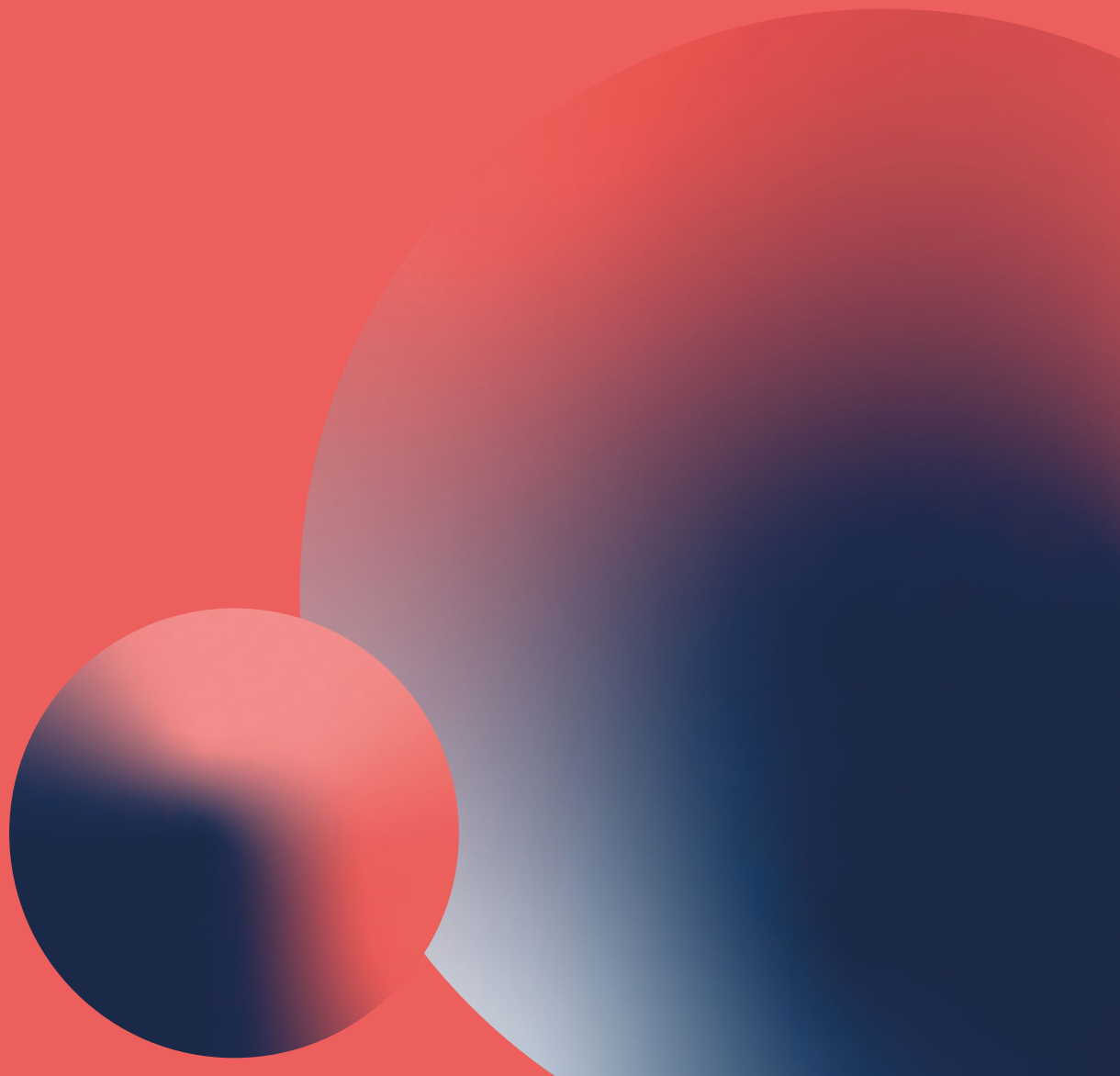


CEPI

# Biosecurity Strategy Implementation Plan

April 2025



# Introduction

In September 2024, recognising its critical responsibility to ensure that its global investments in research and development, and manufacturing (R&D&M) are conducted safely and securely, CEPI published its inaugural **Biosecurity Strategy**. The strategy identifies vulnerabilities in preventing and mitigating biosafety and biosecurity risks associated with vaccine R&D&M. To address these vulnerabilities, the strategy defines five priority areas to prevent accidental and deliberate misuse of pathogens associated with CEPI-sponsored research (Figure 1), in support of the 100 Days Mission (100DM) – a bold goal to accelerate vaccine development to within 100 days of a viral threat being identified.

Informed by stakeholder feedback, this Implementation Plan describes actions CEPI will take, covering the two-year time period of 2025–2026. The Implementation Plan is envisaged as a “living document”, possibly undergoing periodic review and updates (see Monitoring and Evaluation). As such, greater emphasis and detail is included for objectives to be implemented over the first 12 months of the plan.

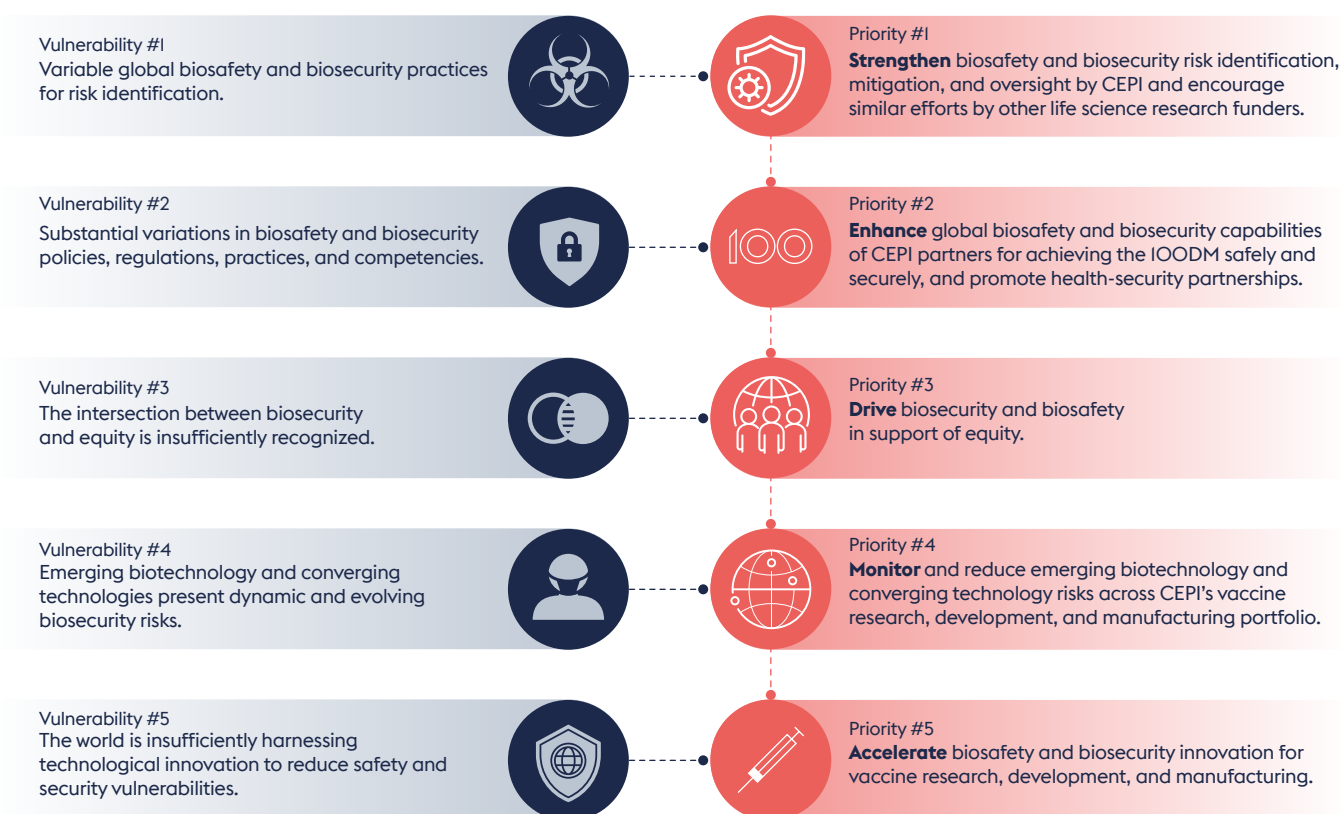


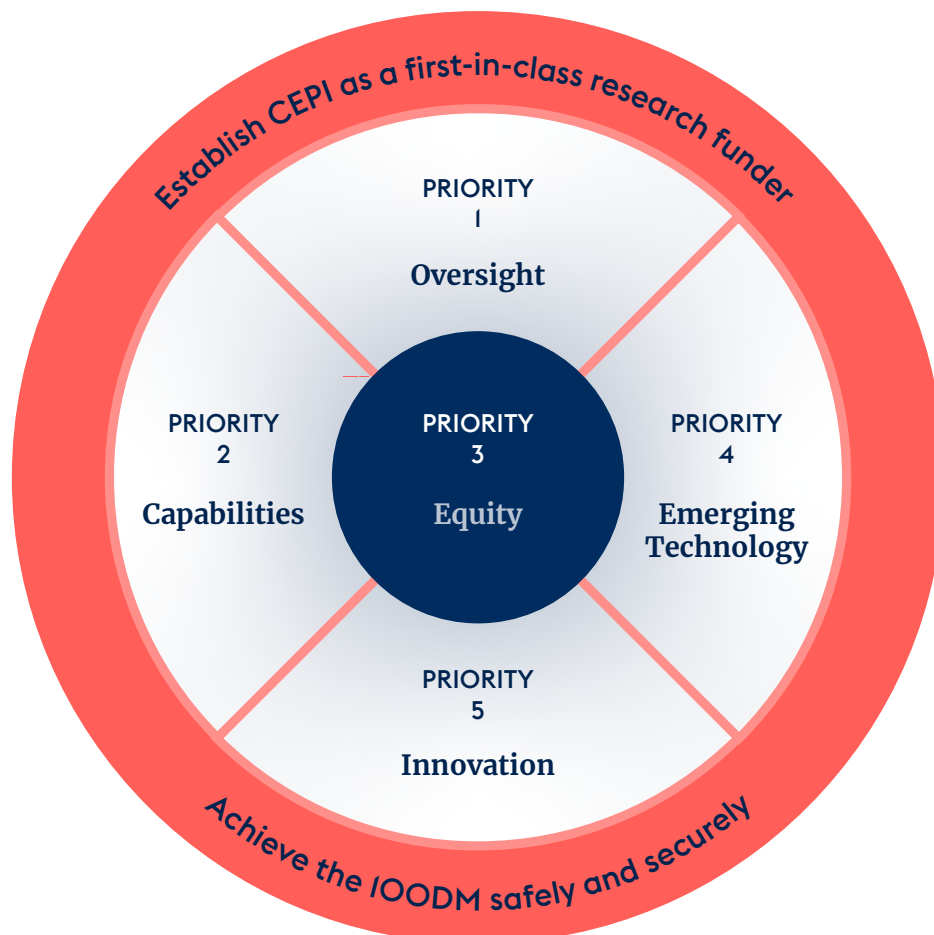
Figure 1: CEPI-identified global biosecurity vulnerabilities and priorities outlined in CEPI's inaugural Biosecurity Strategy

This document describes activities through calendar year 2026 to align with the timeframe of CEPI's current strategic plan, CEPI 2.0, which spans 2022–2026. As CEPI works to define its next organisational strategy for 2027–2031 (i.e., CEPI 3.0 strategy), the activities included in this Implementation Plan will help set the stage for integrating and embedding biosecurity and biosafety explicitly as a core component of the CEPI 3.0 approach; therefore, a separate future Biosecurity Implementation Plan beyond 2026 will not be necessary.

Importantly, the objectives and activities described below are interrelated, mutually-reinforcing, and will collectively serve to establish CEPI as a first-in-class research funder and ultimately achieve the 100DM safely and securely. Equity is at the core of CEPI and its Biosecurity Strategy (Priority 3), and central to how all the priorities will be implemented.

CEPI will embed oversight for biosecurity and biosafety without unduly impeding speed or equity (Priority 1), and therefore also support equitable, safe, scientific collaboration by strengthening capabilities of CEPI lab partners around the world (Priority 2). To achieve the 100DM safely and securely, CEPI will enable the benefits of emerging technology by minimizing biosecurity and biosafety risks (Priority 4), and these approaches will inform and be integrated into enhanced CEPI oversight and capability-building efforts with partners, as appropriate. Similarly, CEPI will also drive new approaches in biosecurity and biosafety to harness safe innovation that enables the 100DM (Priority 5) and feeds our oversight and capacity building approaches. To the extent possible, we have noted these interrelationships in the relevant objectives below and shown this schematically in Figure 2.

Figure 2: Schematic showing the interrelationships between the five Biosecurity Strategy priorities, with equity at the core and all five priorities collectively serving to establish CEPI as a first-in-class research funder and ultimately achieve the 100 DM safely and securely



1. Oversight
2. Capabilities
3. Equity
4. Emerging tech
5. Innovation

## Assumptions and Principles

The success of this Implementation Plan is, by design, linked closely to the Biosecurity Strategy, and therefore assumes that the landscape of biosecurity and biosafety vulnerabilities identified in that document remain relevant through 2026. Nevertheless, the Implementation Plan is intended to be flexible and responsive to new and emerging risks. Likewise, it assumes that CEPI's broader mission, priorities, and operational structure will not dramatically change.

CEPI's biosafety and biosecurity efforts are guided by its mission to ensure global, equitable access to life-saving vaccines. This requires integration across CEPI Departments and partnerships to ensure cohesive efforts that effectively balance scientific progress, rapid response and reducing risks. It also obliges research funders like CEPI to consider how to ensure adequate biosafety and biosecurity controls are being applied without unduly impeding vital international scientific cooperation. Speed and agility are essential to achieve the 100DM. CEPI will approach biosecurity and biosafety risk mitigation in a way that enables speed by defining best-practices and rules of the road in advance of an outbreak, rather than during (a key lesson from the COVID-19 pandemic). Practiced and defined biosecurity and biosafety (BSS) processes will enable us to achieve the 100DM safely and securely. Finally, CEPI will emphasise transparency, accessibility and accountability, fostering trust through thought leadership and by sharing best practices for responsible research across stakeholder communities.

Consistent with CEPI's approach in other areas, if CEPI provisions or requirements are in conflict with applicable national laws or regulations, CEPI partners will be expected to apply the highest standards consistent with such national laws and regulations and make CEPI aware of this conflict and their planned approach.

## Monitoring and Evaluation

To ensure successful implementation, CEPI will monitor progress and evaluate outcomes.

Each priority area includes objectives, with specific activities and a defined timeline. The Biosecurity Department will periodically review progress towards achieving the objectives.

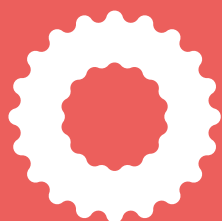
At the end of year one, a review of the Implementation Plan will be conducted in coordination with CEPI Management and Board. This could include updating and refining objectives, outputs and activities for 2026 in light of opportunities, challenges and implementation progress in 2025.

The review will also consider potential changes to the broader biosecurity landscape, CEPI priorities and strategic planning, lessons learned and stakeholder feedback and other relevant developments. If modifications are made to the implementation plan, these will be communicated with relevant internal and external stakeholders and an updated implementation plan made publicly available. Where appropriate and feasible, programmatic metrics will be collected to align with investor requirements.

# 2025-2026 Implementation Plan for CEPI Biosecurity Strategy

## Biosecurity Strategy Priority I:

**Strengthen biosafety and biosecurity risk identification, mitigation and oversight by CEPI and encourage similar efforts by other life science research funders**



As a global leader in vaccine R&D&M for epidemic and pandemic threats, CEPI is committed to advancing biosafety and biosecurity practices for CEPI-sponsored research. The rapidly evolving landscape of biological research and biotechnology presents unprecedented opportunities to accelerate progress toward 100DM scientific goals, but also new and evolving biosecurity risks that must be managed responsibly.

By embedding robust biosafety and biosecurity oversight into its own operations, CEPI aims to model best practices while fostering an international culture of shared responsibility for reducing these risks. Through CEPI's extensive laboratory and manufacturing network, we have an opportunity to catalyse best practices among CEPI partners and ensure that our oversight practices appropriately reflect the significant relationship we have established with these partners who are part of a 'CEPI network.'

We can also leverage the CEPI lab networks to facilitate a community of practice (see also Priorities 2 and 5). Coordinating with other research funders also creates invaluable opportunities to exchange knowledge and best practices for managing risks associated with quickly emerging technologies, including powerful new tools like artificial intelligence (AI).

Through targeted engagement, including with initiatives like the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP) and the Bio Funders Compact - launched in June 2024 by CEPI, NTI, and partners Sentinel Bio and Global Health Security Fund - CEPI seeks to galvanise collaboration across governments, industry and other research funders, driving the adoption of consistent, effective and globally-recognised biosafety and biosecurity practices for epidemic and pandemic pathogen research.

### Objective 1.1: Establish CEPI as a first-in-class global research funder that appropriately balances innovation and reducing biosafety and biosecurity risks across our research portfolio

- **Output 1.1.1** Consistent application of biosafety and biosecurity risk identification and reduction practices across CEPI
  - **Activity 1:** Develop and publish CEPI Biosecurity Policy and develop accompanying procedure that integrates biosafety and biosecurity risk considerations into existing CEPI pre- and post-award review processes (**Q3 2025**)
  - **Activity 2:** Develop and implement a biosecurity and biosafety risk assessment framework to be applied across CEPI projects, and enable evidence-based decision-making on mitigation needs (**Q3 2025**)
  - **Activity 3:** Develop and implement CEPI workforce training to enable implementation of the biosafety and biosecurity procedure among relevant CEPI departments, aligned with existing staff training processes (**Q3 2025 and ongoing**)
  - **Activity 4:** Biosecurity Department to provide ad hoc expert advice and risk assessment on evolving or acute biosecurity and biosafety needs across CEPI's activities (**Ongoing**)

### Objective 1.2: Leverage CEPI biosecurity leadership to encourage global research funders to prioritize and fund biosafety and biosecurity risk reduction

- **Output 1.2.1** Demonstrate CEPI as an exemplar of medical countermeasures research funders by prioritising biosafety and biosecurity risk reduction, informed by globally recognised best practices
  - **Activity 1:** Share best practices for biosecurity and biosafety risk assessment and mitigation among leading global research fund funders (**Quarterly**)
  - **Activity 2:** Advocate for other life science research funders and stakeholders to sign and support the Bio Funders Compact (**Ongoing**)



## Biosecurity Strategy Priority 2:

Enhance global biosafety and biosecurity capabilities of CEPI partners for achieving the IOODM safely and securely, and promote health-security partnerships



CEPI is well positioned to champion consistent and effective biosafety and biosecurity practices across its globally diverse and geographically representative network of laboratories and sponsored institutions. Strengthening biosafety and biosecurity across this research ecosystem is critical to achieving the IOODM while safeguarding global health security and can enable evaluation of adherence to globally-recognised biosafety and biosecurity practices as part of CEPI funding decision-making and oversight, aligned with Priority 1.

To achieve this vision, over the course of the next two years, CEPI will collaborate with CEPI-supported R&D&M facilities to demonstrate the feasibility of implementing and monitoring biosafety and biosecurity risk management performance-based standards across a diversity of laboratory settings and resource environments, and address critical vulnerabilities in the safe and secure acquisition, transfer and storage of biospecimens. Both efforts share a common goal of building resilience and trust within the global vaccine R&D&M ecosystem, ensuring that CEPI-supported facilities operate with safety, security and equity at their core.

CEPI can also play an important role in cultivating broader health-security partnerships, advocating for the IOODM vision to be viewed as a security goal, as well as a health one. CEPI can work to establish greater collaboration between sectoral siloes at the health-security interface, and maximise investments across health, development and security sectors for CEPI initiatives.

### Objective 2.1: Accelerate implementation of globally-recognised, performance-based standards for biosafety and biosecurity, including ISO 35001

- **Output 2.1.1** Support uptake and implementation of performance-based standards for biosecurity and biosafety, such as ISO 35001
  - **Activity 1:** Leverage CEPI's convening power to gather expert input and feedback on challenges and opportunities for roll-out and implementation of performance-based standards, such as ISO 35001 (**Ongoing**)
  - **Activity 2:** Establish collaborative efforts with other partners to support dissemination and uptake of relevant performance-based standards (**Ongoing**)

- **Output 2.1.2:** CEPI-supported lab facilities implementing performance-based standards in biosafety and biosecurity
  - **Activity 1:** Conduct needs assessment with CEPI-supported facilities to identify needs, priorities, constraints and opportunity areas (including for within-network mentorship, training and twinning) for implementation of performance-based standards in biosafety and biosecurity (will also support implementation of risk mitigations as identified under Output 1.1.1) (**Q3 2025**)
  - **Activity 2:** Design and support pilot implementation of performance-based standards (e.g., ISO 35001) in up to 10 CEPI-sponsored institutions (**Q2 2025–Q1 2026**)
  - **Activity 3:** Identify factors facilitating successful implementation, achievement of compliance/certification and sustainability across pilot facilities (**Q1 2026**)
  - **Activity 4:** Use data from pilot (per Outcome 2.1.1) to guide global roll-out and implementation (**Q2–Q4 2026**)
  - **Activity 5:** Expand implementation of performance-based standards to additional CEPI-supported or prospective partner facilities (**Q1 2026–Q4 2026**)

**Objective 2.2: Strengthen biosafety and biosecurity capabilities of CEPI partners for acquiring, transferring, and storing biospecimens during emergency and non-emergency settings**

- **Output 2.2.1:** Resources for CEPI partners on biosafety and biosecurity best practices pertaining to biospecimen acquisition, transfer storage and inventories developed
  - **Activity 1:** Convene CEPI partners engaged in biospecimen acquisition, transfer and/or storage, including those involved in recent emergency responses, to discuss current practices, gaps and needs regarding biosafety and biosecurity (In alignment with Outputs 2.1.2, 2.2.2) (**Q2 2025**)
  - **Activity 2:** Review existing international, regional and (where relevant) national guidance documents for biospecimen management to identify biosecurity and biosafety best practices relevant for CEPI portfolios (**Q3 2025**)
  - **Activity 3:** Develop resources (e.g., checklists) for CEPI partners consistent with international norms and standards, and adaptable to diverse implementation contexts, for safe and secure biospecimen acquisition, transfer and storage (**Q4 2025**)



- **Output 2.2.2:** CEPI partner capabilities for safe and secure biospecimen acquisition, transfer, storage and inventories strengthened in line with best practices and international standards
  - **Activity 1:** Convene follow up meeting for CEPI partners engaged in biospecimen acquisition, transfer and/or storage, including those involved in recent emergency responses, to review the CEPI resources and identify priority areas for capacity strengthening (**Q1 2026**)
  - **Activity 2:** Design and implement capacity strengthening approach, in collaboration with CEPI partners, for addressing priority capacity strengthening areas in line with the developed resources (**Q1-Q4 2026**)
  - **Activity 3:** Provide rapidly deployable capacity strengthening during emergencies to address priority biosafety and biosecurity risks related to biospecimen acquisition, transfer and management (**As needed**)

### Objective 2.3: Strengthen CEPI's partnerships with the security community and catalyse health-security partnerships in support of the 100DM

- **Output 2.3.1:** The global security community embraces 100DM vaccine R&D&M capabilities as important components of the Biological Weapons Convention and the global biological nonproliferation agenda
  - **Activity 1:** Articulate the role of 100DM capabilities in supporting the Biological Weapons Convention and global biological nonproliferation objectives, which will also demonstrate the strong interlinkages between global health and security goals (**Q1 2025**)
  - **Activity 2:** Showcase the security relevance of CEPI investments at high-level international gatherings of security stakeholders, including the Biological Weapons Convention, the GP, Munich Security Conference and other relevant security fora. (To be coordinated with Output 3.2.2 engagement and convenings at these events) (**Ongoing**)

## Biosecurity Strategy Priority 3:

### Drive biosecurity and biosafety for equity



Equity and access are foundational values underpinning CEPI's mission and are central to its Biosecurity Strategy. Insufficient recognition of the intersection between biosecurity and equity represents a significant vulnerability that risks undermining global responses to epidemic and pandemic threats, including progress towards the 100DM.

While global health equity and biosecurity are sometimes perceived as competing priorities, they are deeply interconnected. Supporting global R&D&M capacity alongside promoting standards that advance safety and security—without creating undue barriers to scientific collaboration and innovation—provide global benefits, ultimately strengthening global health security and protecting all nations from infectious disease threats.

By driving cross-sectoral partnerships and exploring cost- and responsibility-sharing frameworks, CEPI aims to build a more resilient, equitable, and innovative global pandemic preparedness and response ecosystem – one in which biosecurity and biosafety are not obstacles, but enablers of equitable vaccine access and scientific innovation.

#### Objective 3.1: Deepen awareness and understanding of the important interrelationship of biosecurity and equity in the context of vaccine R&D&M and achieving the 100DM

- **Output 3.1.1:** CEPI articulates the interrelationship of biosecurity and equity in advancing the 100DM and identifies opportunities for sustainable cost-sharing mechanisms for biosecurity and biosafety risk reduction, including financing mechanisms
  - **Activity 1:** CEPI publishes paper on biosecurity-equity nexus in consultation and coordination with health security stakeholders (**Q4 2025**)
  - **Activity 2:** Bio Funders Compact signatories consider funding support for biosafety and biosecurity capabilities as part of their awards (implemented through Objective 1.2) (**Q4 2025**)
  - **Activity 3:** CEPI mobilises new advocates for biosecurity and equity across the global health and security communities (implemented through Output 2.3.1 and 3.2.2) (**Ongoing**)

### Objective 3.2: Strengthen biosecurity and biosafety capabilities for vaccine R&D&M of CEPI partners in the Global South and catalyse regional capacity building

- **Output 3.2.1:** CEPI's biosecurity and biosafety programmes are leveraged to build capabilities in the Global South and not unduly hamper broad scientific participation in the 100DM
  - **Activity 1:** Biosafety and biosecurity capability building programmes focus on the Global South and are implemented sustainably and in collaboration/coordination with complementary efforts such as the Signature Initiative for Mitigating Biological Threats in Africa and BioPrevail, where appropriate (implemented through Objectives 2.1, 2.2, 4.2, 5.1, 5.2) (**Ongoing**)
  - **Activity 2:** Biosecurity Department contribution to development of CEPI-sponsored data sharing platform(s) based on transparent criteria established for artificial intelligence for vaccine design, which enables both equitable scientific participation and robust biosecurity risk mitigation (implemented through Objective 4.2) (**Q3 2025**)
  - **Activity 3:** CEPI's Biosecurity Policy and procedure are informed by the wide range of resource settings in which CEPI research takes place, and do not serve to unduly impede diverse participation in CEPI-supported research<sup>1</sup> (implemented through Objective 1.1) (**Q2 2025**)
- **Output 3.2.2:** CEPI mobilises voices from the Global South to help broaden the global dialogue on biosecurity and biosafety risk reduction
  - **Activity 1:** Sponsor Global South experts to gain operational experiences in biosafety and biosecurity at CEPI (**Ongoing**)
  - **Activity 2:** Sponsor and spotlight Global South leaders, including rising leaders, at global health security engagements (implemented through Outputs 2.3.1 and 4.1.2) (**Q1 2025 and ongoing**)
- **Output 3.2.3:** CEPI biosecurity and biosafety activities catalyse regional progress towards safe and secure vaccine R&D&M in the Global South
  - **Activity 1:** Oversee Africa CDC implementation of the Biosecurity pillar of the CEPI/Africa CDC Joint Action Plan (**Q1 2025 – Q4 2026**)

<sup>1</sup>– Consistent with CEPI's approach in other areas, if CEPI provisions or requirements are in conflict with applicable national laws or regulations, CEPI partners will be expected to apply the highest standards consistent with such national laws and regulations and make CEPI aware of this conflict and their planned approach.

## Biosecurity Strategy Priority 4:

### Monitor and reduce risks of emerging and converging biotechnologies



In an era of rapid technological advancement, emerging and converging technologies present both unprecedented opportunities and evolving risks for the 100DM and global health security. AI holds immense potential to accelerate vaccine development and enhance preparedness efforts but also introduces new complexities, including biosecurity risks. Ensuring the safety and security of CEPI's vaccine R&D&M efforts requires a proactive approach to understanding, identifying and mitigating these risks.

By strengthening our ability to anticipate technological shifts and fostering responsible technology development and innovation, CEPI aims to harness the benefits of cutting-edge tools, like artificial intelligence, while mitigating potential challenges. This will be essential to advancing the 100DM and supporting global preparedness efforts against future epidemic and pandemic threats.

#### Objective 4.1: Promote responsible AI applications for 100DM capabilities development

- **Output 4.1.1:** CEPI implements a consistent approach to identifying and managing biosafety and biosecurity risks for AI-enabled vaccine/biological design tools
  - **Activity 1:** Contribute to CEPI's overall AI risk assessment process (**Q2 2025**)
  - **Activity 2:** Integrate AI risk identification and mitigation elements into CEPI's Biosafety and Biosecurity Policy and procedure, ensuring relevant subject matter input sought from across CEPI (implemented through Output 1.1.1) (**Q2 2025**)
  - **Activity 3:** Pilot risk mitigation approaches in CEPI's AI investments and share best practices with other research funders; provide incentives for implementing them as part of CEPI awards (**Q3 2025**)
  - **Activity 4:** Design and implement a safe, secure and accessible data sharing platform for CEPI's AI/vaccine design efforts (**Q4 2025**)

- **Output 4.1.2:** CEPI's Global South partners are regularly contributing to global dialogues on balancing risks and benefits associated with AI applications in vaccine development
  - **Activity 1:** Cultivate Global South champions for strengthening regional and global governance of AI/biosecurity risks associated with vaccine R&D&M (**Ongoing**)
  - **Activity 2:** Consistently integrate Global South perspectives into every global AI technology dialogue in which CEPI participates (**Ongoing**)
  - **Activity 3:** Under the CEPI/Africa CDC Joint Action Plan, launch two AI/biosecurity pilot projects in the African region (implemented through Output 3.2.3) (**Q2 2026**)

**Objective 4.2: Establish a horizon-scanning function for systematically monitoring emerging biotechnology risks impacting CEPI's vaccine R&D&M portfolio**

- **Output 4.2.1:** A framework for horizon scanning, tailored to emerging biotechnology and converging technology risks, is developed and operationalised
  - **Activity 1:** Develop a risk identification and prioritisation matrix to evaluate emerging and converging biotechnologies based on their potential impact on CEPI's mission, in alignment with other relevant CEPI horizon scanning functions and connected with relevant external efforts as appropriate, including WHO's Foresight and the GP's WMD Relevant Technologies Initiative (**Q2 2026**)
  - **Activity 2:** Establish a systematic process for collecting and analysing information from diverse sources, including scientific literature, security reviews, policy documents and industry trends (**Q4 2026**)

## Biosecurity Strategy Priority 5:

Accelerate biosafety and biosecurity innovation for vaccine research, development, and manufacturing



CEPI is already a recognised world leader in supporting creative and ground-breaking R&D&M for epidemic preparedness and response. To this end, CEPI envisages accelerating progress in these areas, and in support of equitable distribution of R&D&M capacities, through catalysing new approaches to biosafety and biosecurity in support of vaccine and biologic R&D&M goals.

Achieving this vision will require both global engagement and thought leadership across diverse partners and stakeholders, including alignment with efforts to seek innovation in support of the 100DM across other parts of CEPI. It can also be facilitated through direct investments in innovative approaches to biorisk management in topics areas relevant to the 100DM, emphasising sustainable solutions for all settings, in alignment with Priority 3. We anticipate that emerging technologies will play an important role in advancing safe and secure research, necessitating close coordination with Priority 4 activities.

### Objective 5.1: Establish a community of practice across the CEPI lab networks for identifying and promulgating biosafety and biosecurity innovations

- **Output 5.1.1:** Improved coordination and dissemination of biosafety and biosecurity innovations for vaccine R&D&M
  - **Activity 1:** Establish a biosafety and biosecurity “community of practice” to identify, collate and promulgate innovations and best practices across the CEPI lab and manufacturing networks (Implemented in coordination with Outputs 2.1.1, 2.1.2 and 4.1.2) (**Q2 2025**)
  - **Activity 2:** Engage a diversity of partners to understand the landscape of actors and opportunities for innovation in biosafety and biosecurity related to vaccine/biologics R&D&M (**Q3 2025**)
  - **Activity 3:** Contribute to global initiatives related to biosafety and biosecurity innovation in vaccine R&D&M (**Q4 2025**)



**Objective 5.2: Drive innovation in biosafety and biosecurity risk reduction for CEPI's vaccine research, development, and manufacturing portfolio**

- **Output 5.2.1:** Novel innovations for safe and secure vaccine R&D&M identified and adopted
  - **Activity 1:** Launch (or co-launch) a solicitation for grants to design, develop and/or implement innovations in biosecurity that will enable accelerated progress towards the 100DM, in alignment with other CEPI innovation functions (**Q2 2026**)
  - **Activity 2:** Competitively select up to 10 proposals for proofs-of-concept projects (**Q3 2026**)
  - **Activity 3:** Use findings from implemented proof-of-concept projects to establish initial evidence-base for innovative approaches to biosecurity, biosafety and laboratory systems that can be sustainably applied in diverse settings (**Q4 2026 and beyond**)

CEPI