – is the progress of all the main activities in the ToC monitored with relevant indicators?
- **mission** – is the mission realistic? Can we expect it to come about as a result of the intended outcomes? Does the mission adequately encompass the entire scope of the activities and outcomes included in the ToC?
- **causal pathways** – is there a logical causal pathway between all the activities, outputs, outcomes and strategic objectives and the mission?

Because CEPI's current ToC does not include explicit assumptions, we mapped these for the revised ToC as part of the inception phase and then tested them against the evidence collected as part of process tracing and other data collection activities as part of the MTR (see Table 1, which also informs aspects of the process tracing exercise presented in Section

[5] Innovation Network 2014, Do-It-Yourself Logic Models, www.innonet.org.

5.7).

Table 1. Analysis of CEPI's ToC assumptions

Assumption	Has the assumption been validated?
Design	
1. CEPI 2.0 is addressing the most pressing global needs that require CEPI's input.	**Validated:** CEPI 2.0 was designed to respond to emerging global needs and priorities, as identified during the Covid-19 pandemic. The document review and a range of stakeholders from all groups interviewed reflected that CEPI 2.0 and the 100 Days Mission were designed to be, and have remained, highly relevant to global needs, which reflected regional, country and partner needs and priorities. *Referred to in Findings 3 and 4.*
2. There is sufficient political buy-in and willingness to fund global health security/vaccine development.	**Mostly validated:** The Covid-19 pandemic stimulated much interest and political will to fund global health security/vaccine development. However, CEPI's 2.0 Strategy was not fully funded, and evidence suggests that political support in this area has waned in the years following the start of the pandemic. *Referred to in Finding 3.*
3. CEPI's approach strikes the right balance between risk tolerance and flexibility.	**Mostly validated:** CEPI's role in early-stage product development is inherently risky. The MTR finding that CEPI has been responsive to global needs, involving a substantial shift in strategy between CEPI 1.0 and 2.0, suggests a high degree of flexibility. CEPI's willingness to engage in broad areas of work in downstream issues and ecosystem strengthening further suggests flexibility, although many stakeholders questioned whether this is appropriate for CEPI. A large majority of staff indicated in the 2023 Staff Survey that they are encouraged to be innovative even though some initiatives may not succeed. This is in contrast with other MTR findings that the growth of the organisation, systematising ways of working and lack of internal cohesion have, in some instances, resulted in staff at CEPI being reluctant to take risks and in a reduced ability of the organisation to be agile – a trend management will need to monitor closely. *Referred to in Findings 3 and 22.*
4. CEPI's portfolio composition will enable it to meet its vaccine candidate targets.	**Not validated:** CEPI is pursuing a set of activities that are highly relevant and aligned to the CEPI 2.0 strategic objectives, although it lacks a clear articulation of how its investments link together at the pathogen/SRA level relative to other actors, and of how the portfolio as a whole leads to the achievement of higher-level goals. Vaccine candidate targets are likely not to be realised except for the SARS-CoV-2 vaccines. The majority of vaccine candidate targets will not be reached by 2026. The MTR analysis found that several of these targets were unrealistic – many having a low to medium chance of course correction by the end of 2026. *Referred to in Findings 4, 5 and 48.*
5. The selection of CEPI's portfolio and its management will enable expenditure for the	**Not validated:** CEPI's portfolio is mostly comprised of early-stage, low-value projects with small and medium-sized biotech companies. These projects have limited ability to scale up quickly, partially explaining the reported underspend in the early part of CEPI 2.0 and

portfolio to match its budget allocation	the organisation's inability to significantly increase spending without undergoing significant reprioritisation.
6. Development of new vaccines/other biologic countermeasures will result in demand for these products.	**Not validated:** There is concern over low potential demand for some products, e.g. RVF, Nipah, Chikungunya. CEPI has recently reported placing more resourcing into understanding downstream issues for its products, including demand estimation and working with country decision makers to stimulate demand, although its role in this area is not fully clear. *Referred to in Findings 43 and 47.*
7. Projected outputs and outcomes for the five-year 2.0 Strategy have taken into account factors affecting them that are outside of CEPI's control.	**Not validated:** The Strategy was developed during the Covid-19 pandemic and set out a grand vision for shifting the PPR ecosystem. However, key informants commented on the technical feasibility of the CEPI 2.0 strategic objectives and the 100 Days Mission, many suggesting that these could never have been achieved within the CEPI 2.0 time frame. Linked to this is the "practical impossibility" of CEPI spending the requested $3.5 billion within a five-year period. *Referred to in Finding 2.*
8. CEPI's partnerships will enable it to fulfil its end-to-end scope of work.	**Mostly validated:** CEPI has been collaborating with partners along the R&D&M continuum from multilaterals and regional organisations working in PPR, industry, academic laboratories, governments, institutions, manufacturers, NGOs, and regulators. The MTR found that CEPI needs to strengthen engagement with MNCs. The MTR Team understands that management is in the process of designing and adopting a more proactive, tailored and strategic approach to selecting and engaging with partners to meet specific objectives, which vary by partner type. *Referred to in Findings 10 to 13.*
9. Equitable access principles are woven into CEPI's work.	**Validated:** Equitable access principles have been included in R&D funding agreements, work in manufacturing and supply chain and advocacy for areas outside of CEPI's control. *Referred to in Findings 41 to 46.*
Outcomes	
10. CEPI's support in upstream development will lead to downstream access to new vaccines/other biologic countermeasures.	**Not validated:** It is too early to tell if this will be realised, although early indications are that unless significant work is put into understanding and addressing barriers and enablers to downstream access, there is a significant risk that this assumption will not be realised. The MTR understands such work is under way, although CEPI's role in some of these areas is the source of much debate. *Referred to in Finding 8.*
11. Enhancing regional manufacturing capability will increase the efficiency of supply.	**Not validated:** It is too early to tell if this will be realised. CEPI has made good progress in expanding the manufacturing network and signing new agreements with manufacturing partners in the Global South. However, it is too early to determine if this will result in increased efficiency of supply, which (however defined) will only be tested when manufacturing begins at scale.

	Referred to in Findings 9 and 44.
12. Safe and effective vaccines and other biologic countermeasures are developed within the five-year timeline.	**Not validated:** This is likely not to be realised (see assumption 4).
13. CEPI will be able to fulfil its equitable access commitments.	**Not validated:** It is too early to tell if this will be realised; however, the evidence under assumption 8 and from Covid-19 suggests that there are substantial risks in this area. For Covid-19, CEPI's investment in the supported vaccine that was most widely used in the early phases of the pandemic, when supply was constrained (Oxford/ AstraZeneca), was small and limited in scope, as it was for the Moderna mRNA vaccine, which became available to COVAX and most LMICs only in 2022, when supply was no longer constraining equitable access. The two vaccines for which CEPI investments were large – Novavax and Clover – were significantly delayed in development, becoming available only from 2022 onwards. *Referred to in Findings 41 to 46.*
14. The ToC outcomes will be sustained.	**Not validated:** It is too early to tell if this will be realised. Once there is access to new vaccines, there are many factors beyond CEPI's control which will determine if this access will be sustained. The future of vaccine libraries, technology platforms and global networks (e.g. for laboratories and regulators) will be reliant on sustainable funding, engagement and leadership. It is noted that analysis of sustainability is not within the scope of this MTR.
15. CEPI is able to leverage its soft power to contribute to wider global/regional/national R&D systems goals, including pandemic preparedness and equitable access.	**Validated:** CEPI is using soft power to build partnerships (recent deal with SII) and yield influence on partners to support CEPI's mission (G7 Hiroshima Leaders' Communiqué) and encourage relevant partners to meet gaps, given that CEPI has an end-to-end remit for pathogens with epidemic/pandemic potential but cannot do everything. Through staff participation in key global events and meetings (e.g. sitting on panels at UNGA, World Vaccine Congress and technical summits), CEPI is contributing to shaping the agenda, which it is also directly supporting via funding to deploy partners. CEPI's commitment to transparency can be viewed as a vehicle to build trust and further establish soft power. *Referred to in Finding 49.*
Process	
16. CEPI's matrix management supports the multidisciplinary work of CEPI.	**Not validated:** Although management worked effectively during Covid-19, the management of the broadened remit under 2.0 has not been cohesive, and the process of transdisciplinary disease teamwork and cross-team collaboration is not always effective. A number of key informants noted that the matrix management model is not working optimally and has been part of the problem with organisational ways of working. *Referred to in Finding 22.*

17. CEPI's governance structures work efficiently and effectively to provide the right high-level guidance and oversight for CEPI's work.	**Validated:** The Board is generally functioning well, as are several of the governance committees. There has been an issue with the right level and type of documentation provided to these committees in order to enable efficient decision-making processes. *Referred to in Findings 18 to 20.*
18. CEPI's Management Team has sufficient staff and systems, and the workload is managed effectively across teams.	**Mostly validated:** Internal systems and processes are being strengthened to keep pace with the rapid growth in staff numbers. There is evidence that certain teams are being established or expanded. Hence, although it is a work in progress, the staffing and systems are not yet adequate and embedded. Staff workloads being unsustainable were cited in several KIIs. *Referred to in Finding 22.*
19. CEPI's reputation is maintained.	**Validated:** CEPI has maintained a strong, independent reputation among external stakeholders. Risks to this include a dilution of CEPI's mandate and slower R&D progress than anticipated by the end of CEPI 2.0. *Referred to in Finding 49.*
20. Global events (e.g. novel pandemics, supply chain disruption or climate-related shocks) and disruptive technologies/AI do not prevent the completion of the core programme of work for 2.0.	**Not validated:** It is too early to tell if this will be realised. CEPI is undertaking work to understand the potential impacts of AI on its portfolio, incorporate biosecurity risks, prepare for novel pandemics and address supply chain issues. The MTR has not seen evidence of it taking climate-related health impacts into account.
21. An internal learning culture within and between teams drives continuous quality improvement and increased efficiency and effectiveness and ensures ongoing relevance and appropriateness of CEPI's work.	**Not validated:** This has only been partially realised. Evidence of review and learning processes within CEPI is sporadic but does exist. Adequate systems for cross-team learning do not exist. *Referred to in Finding 50.*

5.6. Capability, culture and practice framework

This relates to EQ2 (To what extent are CEPI's management and governance systems fit for purpose vis-à-vis implementation of the programme of work?).

Benchmarking is proposed as an analytical tool to ascertain whether the right capabilities, culture and practices were/are in place to best enable and support CEPI's operations and to understand the way accountability works between key stakeholders at different levels and the reasons/drivers for any failures or successes. As per the issues identified in the inception phase, it is important to ensure that the evaluation remains focused on CEPI while also considering the interconnectedness of roles, responsibilities and ways of working between agencies.

The capabilities, culture and practices framework draws on the approach used in Global Accountability Reports[6] and the Multilateral Organisation Performance Assessment Network (MOPAN) 3.1 methodology,[7] as articulated in Figure 8.

Figure 8. Components of capabilities, culture and practices framework

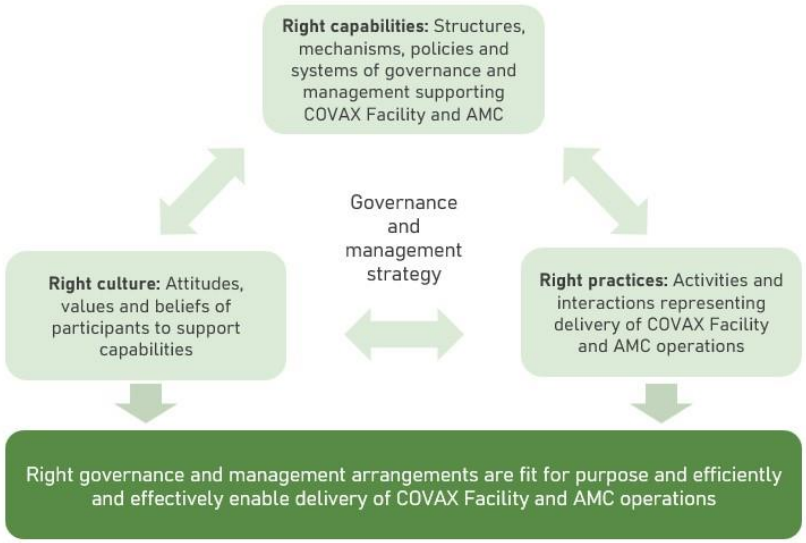


Table 2 is used as an internal tool to systematically assess whether the design and implementation of CEPI management structures and governance arrangements is aligned to the different components of the capabilities, culture and practices framework. The components, tailored to answering the EQ, are drawn from the references above, from Cross and Carboni's (2021) categorisation of patterns of network connectivity and collaborative practices that lead to dysfunction which undermines performance,[8] and from established key principles of good governance.[9]

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[6] Based on the framing adopted in the Accountability Reports 2008 and 2011: Lloyd, R., Warren, S. and Hammer, M. (2008) *2008 Global Accountability Report.* One World Trust. http://www.oneworldtrust.org/uploads/1/0/8/9/108989709/2008_global_accountability_report.pdf; Hammer, M. and Lloyd, R. (2011) *Pathways to Accountability II - The 2011 revised Global Accountability Framework*. One World Trust. https://acfid.asn.au/sites/site.acfid/files/resource_document/Pathways-to-Accountability-II.pdf.

[7] https://www.mopanonline.org/ourwork/themopanapproach/Methodology_3.1_FinalUnformatted.pdf.

[8] Cross, R. and Carboni, I. (2021) *When collaboration fails and how to fix it*. MIT Sloan Management Review. Winter 2021.

[9] These are that: governance structures provide a comprehensive view on the investment of public funds, enabling the right decisions to be taken in a timely manner; appropriate members are selected for critical advisory groups; decision making is done in an impartial and fair manner, with appropriate consideration given to conflicts of interest, which are identified and managed appropriately; and information on critical discussions and progress is provided in a transparent and timely manner. COVAX (2020, 17 March) *COVAX: The Vaccine Pillar of the access to COVID-19 tools (ACT) accelerator structure and principles*.

Table 2. Analytical tool for assessment against capabilities, culture and practices framework

Mgt. (M)/ gov. (G)	Framework components	Evidence of alignment to principles
Capabilities		
M	Staff capacity (quantity of staff and mix of skill sets) is considered to be sufficient to fulfil roles and responsibilities	Several KIIs said that they respected and acknowledged the calibre of technical staff at CEPI and their skill sets. There is evidence that certain teams (e.g. biosecurity, alliance management) are being established or expanded to fulfil recognised roles for CEPI. It was also noted that CEPI does not necessarily have expertise in certain downstream areas, e.g. scale-up of production, which feeds into discussions about CEPI's remit. Workloads of staff that were unsustainable in peacetime were cited in KIIs.
M & G	Roles, decisions, rights and incentives are well structured for an entity working in an emergency setting	The document review found that CEPI proved to be agile and responsive during Covid-19. Since then the organisation has grown considerably, and decision-making remits of governance structures have been recently clarified. Arguably, necessary additional layers of operational processes and systems commensurate with a larger organisation have hampered CEPI's ability to be nimble. This is a tension which will need to be carefully managed. A few staff and governance committee KIIs noted that the appointment of a Deputy CEO to provide administrative leadership to enable the CEO to focus on strategic leadership and engagement is likely to improve the agility of senior management and decision-making processes.
G	Governance structures provide a comprehensive view on the investment of public funds, enabling the right decisions to be taken in a timely manner	According to the document review, the Investment Management System (IMS), which enables visibility of the project pipeline and forecasting, is still being embedded and fully utilised across the organisation. The implementation of the IMS is designed to enable governance and management structures to have a comprehensive view of CEPI's financial position and its portfolio at any point in time; this capability has not yet been possible.
G	Appropriate members are selected for advisory groups, including technical expertise and LMIC representation	According to a few governance committee members, CEPI has reviewed and has been intentional about ensuring diverse representation on its governance committees, including drawing in additional external expertise where needed. The Board membership is now generally viewed as adequate. According to a few governance committee and staff, as well as the document review, the Portfolio Strategy and Management Board (PSMB) needs more strategy/portfolio-level expertise.
Culture		
M	Attitudes and behaviours of staff, such as their perceptions of external stakeholders	In the CEPI Staff Survey 2023, a large majority of people reported being proud of working for the organisation and motivated to go beyond what they would do in a similar role elsewhere. Staff interviewed for the MTR generally reported good collaboration with external stakeholders, working towards common goals. There were

	and how they interact with them, support capabilities	some points of tension with certain partners, mainly as a result of individual relationships, or frustration with internal processes delaying activities with external partners.
M	Management structures are not overly hierarchical, and/or leadership is not overly controlling, allowing for independent decision making	There was contradictory evidence on this point. The Deloitte Dec 22 Voice of Customer and Partner Report found that CEPI teams managing CfP processes at times felt a lack of empowerment, unclear expectations of them, and that CEPI had a complex hierarchy and were apprehensive in making and owning decisions. Although this is likely more to do with organisational size than hierarchy, a few KIIs noted the inability of project teams to be able to communicate with management to understand and challenge decisions affecting their work. However, the 2023 Staff Survey reported that a large majority of staff said they were encouraged to be innovative even though there was a risk of failure, and that there was open and honest two-way communication at CEPI.
M	Team members work collaboratively (albeit without a culture of overinclusion) for the attainment of joint goals	The document review and a few staff KIIs reported evidence of some disease/project teams working effectively and some finding transdisciplinary work challenging. This evidence also identified a lack of cohesive decision making among the executive leadership. The Deloitte Dec 22 Voice of Customer and Partner Report found that partners noted a perceived disconnect between the administrative and technical teams within CEPI, resulting in delays in adopting agreed changes to projects and funding being released.
M & G	Expert and wider stakeholder inputs are sought in an inclusive manner, without an overreliance on a few stakeholders or on one stakeholder group	The MTR document review found that some CEPI governance groups draw upon external expertise effectively to robustly address a diversity of portfolio issues, e.g. Joint Coordination Group (JCG), Investors' Council (IC). Some Board and other meetings are also being held in Global South countries to strengthen engagement and committee membership, broadened to reflect the diversity of CEPI's stakeholders. Among its peers, CEPI is perceived by external stakeholders to be apolitical and thus more inclusive.
Practices		
M & G	There is limited divergence between what is included in the formal documentation and what happens in practice	In the document review there was evidence that management responses to reviews/staff surveys were generally actioned. It also found that the ToRs for the governance committees generally matched the actions of that committee, with the exception of the PSMB, which needed to better implement its strategic remit. However, only 63% of staff agreed that CEPI's organisational values matched how they actually worked in the 2023 Staff Survey. The MTR was unable to verify whether ToRs matched actions for internal structures within CEPI, such as the operation of its Disease Programme Teams.
M & G	Meeting and communication norms are effective	A few staff KIIs noted that the members of the Extended Leadership Team could be more coherent and work more collaboratively for the good of the organisation. A number of KIIs and documents pointed to inefficiencies in the documentation provided to CEPI's governance committees, hampering the effectiveness of decision-making

		processes. The MTR understands that documentation processes are being strengthened.
M & G	Decision making is done in an impartial and fair manner, with appropriate consideration given to conflicts of interest, which are identified and managed appropriately	Several KIIs, including from CEPI's research & development & manufacturing (R&D&M) partners, said that CEPI is perceived as a politically neutral organisation, able to make impartial decisions in support of its mandate. This view was generally supported by the other findings of the MTR, which noted that the governance committees operated with integrity and generally with a view to upholding CEPI's mission. However, as noted above, the Extended Leadership Team was noted to be less cohesive. Several positions on the ELT are being filled, which presents an opportunity to strengthen the decision-making processes of the ELT once the new team is on board.
M & G	There is a clear and appropriate delineation between decision making carried out by the Board, investors and management	A few informants from CEPI's governance committees confirmed that there is generally clear delineation between decision making by the Board and decision making by management. On occasion, the Board has been involved in operational discussions that are usually deemed to be the role of management, or decisions that could be taken by management. There have been mixed reasons given for this, including lack of clear documentation or that it is the legacy of a smaller organisation working in an emergency context. The same group of KIIs noted that there is clear delineation in the decision making carried out by the IC.
M & G	Information on critical discussions and progress, including to inform decisions, is provided in a transparent and timely manner	According to several KIIs among the staff and governance committees and the documents reviewed, CEPI has struggled to prepare documents for governance committees and provide good day-to-day visibility of their funds. Both issues are being addressed, including through the introduction of the IMS. A few of CEPI's grantee partners noted that decisions on CfPs can take extended periods of time to be made and relayed to entities submitting proposals. The feedback provided to those entities is inconsistent; at times extensive information is provided, and at other times very little detail is provided.

Note: The last components of both the Capabilities and Practices sections have been adapted slightly to be fit for purpose for this MTR.

5.7. Process tracing

The overall contribution claim is that CEPI prioritises the highest potential impact interventions, which lead to a strengthened and coordinated R&D ecosystem, accelerated vaccine development for priority pathogens, and transformed vaccine manufacturing, contributing to lowering the global threat of epidemics and pandemics. As set out in the illustration of the ToC, this incorporates three interlinked causal chains – Prepare, Transform and Connect.

The tests and evidence to gather to establish a degree of confidence in this contribution claim are shared in Table 3.

Overall, the process tracing exercise has not been able to validate the contribution claim. To do so would, notably, require further evidence of timely investments being made and progress towards outputs, outcomes and strategic objectives:

- One straw in the wind test related to the achievement of intended outputs is disputed, as per the KPI assessment and overall delays in CEPI 2.0 implementation progress. Another test on whether a culture of learning exists within the Management Team is unclear. Together this suggests that the contribution claim may not be relevant, but it does not in itself eliminate it.
- Only two tests were smoking gun tests (and none were doubly decisive tests), which reflects a challenge in applying the methodology in an evaluation such as this. One, related to stakeholders acknowledging that CEPI's management and governance enabled implementation of the project/programme, is disputed. Another, that stakeholders acknowledge that CEPI was a key factor in the achievement of outcomes and strategic objectives, is unclear given the lack of progress at this level. This does not eliminate the contribution claim, but it reduces confidence in it.
- Despite many hoop tests being validated (10 out of 14), three are disputed and the evidence for one is unclear, which is sufficient to refute the contribution claim. Most evidently, the hoop tests failed relate to: (a) CEPI management and governance working to make priority investments in a timely manner; (b) cross-functional alignment within the management team to enable CEPI 2.0 objectives; and (c) having sufficient evidence to demonstrate that desired outcomes and strategic objectives are likely to be achieved within the CEPI 2.0 time frame.

Table 3. Process tracing tests, test type, and evidence

Evidence to prove contribution claim	Test type	Analysis of evidence	Finding ref.
Fund			
CEPI makes expert and evidence-informed decisions on investing in the most relevant and high-value opportunities to meet the 2.0 Strategy objectives	Hoop	**Confirmed:** Evidence from the Board Effectiveness Review, other documents and several CEPI staff and governance interviews indicates that the Board contains the right expertise and representation and that detailed information is made available to them, so that it engages in critical analysis of issues brought to its attention and has a robust decision-making process which both approves and rejects matters brought to their attention as appropriate for CEPI's portfolio and to uphold its mission. A range of activities has sought to clarify the roles of each governance committee and ensure appropriate membership to fulfil these roles. Over the past 18 months, the roles of CEPI's governance committees have been articulated, terms of reference (ToR) written, and decision-making mandates clearly articulated in terms of which committee should make a decision for a specified quantum of investment. In particular, efforts have been made to differentiate between the work of the PSMB and that of the Vaccine Research and Development and Manufacturing Committee (VRDMC).[12] Meanwhile, the Audit and Risk Committee is reported to be working with finance staff to manage the underspend and strengthen financial reporting. Reportedly, the Scientific Advisory Committee (SAC) is providing valuable input and drawing effectively upon external input to cover a wide range of topics, and the IC is generally functioning well. However, some issues remain. In particular, there are challenges in the functioning of some committees. Notably, evidence suggests that the PSMB lacks the expertise to provide guidance on CEPI's investment portfolio strategy, which is its core responsibility, focusing instead on the technical aspects of proposals.	18–20, 38–40
CEPI's Management Team ensure sufficient resources are available to respond to prioritised activity areas, as approved by the Board	Hoop	**Confirmed:** The Covid-19 pandemic stimulated much interest and political will to fund global health security/vaccine development. However, CEPI's 2.0 Strategy was not fully funded, and evidence suggests that political support in this area has waned in the years following the pandemic. Nonetheless, CEPI has consistently reported that it has sufficient resources at its disposal to implement the desired set of activities. A consistent issue with underspending suggests that this is the case.	3, 30–31
CEPI's Management Team release calls for proposals and work to generate interest among potential applicants	Hoop	**Confirmed:** CEPI has released a range of CfPs throughout the CEPI 2.0 period. Importantly, it has also shifted away from relying purely on narrowly defined CfPs towards more open-ended calls alongside strategic partnership agreements, which, evidence suggests, is working to engage with applicants that may not have engaged with CEPI through narrow CfPs, and in a more meaningful and long-term manner.	32
Stakeholders consider that CEPI calls for proposals are sufficiently well designed and powered to incentivise industry partners to respond with well-articulated and promising applications that are likely to meet CEPI goals	Hoop	**Confirmed:** CEPI has a strong track record of engaging with partners for agreed outcomes through its CfP process. However, a range of challenges also affected CEPI's ability to attract strong partners to respond to its CfPs in 2022 and 2023. Perhaps most importantly, this relates to a 'hangover' from Covid-19 and a period of consolidation for many of CEPI's potential R&D partners (although this situation has also provided opportunities, such as with Moderna). As above, its shift towards more open-ended calls alongside strategic partnership agreements appears to be working to engage with applicants that may not have engaged with CEPI through narrow CfPs, and in a more	34–35, 45

		meaningful and long-term manner. There remains an issue in engaging MNCs, which, as set out in the main report, is sectorwide and likely linked to the scale of the incentive to justify their engagement from a purely commercial perspective. Recent announcements of agreements with BioNTech and Moderna are promising, and it is understood that discussions with other MNCs are ongoing, with announcements forthcoming.	
CEPI management and governance bodies work as intended to approve the application(s) in a timely manner, such that investments are made in priority disease areas in line with workplans and anticipated resource needs	Hoop	**Disputed:** There were mixed views on the timeliness of review and approval of CfPs, as well as on communication to awardees during this process. The Deloitte Dec 22 Voice of Customer and Partner Report noted that some awardees found that communication from CEPI during the evaluation and negotiation phase of a CfP was clear, timely, and receptive to partner feedback. Others found the application process complex and inflexible, with unclear requirements and expectations; they noted insufficient communication with applicants and slow and lengthy contracting processes, impacting awardees' cashflow. A few KIIs (partners and governance) confirmed that the latter finding is still an issue, i.e. that feedback on proposals from CEPI was inconsistent and the timing ad hoc. In particular, CEPI's decision-making processes are not always well understood by R&D partners, which can cause delays and frustration.	21–22
Applications selected based on criteria weighted towards the achievement of one or more strategic objectives	Hoop	**Confirmed:** The Deloitte Dec 22 Voice of Customer and Partner Report found unclear strategic alignment between CEPI's and some awardees' objectives. According to CEPI's Ways of Working Manual (2024), the PSMB is responsible for the identification, selection, management and evaluation of CEPI's R&D&M portfolio and considers proposals in light of the 2.0 strategic objectives and the 100 Days Mission and equitable access principles. However, the MTR notes that the PSMB Effectiveness Review (2022) found that this body was not considering CEPI's target portfolio in its decisions but rather was focusing on technical review, which, according to the above manual, is the role of the VRDMC. This review highlighted a lack of alignment between the projects approved by the PSMB and CEPI's strategic objectives, resulting at least in part from a gap in PSMB expertise to conduct strategic, portfolio-level discussions. This finding was confirmed by the PSMB ToR Analysis (Nov 23), which also noted that the PSMB is caught between the technical discussions at the VRDMC and the strategic discussions at the EIC/Board level. Nonetheless, and although the MTR has not cited reviewer comments on applications, the MTR analysis of CEPI-funded activities and their alignment with the 2.0 Strategy found a high level of alignment (see Annex 6.3), suggesting that reviewers are ensuring that proposals will contribute to achieving the 2.0 strategic objectives.	18–19
Equitable access solutions are integrated into CEPI investments	Hoop	**Confirmed:** CEPI demonstrated a strong commitment to ensuring equitable access to vaccines during the Covid-19 pandemic. An external review found that CEPI's strong commitments to equitable access had been translated into equitable access provisions in CEPI's Covid-19 vaccine development agreements, and this was reinforced through KIIs. The CEPI Equitable Access Framework (EAF) sets out a comprehensive approach to addressing equity across CEPI's scope of work. Multiple teams within CEPI are responsible for ensuring that equitable access (EA) is enabled for any given CEPI investment. CEPI's resulting agreements with R&D partners must include specific and measurable objectives as captured in an EA Plan, including obligations and deliverables as part of performance of each stage of the project. Access provisions are embedded in CEPI's contracts with partners, as evidenced by the document review and KII respondent inputs. For example, KII respondents commented on the inclusion of terms which include: a fair pricing gap; guarantee fair distribution of products to countries; and clauses that aim to build and foster a regional network in the respective countries.	41–46

CEPI provides funding to selected applicants in a timely manner and at the scale required to achieve objectives	Hoop	**Confirmed:** CEPI has a strong track record of engaging with partners for the achievement of agreed outcomes. As highlighted in the main report, much programmatic progress has been made across the CEPI portfolio within CEPI 2.0, and building on CEPI 1.0, to suggest that project-level objectives are often achieved, even if many are delayed.	21–22
Expert assistance is provided to CEPI grantees during implementation, which stakeholders deem to be of critical value to achieving shared objectives	Hoop	**Confirmed:** A range of R&D partners and external commentators reflected very positively on CEPI's technical capacity and the value it brought in advancing technical issues to R&D grantees. CEPI's work on CMC, in which it engages with a group of experts to troubleshoot emerging issues, was noted as being a particularly strong example.	49
Achievement of intended outputs	Straw in the wind	**Disputed:** For strategic objective 1, one output KPI target has been achieved; one is not on track but has a plausible expectation of course correction; two are considered as not on track, with no plausible expectation of course correction; and one is no longer relevant. For strategic objective 2, one is broadly on track, with risk mitigation plans in place; one is not on track but has a plausible expectation of course correction; and two are considered as not on track, with no plausible expectation of course correction. For strategic objective 3, three are broadly on track, with risk mitigation plans in place; and two are not on track but have a plausible expectation of course correction.	30–36, 37, 48
Stakeholders acknowledge that CEPI was a key factor in industry altering approach within the market	Hoop	**Confirmed:** CEPI's role is often to engage with actors already active in the market but to shift their emphasis and prioritisation of actions towards equitable access. There is a host of examples of where CEPI has been successful in doing this, including for specific R&D projects and wider technological adaptations and innovations. Its success in integrating equitable access provisions within CEPI grant agreements is testament to this. However, there remains a lack of clarity as to what these provisions will mean in practice in the event of a future outbreak or pandemic.	41–45
Lessons are learned from those investments that 'fail' as well as those that 'succeed'	Straw in the wind	**Unclear:** There is mixed evidence on the extent to which CEPI has a strong learning culture. Many monitoring and review processes take place internally, often to inform governance requirements and to facilitate reflection on progress and issues encountered, but these largely lack critical analysis of why identified issues have arisen, what CEPI has done well and less well, what CEPI can and cannot do differently, and what the trade-offs would be if CEPI were to engage in a different manner. Key informants noted that this does happen within the organisation but to varying extents across teams, with some noting that it is stronger for PPR, where after-action review processes are common. Other key informants noted that it can be challenging to focus on reflective activities alongside a busy day job. There are some positive examples in R&D, for instance in relation to MERS, where learnings from earlier investments were used to speed up Covid-19 vaccine development and are now being applied to BPBCV.	50
Catalyse and advocate[10]			
CEPI builds relationships with partners who are engaged in similar areas and where synergies can be harnessed	Hoop	**Confirmed:** In several CEPI documents, there are descriptions of the types of CEPI partners that CEPI has or would like to have, rather than a formal definition. Although CEPI has a good understanding of its partnerships, the MTR understands from a few CEPI staff KIIs that it is in the process of developing a plan to identify the partners that it needs and to then more proactively select partners based upon both their technical capability and their objectives/motivations. CEPI has partnership agreements in place, including with its recently formed Strategic Partnerships. In the agreements reviewed for the MTR, common partnership objectives and/or activities or common	24–29

[10] Some tests related to CEPI's advocacy role have been streamlined as they are not, with the benefit of having now concluded data collection, felt to add value to the exercise.

		interest have been identified. A few KIIs noted that parallel project management structures in CEPI and grantee organisations for R&D projects have made decision making challenging, indicating that roles and responsibilities could be clearer. Several KIIs noted challenges in CEPI finding points of collaboration with MNCs and in engaging in the right way (i.e. considering sustainability and viability issues and scope of CEPI's involvement) with regional manufacturing partners in LMICs. CEPI also engages in a range of activities designed for ecosystem strengthening in aid of PPR in particular. This has included, for instance, regional-level engagement with Africa CDC and PAHO and global-level participation through the WHO-led i-MCM-Net, the xVAX initiative, CEPI's JCG and other global forums, such as the G7 and G20, UNGA.	
Cross-functional alignment of enabling activities at disease programme level aligns with success measures to achieve 2.0 objectives	Hoop	**Disputed:** Linked to the high-level CEPI 2.0 Strategy document, what CEPI planned to do within each priority pathogen and for other SRAs as part of an end-to-end approach, alongside the role of others and in a manner that contributes in a holistic way to the desired objectives, was not detailed. Evidence suggests that this issue, alongside challenges with cross-departmental working and in ensuring that project-level staff are working towards higher-level outcomes in a coherent manner, has constrained cross-functional alignment within and across the organisation.	6, 14–16
CEPI expert assistance is provided to influence priorities/actions of partners for the achievement of shard objectives	Hoop	**Confirmed:** A range of R&D partners and external commentators reflected very positively on CEPI technical capacity and the value it brought in advancing ecosystem strengthening, for instance in promoting regulatory alignment and in PPR.	49
Overall results			
Achievement of outcomes and strategic objectives	Hoop	**Disputed:** Overall, much progress has been made against Strategic Objective 1 (to prepare for known epidemic and pandemic threats). With the acute phase of the Covid-19 pandemic ending, CEPI's investments across its portfolio have promoted the development of priority pathogen vaccines and have contributed to reducing the risks of further coronavirus pandemics. However, the development of vaccines and other biologic countermeasures against known high-risk pathogens being accelerated is at high risk of not being achieved. In terms of outcome KPIs, one outcome KPI target has been achieved; one is not on track but has a plausible expectation of course correction; and one is considered as not on track, with no plausible expectation of course correction. Some progress has been made against Strategic Objective 2 (to transform the response to the next novel threat), albeit with work delayed in some areas, for instance on vaccine family libraries, and further progress required, including in enabling science and manufacturing. In terms of outcome KPIs, one is broadly on track, with risk mitigation plans in place; and two are not on track but have a plausible expectation of course correction. Progress has also been made against Strategic Objective 3 (to connect stakeholders and experts in EIDs to enable rapid countermeasure development, effective response and equitable access for those in need). However, the KPIs related to coordination to enable system readiness and putting in place equitable access principles as the foundation of any effective response are off track. In terms of outcome KPIs, one is broadly on track, with risk mitigation plans in place; and two are not on track but have a plausible expectation of course correction.	48
Achievement of equity objectives	Hoop	**Unclear:** Multiple CEPI staff commented on the critical importance of and deep focus on securing EA provisions in contracts and advocating to other relevant actors to do the same. Multiple external respondents (partners) reflected on such EA provisions being a fundamental part of CEPI's approach, and others (contract holders) on the obligations	41–46

		CEPI places on them. However, the success of any of these measures will become evident only when products are released to market and/or become in high demand in the event of an epidemic/pandemic.	
Stakeholders acknowledge that CEPI was a key factor in the achievement of outcomes and strategic objectives	Smoking gun	**Unclear:** It is too early to conduct this form of assessment, principally because outcomes and strategic objectives have not yet been achieved and, in many cases, are off track. Although CEPI's activities and outputs are considered to be relevant and important to the achievement of the desired outcomes and strategic objectives, stakeholders also noted that the CEPI 2.0 strategic objectives and the 100 Days Mission could never have been achieved within the CEPI 2.0 time frame.	N/A
Cross-cutting			
Contextual factors remain conducive to the implementation of CEPI activities and achievement of related outcomes, as anticipated at the approval and outset of the activity	Hoop	**Confirmed:** The document review and a range of stakeholders from all groups interviewed reflected that CEPI 2.0 and the 100 Days Mission were designed to be, and have remained, highly relevant to global needs, which reflected regional, country and partner needs and priorities. In particular, interviewees noted that CEPI's role in the development of vaccines against epidemic and pandemic threats, particularly where there is little commercial incentive to do so, is unique and critical. Several developments in the global R&D&M ecosystem have occurred since the launch of CEPI 2.0 which were not envisaged; however, CEPI's role remains relevant, and it is still able to operate as intended. Some contextual factors have likely made the implementation of CEPI activities and achievement of related outcomes more challenging. Most notably, stakeholders referred to many of CEPI's potential R&D partners as suffering from a 'hangover' from Covid-19 which may constrain their willingness to enter into agreements with CEPI (although this situation has also provided opportunities, such as with Moderna). Stakeholders also referred to CEPI's 2.0 Strategy not being fully funded and to political support for PPR waning in the years following the pandemic, which also present substantial challenges to CEPI and the achievement of its strategic objectives.	3–4
CEPI makes appropriate decisions to advance progress towards its strategic outcomes and outputs, which stakeholders deem to be of critical value to achieving shared objectives	Hoop	**Confirmed:** CEPI is a technically astute organisation that is able to identify issues and areas where there is a significant need for intervention to achieve CEPI's strategic objectives. This was demonstrated by CEPI's role in the Covid-19 pandemic as well as through the design of CEPI 2.0, which responds to the gaps in the ecosystem, laid bare by the pandemic, to ensure equitable access to vaccines. CEPI's ability to invest in the right areas is also demonstrated by the strong relevance of CEPI's existing portfolio (see EQ1), the progress being made towards programmatic results (see EQ5), and the unique role that CEPI often plays to facilitate these results (see EQ6). As noted above, robust governance procedures are in place to ensure the technical quality of new investments. A significant issue relates to CEPI's ability to prioritise across the portfolio to optimise performance against its strategic objectives within the available resource envelope and given the inevitable limits of management's time and attention.	38–40
Stakeholders acknowledge that CEPI's management and governance enabled implementation of the project/programme	Smoking gun	**Disputed:** CEPI's management and governance enabled the organisation to be agile and responsive during Covid-19. Since then, the organisation has grown considerably, and decision-making remits of governance structures have recently been clarified. Although much progress has been made, substantial challenges within the Management Team have impacted on CEPI's ability to deliver against the CEPI 2.0 Strategy. This relates to CEPI's systems, processes and ways of working, which were widely considered by key informants to be inadequate for operating at the scale and breadth that CEPI 2.0 required. Although progress has been made to address some of these issues, further strengthening is required.	18–23, 38–40

5.8. CEPI 2.0 KPI target ratings

	Target	Progress as of end 2023	Plausibility of target being met	Comments
Strategic Objective 1: Prepare for known epidemic and pandemic threats				
OC 1.1	Two variant-proof broadly protective SARS-CoV-2 candidates demonstrate clinical proof of concept (by end 2023)	• CEPI supported the development, licensure and availability of two SARS-CoV-2 vaccines favourable for LMICs, due to improved thermostability qualities, through the COVAX facility. • CEPI continued to progress 11 BPCV vaccine candidates, with most in preclinical development and one candidate in Phase I. • CEPI-supported taskforce developed seven preclinical models for the original prototype SARS-CoV-2 and four variant models, and obtained and evaluated all newest SARS-CoV-2 variants for changes in virulence and immune escape. • Seven preclinical models have been developed for the original prototype SARS-COV-2. • CEPI's efforts have shifted to reducing the risk of future coronavirus pandemics. The variant-proof coronavirus targets and the beta coronavirus targets have now been merged into pan-sarbecovirus. • Following WHO's announcement in May 2023 of the end of the acute phase of the Covid-19 pandemic, CEPI continued to support COVAX operations until its closure in December 2023.	**At least two SARS-CoV-2 vaccines favourable for LMICs available (by end 2022):** Attained. **Two variant-proof broadly protective SARS-CoV-2 candidates demonstrate clinical proof of concept (by end 2023):** CEPI's efforts have shifted to reducing the risk of future coronavirus pandemics. The variant-proof coronavirus targets and the beta coronavirus targets have now been merged into pan-sarbecovirus.	• CEPI played a critical role in COVAX by supporting science, registering seven vaccines, two favourable for LMICs (SK bioscience and Clover), and backing Phase 1 novel self-amplifying RNA vaccine development with Gritstone. • Distribution of vaccines during the pandemic was uneven, because initial access to Covid-19 vaccines for LMICs was poor and created challenges in vaccine coverage into the 2.0 period. The response fell short, especially in securing timely production for at-risk populations. CEPI's EAF evaluated the response. • Most of the challenges were beyond CEPI's control because political and economic complexities interfered with regulatory processes and deployment of vaccines despite CEPI's negotiations to ensure access.
OP-1.1.1	100% of interim milestones achieved	• CEPI supported the development, licensure and availability through the COVAX Facility of two SARS-CoV-2 vaccines favourable for LMICs, owing to improved thermostability qualities. • Following WHO's announcement in May 2023 of the end of the acute phase of the Covid-19 pandemic, CEPI continued to support COVAX operations until its closure in December 2023.	Majority of interim milestones on track.	CEPI's efforts have shifted to reducing the risk of future coronavirus pandemics. The variant-proof coronavirus targets and the beta coronavirus targets have now been merged into pan-sarbecovirus.
OP-1.1.2	At least three CEPI-funded enabling science programmes	• By the end of 2023, seven preclinical models had been developed for original prototype SARs-CoV-2. Nine developers were supported with testing using those models in 14 different project service orders. In	Not applicable.	The 2023 Annual Progress Report states that this target is no longer relevant for the

	and innovative tools available for use in Covid-19 vaccine candidate development	addition, four variant models were provided in 2023, making 17 in total, mostly based on the CEPI-UKHSA-NIBSC Agility programme. Four developers were supported with refined variant models in total. • As part of the evolution of the BPCV portfolio, the animal model work is gearing toward developing preclinical models for BPCV via investments into MERS-CoV, SARS-CoV, and other pre-emergent coronavirus animal model discovery. This target is therefore no longer relevant for the remainder of CEPI 2.0.	This target is reported to no longer be relevant for the remainder of CEPI 2.0.	remainder of CEPI 2.0. For more detail, see KPI 2.2.1.
OC 1.2	At least two vaccines reaching licensure for two or more priority pathogens, including at least one WHO Prequalification At least two monoclonal antibodies for two more priority pathogens to ready to use under outbreak conditions	• CEPI did not directly support the process, but CHIK-Valneva reached licensure in 2023. A licenced vaccine for another priority pathogen product is unlikely before end of 2026. • One candidate is currently in preclinical and ready to enter Phase I, and four candidates are currently in Phase I and ready to enter Phase II. There is a gap in the number of candidates in mid/late-stage development, owing to candidate down selection and delays owing to Covid-19; this is being addressed through backfilling of additional candidates. • Only one pathogen has initiated a monoclonal antibody to date, with plans to enter Phase 1 clinical trials in 2024	1: High risk, not on track, no plausible expectation of course correction.	
OP-1.2.1	Preclinical: 0 Phase 1: 0 Phase 2: 4 Phase 3: 3 Registration: 0 Licensure: 2	Preclinical: 3 Phase I: 7 Phase II: 1 Phase III: 0 Registration: 1	1: High risk, not on track, no plausible expectation of course correction.	There is a big gap in the number of candidates in mid/late-stage development due to attrition. There are 4 candidates ready to enter phase II and 1 ready to enter Phase I. A licensed vaccine is unlikely before end of 2026 for a second priority pathogen other than Chikungunya, due to project delays and failures across programmes.
OP-1.2.2	At least two monoclonal antibodies ready for use in an outbreak situation	Only one pathogen has initiated a monoclonal antibody to date, with plans to enter Phase 1 clinical trials in 2024.	1: High risk, not on track, no plausible expectation of course correction.	No candidates were in portfolio in 2022.
OC 1.3	Two candidates assessed for clinical proof of concept	• The BPCV programme is focused on two approaches: (1) pan-sarbecovirus (+/- MERS-CoV) vaccine development, and (2) whole coronavirus family vaccine development. • The portfolio is comprised of 11 candidates in preclinical phase, six of which are fully funded and five of which are seed-funded projects. Of the 11 active projects, one has a precursor candidate in Phase I trial, funded by the Government of Canada.	2: Medium risk, not on track, plausible expectation of course correction.	Although this seems to be on track, there is only one project that has a precursor candidate in Phase 1 trial. This is still a prototype and has not met the CEPI definition of 'proof of concept', which is defined as having completed phase 1 clinical development. Results of effectiveness and safety tests to meet

		• Three further projects have been terminated/are in process of being closed out.		proof of concept criteria are still to be seen.
OP-1.3.1	TBC	• The portfolio includes 11 candidates that have started preclinical phase, of which six are fully funded and five are seed-funded projects; in addition, three projects have been terminated/are in process of being closed out, of which two were seed-funded. Among these 11, one has a precursor candidate in Phase 1 trial, funded by the Government of Canada. • Originally, the focus was on broadly protective SARS-CoV-2 and betacoronavirus. Following SAC in April 2023 and governance review (August 2023), the portfolio is transitioning towards pan-sarbeco vaccine.	2: Medium risk, not on track, plausible expectation of course correction.	The focus of the BPBC programme has been shifted to sarbecovirus. This shift might enable CEPI to meet its target because the shift leverages scientific knowledge gained through Covid-19 and viral genetic relationships, reduces product development risk (compared to a broadly protective vaccine), and maintains the potential for positive public health impact in the event of another outbreak of coronavirus disease.
Strategic Objective 2: Transform the response to the next novel threat				
OC 2.1	Two licenced vaccines against viable targets for LMICs using prototype and/or platform innovations Clinical proof of concept for four virus family vaccine libraries	• Four viral families (arenaviruses, paramyxoviruses, poxviruses, coronaviruses) have been prioritised. • CEPI established a partnership with University of California at Davis (UC Davis) to build on their work to rank viruses based on their zoonotic risk. This work aims to expand their "SpillOver" database to identify virus families most likely to emerge as the next Disease X with pandemic potential by using cutting edge AI. • The planned workflow of antigen design and preclinical testing has started for two viral families – poxviruses and arenaviruses. A design has been selected by BioNTech for their Mpox vaccine, which initiated Phase I clinical trial. Production and testing of designs for Lassa and Junín viruses, members of the arenavirus family, was initiated. • Seven new platform technology innovation projects onboarded in 2023, bringing the total to eight prototype vaccines against Japanese encephalitis, SARS-CoV-2, Chikungunya, rabies, yellow fever and influenza in development by end 2023. • The selection and preclinical immunological characterisation of a Japanese Encephalitis vaccine candidate was completed in 2023. All other projects test novel innovative technologies, one of which (Lemonex) has entered Phase I. • CEPI launched a new CfP in October 2023 aimed at advancing cutting-edge vaccine development and manufacturing science and technologies that will contribute to speed, scale and equitable access during future outbreak response.	2: Medium risk, not on track, plausible expectation of course correction.	Target number of vaccine exemplars having successfully completed preclinical and Phase 1 studies for four virus families will be difficult to meet by end 2026, given delays to the start of the programme; with virus family prioritisation complete in 2024, and with key immunogen design partnerships and exemplar vaccine development partnerships now in place, expectation is for preclinical vaccine exemplar testing to really ramp up in 2024.
OP-2.1.1	Clinical proof of concept for four virus	• Target number of vaccine exemplars having successfully completed preclinical and Phase 1 studies for four virus families will be difficult to	1: High risk, not on track, no plausible	

	family vaccine libraries and preclinical proof of concept for an additional six virus family vaccine libraries	meet by end 2026, given delays to the start of the programme; with virus family prioritisation complete in 2024, and with key immunogen design partnerships and exemplar vaccine development partnerships now in place, expectation is for preclinical vaccine exemplar testing to really ramp up in 2024.	expectation of course correction.	
OP-2.1.2	Two licenced vaccines against viable targets for LMICs using prototype and/or platform innovations	• Seven new prototype projects were onboarded in 2023. In total, eight prototype vaccines against Japanese encephalitis, SARS-CoV-2, CHIK, rabies, yellow fever and influenza are in development, with one candidate in Phase I. • Licensure target will not be met by end 2026, because there have been delays to the start of the programme; risk of delay in start of Phase 3 for the leading candidate beyond the CEPI 2.0 period, owing to regulatory requirements emerging from current plan, but alternative routes are currently being explored.	1: High risk, not on track, no plausible expectation of course correction.	
OC 2.2	Three or more of the enabling science tools developed through CEPI funding used by one or more of CEPI-funded vaccine developers	• Ongoing work to develop preclinical models for BPCV via investments into MERS-CoV, SARS-CoV, and other pre-emergent coronavirus preclinical model discovery research. Seven original protype SARS-CoV-2 virus animal models and 17 SARS-CoV-2 variant-based models were made available as of end 2023. • Additional preclinical model work in progress for MERS and pre-immune models based on approved on-market SARS-CoV-2 vaccines. Progress is on track and reflects the evolution of the SARS-CoV-2 variants and the decision to redefine the focus of the BPCV portfolio in 2023. Active partnership with preclinical model network laboratories with capacity to contribute models for CEPI priority pathogens means that CEPI has in place resources for expedited preclinical testing. • Development launched for Nipah natural history study models for vaccine and mAb preclinical testing in pivotal efficacy studies, planned for delivery in 2024. The Nipah antibody international standard was approved by the WHO Expert Committee on Biological Standardization in October 2023.	3: Low risk, with risk mitigation plans in place.	
OP-2.2.1	Standards, preclinical models, assays, translational immunology, correlates of protection, Sentinel safety surveillance and epidemiological, mathematical models and studies advanced for all CEPI priority	• Ongoing work to develop preclinical model for BPCV via investments into MERS-CoV, SARS-CoV, and other pre-emergent coronavirus animal model discovery. • Animal model available: SARS-CoV-2, 17 SARS-CoV-2 variant-based. • Ongoing animal model work: MERS, SARS-CoV, and pre-immune models based on approved on-market vaccines. • The progress in this area is steady, but it reflects the evolution of the SARS-CoV-2 variants as well as pending the discussion during 2023 to redefine the focus of the BPCV portfolio.	3: Low risk, with risk mitigation plans in place.	

	pathogens and the virus family approach	• Ongoing Nipah natural history study models for vaccine and mAb preclinical testing in pivotal efficacy studies. The model work continues and is planned to deliver in 2024. • Nipah antibody international standard approved by WHO ECBS October 2023. • Interim data available, with expectation that the final report will be available in Q2/3 2024.		
OC 2.3	At least three innovations which demonstrate manufacturing cheaper, faster or closer to an outbreak	• The portfolio comprises 11 candidates in preclinical phase, six of which are fully funded and five of which are seed-funded projects. • Three projects have been terminated/are in the process of being closed out. Of the 11 active projects, one has a precursor candidate in Phase I trial, funded by the Government of Canada. The BPCV programme is focused on two approaches: (1) pan-sarbecovirus (+/- MERS-CoV) vaccine development, and (2) whole coronavirus family vaccine development.	2: Medium risk, not on track, plausible expectation of course correction.	
OP-2.3.1	Five manufacturing innovations projects advanced	• Six additional manufacturing innovation projects signed in 2023, increasing the total to seven. The manufacturing innovation project span across seven countries (US, UK, Netherlands, Spain, Australia, Belgium and Germany) to enable different innovation aspect of thermostability, speed, scale and access. One of the seven projects is no longer active and is subject to contract amendment.	2: Medium risk, not on track, plausible expectation of course correction.	
Strategic Objective 3: Connect to enhance and expand global collaboration				
OC 3.1	Funding for vaccine and other biologic countermeasures preparedness and response R&D	• By December 2023, CEPI had received $2.6 billion in commitments toward CEPI 2.0. • Additional pledges to CEPI secured in 2023 include CAD 80 million from the government of Canada, $100 million from the US and CHF 10 million from Switzerland. • In addition, several pledges were converted into contribution agreements. These include the government of Spain's €75 million (via the International Finance Facility for Immunisation) as well as €35 million from the European Commission. • A philanthropic resource mobilisation strategy was developed and engagement was initiated, with the aim of bringing in additional philanthropic funders, including from the Global South.	3: Low risk, with risk mitigation plans in place.	• 74% of the money has been raised so far by 2023 ($2.6 billion), which is ~$0.6 billion more than in December 2022. The expected amount had been $0.6 billion by 2023, so the organisation met its target. • Concerns about CEPI's underspending that occurred during implementation of CEPI 2.0, especially in 2023 and how this might compromise additional funding to meet the $3.5 billion target set for 2.0. • Current macroeconomic environment and constraints on development aid, and likely competition from other similar organisations (Global Fund, Gavi, WHO, Pandemic Fund), make fundraising more challenging.

				Geopolitical environment and potential regime changes (election in US, European Parliament elections in summer 2024) could have an impact and create uncertainties (even if temporary) for fundraising in the outer years in 2025–26.
OP-3.1.1	$3.5 billion in commitments	• By December 2023, CEPI had received $2.6 billion in commitments toward CEPI 2.0.	3: Low risk, with risk mitigation plans in place.	• 74% of the money has been raised so far by 2023 ($2.6 billion), which is ~$0.6 billion more than in December 2022. The expected amount had been $0.6 billion by 2023, so the organisation met its target. • Despite the geopolitical environment shifting post-European Parliament elections in the summer of 2024 and the US election in November 2024, CEPI seems to have risk-mitigating plans in place to weather the potential impact.
OC 3.2	RACI(s) for 80% of key elements in place	• CEPI co-hosted the first Medical Counter Measures (MCM) R&D Funders Roundtable with the European Commission's HERA to increase visibility, coordination, and opportunities for partnership. A second meeting is planned in 2024, to be co-hosted with the South African Medical Research Council (SAMRC). • CEPI provided thought leadership and staff support for the WHO-convened interim Medical Countermeasures Network (i-MCM-Net), including the R&D component of a report to be shared at 2024 World Health Assembly. • CEPI's JCG discussed stronger collaboration and identification of gaps for "hand-offs" between organisations in the vaccine value chain. A tabletop exercise is planned for January 2024 alongside CEPI's Annual Portfolio Review. • With Gavi, UNICEF, WHO, Africa CDC, PAHO and WHO SEARO, CEPI established the XVAX Network to support operational readiness to respond rapidly to emerging epidemic and pandemic threats. • CEPI hosted session at World Health Summit on partnerships for a pandemic-free future with Africa CDC, EDCPT3, Fiocruz, GPMB and India Council for Medical Research. • CEPI initiated development or revision of Memoranda of Understanding (MOUs) with Africa CDC, Gavi, Korea DCA and PAHO, to be signed in	2: Medium risk, not on track, plausible expectation of course correction.	There were concerns by some that CEPI's JCG might be a productive intervention but might have the right stakeholders to help accomplish access targets. Suggestions were made to make the group smaller and engage with right stakeholders.

		2024. Agreement on collaboration priorities with UNICEF Supply Division.		
OP-3.2.1	At least three networks expanded or established	• Seven new Central Lab projects were signed in 2023, bringing the total to 17. The Central Lab projects span across 14 countries, including five LMICs (Bangladesh, India, Kenya, Senegal and Uganda). CLN has tested over 50,000 clinical samples from various developers using standardised SARS-CoV-2 assays in 2023. • In total there were seven (RVF, Nipah, SARS-CoV-2, SARS-CoV-2 VOC, Lassa, Monkeypox and MERS) international antibody standards through CEPI's partnership with NIBSC, and four were made available in 2023 (Nipah, Marburg, RVF, SARS-CoV-2 VOC). Serum collection process was in partnership with CEPI partners in Bangladesh, Uganda, Korea, Malaysia, Kenya, UK, Nigeria and Sierra Leone. • Development of several immunological assays, such as those for Monkeypox and Nipah, have been initiated at CLN in 2023. These assays, along with several new assays for new diseases, will undergo qualification and/or validation processes. • Four Standards & Assay partners are part of the Animal Model or Central Lab networks (BNITM, Icddr,b, NIBSC, UKHSA). • CEPI have signed with three new Animal Model Partners in 2023, bringing the total up to 11 partners available in the network from six countries (Australia, Canada, Germany, UK, Netherlands and US). • There are two Systems Immunology projects, one of which was completed in 2023.	4: On track, low to no risk, high likelihood of attainment.	CEPI has made progress in expanding its Centralized Laboratory, Animal Model, and Manufacturing Partner Networks – particularly bringing on new partners across Africa, Latin America and South Asia. These networks are available to all and not just for products that CEPI is developing. CEPI will also be announcing a network of controlled human infection model (CHIM) laboratories, which will also be a global resource. Next steps and CEPI recommendations are to clarify how regional developers and regulators can make use of these networks.
OP-3.2.2	Regulatory database available as a pilot to CEPI-funded developers by 2023, with view to wider roll-out towards 2026		2: Medium risk, not on track, plausible expectation of course correction.	Access to the database does not ensure that the information available will be used to inform policies or decision making. The actual utility of the database is when there is an imminent happening and the data needs to be acted upon, which will only be shown in the context of an outbreak.
OC 3.3	Removing at least one key systemic obstacle to access for LMICs Three G20 countries making new funding and/or procurement commitment for vaccines development include reference to	• Ongoing advocacy to broaden the G20 Joint Finance and Health taskforce commitments, including with greater representation from the Global South, to establish and adequately fund surge financing mechanisms, which should allow at-risk investment in R&D of medical countermeasures on recognition of a pathogen. • One new partnership added to CEPI's network to support globally diversified manufacturing capability (Bio Farma, Indonesia), bringing the total number of partners in CEPI's Manufacturing network to three.	2: Medium risk, not on track, plausible expectation of course correction.	• Not clear if CEPI has removed at least one systemic obstacle, according to how they defined "systemic obstacles" in their RBF, especially on pricing, IP and right of first refusal; thus it is difficult to determine their progress. • Pricing concerns were raised on pricing for Chikungunya, because pricing uncertainty has made

	access provisions – initial commitment from one country	• Designed and secured support to launch the second phase of the Regionalized Vaccine Manufacturing Collaborative (RVMC) agreed with Partners. CEPI agreed to host the RVMC Secretariat from 2024. • CEPI's equitable access positions were reflected in the interim draft of the Pandemic Agreement, and CEPI's role in the PPR ecosystem was reflected in the G7 Leaders communiqué, the G20 Health Ministers meeting outcomes and in the work of the G20 Joint Finance and Health Task Force. • Engaged with CEPI IC members and their relevant agencies on need for equitable access terms in MCM R&D contracts. CEPI welcomed that the National Institutes of Health (NIH) proposed to develop and implement a new policy within its Intramural Research Programme (IRP) to promote access to products stemming from taxpayer-funded inventions.		negotiations challenging. Although CEPI aims to ensure access to LMICs, their formulated requirements pose difficulties; thus some organisations cannot commit to a price without clearer production cost estimates, especially when they are for profit.
OP-3.3.1	100% of CEPI-funded products/platforms with relevant access plans in place	• The EAF was published in May 2023.	2: Medium risk, not on track, plausible expectation of course correction.	Review of the Chikungunya access arrangements will start after the CFP3iii agreements, now expected in Q1 2024 following delay in call launch with European Commission. Review of Lassa access arrangements will be arranged following internal alignment on CEPI's late-stage involvement. Reviews of RVF, MERS and Nipah access agreements would be premature given the stage of the programmes.
OP-3.3.2	At least five agreements in place over two regions that support manufacturing capacity strengthening to support LMICs	• By December 2023 funding agreements had been signed and execution of work packages/workstreams progressed with Aspen (RSA), IPD (Senegal) and BioFarma (Indonesia). • By December 2023 further funding agreements were in advanced stages of negotiation.	4: On track, low to no risk, high likelihood of attainment.	Agreements need further investigation to determine if they address underlying assumptions.

5.9 CEPI 2.0 activities – planned, actual and other activities**

CEPI 2.0 Strategy	Activities aligned with 2.0	Other activities undertaken/explored by CEPI
PREPARE		
• COVID-19 vaccine development • Develop vaccines and other biologic countermeasures against high-risk pathogens • Develop BPBC vaccine • Biological therapeutics • Prophylactic vaccine-like technologies • Diagnostics	✓ MERS 2 vaccines PhI ✓ BPBC – 1 vaccine PhI, 10 preclinical ✓ Lassa fever vaccines (1x preclinical, 1x PhI,1x PhII) ✓ Nipah – 3 vaccines PhI ✓ Nipah mAb treatment (preclinical) ✓ Chikungunya – 1x licenced vaccine to be transformed for broader use, 1 vaccine PhII/III ✓ Rift Valley Fever – 1 vaccine PhI, 1 vaccine preclinical ✓ Rapid diagnostic test for Lassa (+FIND)	➢ Antibody standard for Ebola** ➢ Sourcing serum for other haemorrhagic fevers** ➢ Second-gen Ebola vaccine – product development** ➢ Support for Zika vaccine candidates**
TRANSFORM		
• Vaccine or mAb platforms • Vaccine libraries • Enabling science • Regional manufacturing • Manufacturing innovations	✓ 2 vaccines developed (PhI) ✓ Prototype vaccine initiated (Phi/II study) ✓ 4 vaccine libraries for Disease X ✓ Novel self-amplifying RNA vaccine Ph 1 ✓ 14 preclinical models** ✓ Establishment of Community of Practice ✓ Working Group for Standardizations and Assays (with WHO) ✓ International Standards for Lassa, MERS, Covid-19 ✓ Epidemiological studies for Nipah and Lassa ✓ Centralized Laboratory Network ✓ 5 manufacturing agreements in Global South ✓ 7 manufacturing innovation projects	➢ Researching impacts of AI on CEPI investments, e.g. detecting Disease X ➢ Mpox programme – including assays, standards, support to a vaccine candidate (Ph1)
CONNECT		
• Financing • Stakeholder coordination • Equitable access principles	✓ Worked to set up Pandemic Fund and secured financing against CEPI 2.0 ✓ JCG, Centralized Laboratory Network, involvement in xVAX, i-MCM-Net, Regional Vaccine Manufacturing Collaborative, disease-specific coordination and others ✓ Equitable access provisions in project funding agreements	➢ Commencing work in biosecurity/biosafety ➢ Researching enablers/barriers to market for CEPI-supported products ➢ Global, regional and national advocacy

* 'Other activities' include those that are not explicitly addressed in CEPI 2.0 but that broadly fall within its remit.

** Work on these activities commenced prior to January 2022 but continued during the MTR period.

Annex 6. Mapping conclusions to findings

Aspect of conclusions	Related finding(s)
In the midst of the Covid-19 pandemic, CEPI 2.0 and later the 100 Days Mission helped to galvanise global commitment to CEPI's mission: 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. However, Covid-19 and CEPI 2.0 pose a range of very challenging issues for CEPI to deal with. This fundamentally relates to an expansion of CEPI's role and scope beyond R&D development to Phase II to include licensure and the full suite of downstream issues that affect equitable access, including regulatory affairs, manufacturing and ecosystem strengthening. It also critically relates to CEPI engaging beyond a set of pathogens that primarily affect LMICs under CEPI 1.0 to include efforts to ensure preparedness for infectious diseases that are more likely to affect all regions and countries, including HICs, for which other R&D funders, including agencies of HIC governments, are active and where the issues surrounding product development and equitable access are very different.	1
CEPI has made good progress in addressing the implications of this fundamental strategic shift, notably through the EAF and its evolving work to define pathogen and partner archetypes to guide ways of working across the portfolio. However, this has taken time, and there remain divergent opinions as to what CEPI's role should be and how it should engage with other partners as part of an end-to-end approach. It is also evident that some issues still need to be worked through, for instance in relation to how manufacturing capacity is built sustainably and how this can be deployed for outbreak response.	9, 13, 32 8
Overall, the process tracing methodology employed to assess causal inference has not been able to confidently validate the contribution claim that CEPI's actions and activities are being implemented as intended and the assumptions underpinning the ToC are working as intended to achieve the desired outcomes and strategic objectives. To do so would notably require further evidence of timely investments being made and progress towards outputs, outcomes and strategic objectives. The evidence collected and analysed through the MTR suggests that much programmatic progress has been made providing an encouraging signal that the contribution claim could be validated at a later date, but potentially after the CEPI 2.0 period. The justification for this statement and the primary reasons for a lack of progress to date are articulated below.	14, 15, 16 (supported by findings throughout report and annexes 5.5 & 5.7)
Planning for CEPI 2.0 was inadequate, in part due to taking place during a pandemic and also because fundraising took place within the	30, 31

implementation period; this has contributed to a disconnect between the technical progress that CEPI is making and the level of ambition that stakeholders expect of CEPI, both in terms of spending and programmatic progress. The context has also evolved substantially since CEPI 2.0 was developed, as have CEPI's ways of working in response to its expanded role, which is not fully captured in the strategy.	20 3
Alongside this, and given that many programmatic targets were not technically evaluated for feasibility, it suggests the need for a comprehensive clarification of: • CEPI's strategy to clarify CEPI objectives by pathogen and SRA, as well as CEPI's role vis-à-vis others across the portfolio • CEPI's theory of change to accurately reflect its current portfolio of work, realistic outcomes, structure and ways of working • spending expectations • programmatic KPIs and targets • how CEPI 2.0 will lead into a new strategic period with surplus resources and an unfinished agenda from CEPI 2.0 and the 100 Days Mission.	17
Strategy operationalisation has been severely challenged for a range of reasons linked to Covid-19, the timing of fundraising, the need to radically shift approach, and an almost constant cycle of reprioritisation which ensued after a slow start to the CEPI 2.0 period. These issues do not exclusively but fundamentally relate to the operational capacity within the Management Team, which has been strained by the effort that CEPI 2.0 has required to implement. There are high expectations for the reorganisation and plans to recruit additional senior leaders to the Management Team, although it remains to be seen whether this will be sufficient to strengthen capacity for the effective execution in the remainder of CEPI 2.0.	30, 31 33-36 22
Although spending and implementation progress has been slower than anticipated in some areas, notably when measured against the CEPI 2.0 budget, substantial programmatic progress has been made in the CEPI 2.0 period. This progress has built effectively on the R&D advances made under CEPI 1.0, with further R&D progress and advances within an end-to-end approach for the achievement of equitable access. Notable achievements include: • the registration of seven Covid-19/SARS-CoV2 vaccines supported by CEPI, two of which were programmatically suitable for LMICs • the rapid advancement of a broad set of BPCV candidates, including one to Phase II development	33 37

- learnings from prior MERS investments being used to speed up vaccine development for Covid-19 vaccine development, although further vaccine development has been slow
- initiation of Phase II trials for Lassa fever, although progress has been slower than hoped for, and efforts to reduce development risk, including by evaluating the potential to employ an mRNA platform for Lassa
- the conclusion of Phase I trials for two Nipah vaccine candidates, with one of these ready to start Phase II, as well as initiation of a project for a monoclonal antibody for Nipah, with plans to enter Phase I in 2024 (the basis of a therapeutic/preventative bridging strategy for disease control)
- advancement of plans to adapt a licensed Chikungunya vaccine to ensure it is accessible to LMICs and for a broader age range
- development of two vaccine candidates for RVF, one of which is now in Phase 1
- expansion of the manufacturing network and initiation of several innovation projects
- establishment of other laboratory, clinical and regulatory networks to strengthen global preparedness and response.

These achievements demonstrate CEPI's ability to select and support strong R&D partners, subject to some attrition and with a commitment to keep learning in this area, and to advance vaccine candidates for priority pathogens and manufacturing where there is significant unmet need. CEPI's work on rapid response technologies and under the Disease X programme continues to show promise, but progress has not been as quick as expected.

In line with the scope of CEPI 2.0, CEPI has also embarked upon, and in many cases has made significant progress in, advancing its agenda for enabling science. Although it has done so without a complete and coherent understanding of where CEPI can and is best placed to fit into the wider ecosystem of actors active in this space – and, as outlined above, CEPI's role in this area is the source of some debate – in many instances its investments have been critical to making both R&D progress and overcoming other hurdles to ensuring equitable access.

37, 38, 44, 47, 48 (KPI 2.2)

8

CEPI has reaffirmed its commitment to equitable access through development decisions, publication of the EAF, and implementation efforts during CEPI 2.0. For example, the BPBC programme engages the California Institute of Technology and other partners to develop a low-cost thermostable vaccine, the agreement with FIND to develop a diagnostic test for Lassa fever includes equitable access provisions, and the CEPI manufacturing network with partners located in the Global South. These

42-46

achievements constitute notable progress. However, CEPI is yet to complete a comprehensive review of the access provisions for late-stage programmes. In the event of another pandemic, access agreements will need to withstand the formidable economic and political forces that manifested during the Covid-19 pandemic.	
A key strength of the CEPI portfolio is its focus on preventive vaccines for multiple pathogens and the opportunity that this provides for technologies and related science to be applied across programmes and for Disease X in support of the 100 Days Mission. There is good evidence that CEPI has capitalised on these commonalities, for example mRNA and ChAdOx viral vector platform technologies were rapidly brought to commercial stage during the Covid-19 pandemic, the latter in large part due to CEPI's support, and these platforms are now being used to develop vaccines for Disease X and Lassa. Enabling science from MERS has also been useful in the Covid-19 and BPBC programmes. Although many further opportunities for shared benefit exist across programmes, such as the development of an expanded laboratory and clinical network in LMICs, ultimately much of the progress on an individual programme relies on efforts specific to that vaccine or pathogen.	37
A potential downside of the portfolio is its sheer complexity, which is further magnified by access commitments and cross-cutting issues such as biosecurity, which, albeit important, place a substantial burden on internal staff and partners. This complexity will increase substantially as the portfolio matures and CEPI engages more substantively in activities related to late-stage development, licensure and vaccine deployment. CEPI' ability to structure clear 'hand offs' to partners will become especially important at this juncture.	47 8
CEPI's work to coordinate and collaborate with industry, R&D funders, regional partners, country governments and regulatory bodies, as well as through its participation in all manner of global fora (e.g. G7. G20, UNGA, WHA), demonstrates the high esteem in which the organisation is held, and the significant soft power it has cultivated within the global health architecture. This has been used to good effect in a number of areas to promote global and regional models for regulatory alignment and PPR and promote the need for and benefits of CEPI-supported vaccines when they reach the market (e.g. for Lassa fever).	11, 37, 43, 47
There is also emerging evidence that CEPI's work in support of the Pandemic Treaty, global PPR fora such as the Global Pandemic Preparedness Summit, and with individual partners such as NIH is working to promote equitable access principles as the foundation for a future global response, linked to the presence of a manufacturing network.	46

Such work is important to CEPI clarifying its role in such a global response vis-à-vis other actors, notable HIC agencies with far greater resources.	8,9
CEPI faces several fundamental challenges to achieving its 2.0 strategic objectives. First, as noted above, its vastly expanded mandate has strained its capacities and resources and, despite ongoing efforts to prioritise its many programmes, it is not clear that it has yet managed to define a feasible set of core activities.	47 22, 31-36
Second, and related to this, it has not yet fully clarified its role relative to other actors in pandemic preparedness and response, particularly the agencies of HIC governments for response to an epidemic strongly affecting these countries. In this and other areas, there is a need for more explicit differentiation of CEPI's role across pathogens.	8, 9
Third, although its overall R&D portfolio is broad, it has relatively few investments and candidates in each of its vaccine programmes, leading to high development risk. CEPI is seeking to address this by reducing reliance on single technology platforms and leveraging R&D developments for other products to the extent possible.	47
Fourth, its vaccine development programmes continue to rely primarily on small and medium-sized biotechs, which may not have the expertise or capacity needed for later-stage R&D, regulatory approval, and manufacturing at scale. CEPI has struggled to date to engage with the MNCs who have this expertise. This constraint can be addressed in part, but probably not through CEPI's partnerships with manufacturers in the Global South.	12, 46, 47
Finally, for some of its programmes addressing pathogens primarily posing a threat to specific regions, demand and its implications for vaccine use and sustainable supply are not yet well understood. CEPI and its partners have expanded their efforts to address this challenge as part of its strengthened end-to-end approach, although this requires considerable continued effort for the remainder of CEPI 2.0.	37, 43, 47

Annex 7: Feasibility of Recommendations

- **Low effort**
- **Medium effort**
- **High effort**

Recommendation	Time sensitivity	Feasibility
Recommendations area 1: Clarify CEPI's role and prioritise the CEPI 2.0 scope of work		
1.1 (Act now): Analyse and more clearly define CEPI's role and end-to-end scope vis-à-vis partners in the R&D&M and global health ecosystem to enable a clear view of the areas of overlap, gaps, strengths, and commitment to equitable access.	High	Medium effort
1.2 (Act now): Based on the analysis and decisions taken in response to recommendation 1.1, re-evaluate the end objective and plans for each pathogen programme and Disease X, considering the possibility that objectives for the programmes may be significantly different from one another and in many cases will not involve end-to-end development by CEPI.	High	Medium effort
1.3 (Act now): Based on a clear understanding of CEPI and partner roles and responsibilities derived from the analyses conducted for recommendations 1.1 and 1.2, structure and advance negotiations around clear 'hand offs' from CEPI to partners for both upstream and downstream activities and for ecosystem strengthening.		Medium effort
Recommendations area 2: Clarify how CEPI works to achieve its strategic objectives and reformulate the results framework to measure progress		
2.1 (Act now): Alongside and based on the actions to respond to recommendations area 1, update the ToC to reflect the agreed portfolio of work and its contribution to the 100 Days Mission, realistic outcomes, structure, and the nuanced ways in which CEPI works and interacts within the broader global R&D ecosystem to achieve its mission.	High	Medium effort
2.2 (Act now): Using decisions taken on CEPI's role under recommendations area 1 and the updated ToC as a guiding framework, update the CEPI 2.0 KPIs and targets to reflect CEPI's prioritised scope of work for the remainder of 2.0, including the use of interim milestones and process indicators.	High	Medium effort
Recommendations area 3: Continue to embed a comprehensive and flexible approach to equitable access		
3.1 (Continue and embed): Distinguish clearly in equitable access planning between pathogens likely to cause		Medium effort

outbreaks primarily in LMICs, for which the primary access challenges may be to find a manufacturing partner and ensure downstream systems for distribution and delivery, and those that pose a potential pandemic threat, for which the greatest challenge may be to secure supply for LMICs in the face of HIC competition.		
3.2 (Continue and embed): Continue implementing a bespoke approach to equitable access provisions in partner contracts, guided by the EAF, the nature of the partnership, and the mutual objectives sought.		Medium effort
Recommendations area 4: Finalise and embed an evolved approach to partner selection and engagement, and strengthen the relationship management function		
4.1 (Continue and embed): Finalise and embed the evolved approach to proactive partner selection and engagement based on technical capability and organisational mandates, guided by the finalised and agreed partner archetypes, to ensure partnerships are structured to fill identified gaps in the end-to-end approach for each pathogen and for PPR, in support of CEPI strategic objectives and equitable access.		Low effort
4.2 (Continue and embed): Continue to seek ways to further engagement with MNCs (a current gap in CEPI's partnership arrangements) to advance R&D&M objectives for priority pathogens and in support of Disease X and PPR objectives.		Low effort
4.3 (Continue and embed): Strengthen CEPI's partner relationship management function.		Medium effort
Recommendations area 5: Continue to clarify decision making pathways and engagement of governance committees		
5.1 (Continue and embed): Continue to clarify who is responsible for different types of decision making, within management and governance arrangements, and in what scenarios, and (a) further streamline decision making; and/or (b) consider decentralising decision-making responsibility from the Board/Committees to management where appropriate.	High	Low effort
5.2 (Continue and embed): Continue to strengthen the documentation prepared by management for governance committee meetings.	High	Low effort
Recommendations area 6: Further strengthen management culture, capabilities and practices		
6.1 (Monitor and course correct): Implement plans to establish the new Executive Leadership team with a strong emphasis on cross-department, division and functional collaboration and decision-making in support of CEPI's role.	High	Medium effort

6.2 (Monitor and course correct): Review the project management structure for grantee projects to ensure clear lines of decision-making between CEPI and the grantees; and further strengthen the programme management function with the new risk framework, IMS and other systems fully embedded.	High	Medium effort
6.3 (Monitor and course correct): Ensure there is clarity among all staff on how projects are expected to report on and deliver project-level results and contribute to wider outcomes of relevance to the portfolio and strategic objectives.	High	Low effort
6.4 (Monitor and course correct): Develop and implement systematic learning processes at a project, department, cross-department and organisational level focused on both technical delivery and ways of working to improve implementation of CEPI 2.0, and to inform a next phase of activity.	High	High effort

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