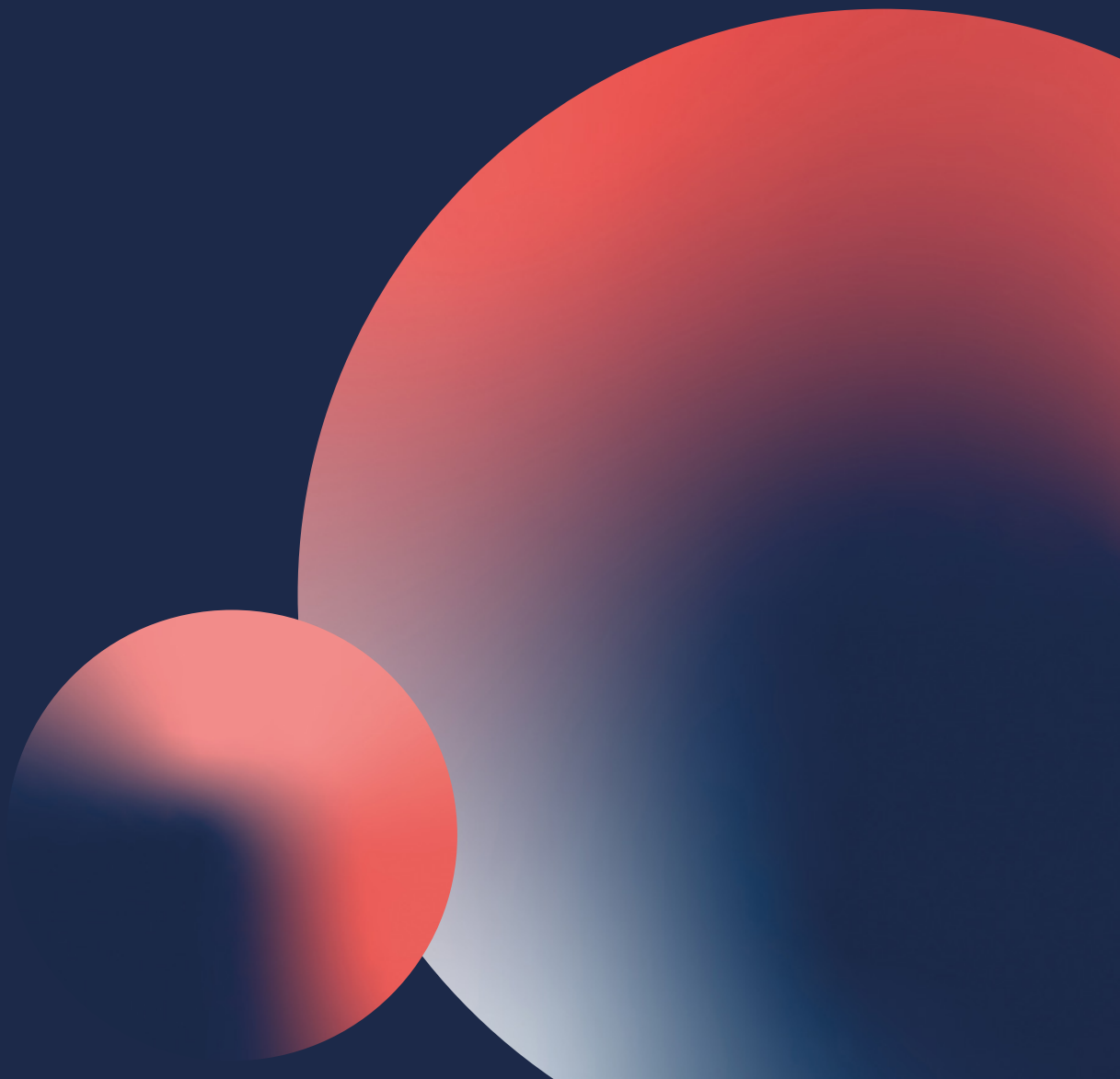
CEPI

Biosecurity Strategy

September 2024



Credit: Tiba Biotech

Foreword

In an era of heightened epidemic and pandemic risk, the world must remain vigilant and be able to respond quickly to infectious disease outbreaks wherever they occur. COVID-19 was a challenge unprecedented in our lifetimes, causing the greatest public health crisis in a hundred years, and opening the eyes of many decision-makers to the devastating global consequences that a pandemic can create. The persistent controversy over the pandemic's origins also heightened broader awareness of the risk of accidental release and deliberate misuse of science.

Most risk created by advances in the biological sciences derives from the fungibility of the tools designed to solve specific problems. The tools that will solve a pressing problem are empowering – but there is no intrinsic limit to their application. Biologists tackle practical problems through the rigorous application of method and technique, and it is this aspect of how science is done that gives rise to the problem of "dual use". Solve the problem of gene insertion and you can cure disease – or enable a virus to evade our countermeasures. But trying to impose limits on scientists as they tackle their problems and develop their techniques presents significant practical challenges and could impede our progress towards legitimate and worthy goals, including the 100 Days Mission.

Against a backdrop of emerging and converging technologies, in particular the advancement in Artificial Intelligence (AI) technology, and the rapid global expansion of high containment facilities around the world, the infectious disease risk landscape is transforming. These technologies and facilities will greatly accelerate scientific progress and make it easier for scientists from around the world to participate in both basic and applied research.

Global scientific participation is critical to the success of the 100 Days Mission and will enable vaccine research, development, and manufacturing to take place in communities that need it, led by those who will benefit from it, and informed by the priorities of the vulnerable communities that are disproportionately impacted by epidemics and pandemics.

But these tools and facilities also increase the risk of accidents or deliberate misuse, and any strategy aiming to achieve health security for the world must embed and reinforce mechanisms to ensure that the highest, most current standards of biosecurity and biosafety are practiced and maintained. As of September 2024, CEPI manages a highly diverse ~ USD 3.1 billion research portfolio in more than 50 countries, which between them have highly variable oversight practices for reducing biosafety and biosecurity risks. Core to the idea of CEPI having a biosecurity strategy is the recognition that as a steward of global funds, no matter where those funds are deployed, we have a critical responsibility to ensure that the research we fund does not lead to the next accident or deliberate incident.

Beyond this threshold obligation, CEPI also has an opportunity to step-up as a thought leader in this emerging area. What role should life science research funders play in ensuring the biosecurity and biosafety of the research they fund? How can we ensure that requirements aren't a barrier to broad, global participation in scientific research, but instead help build the capacities required to pave the way towards equitable, diverse and merit-based scientific collaboration? How can we catalyse partnerships between the health and security communities, recognising our joint goals and leveraging our

collective resources and skills to pave the way for a more resilient pandemic preparedness ecosystem?

To develop our strategy, we have undertaken an extensive consultative process, engaging more than 150 entities across the global health and security ecosystems, representing governments, civil society and industry. We assembled and have been advised by a globally representative Biosecurity Strategy Group of external advisors, with members from five continents; we have solicited expert feedback in discrete strategy priority areas; and we have convened panels, conducted tabletop exercises and signed agreements with critical partners as the strategy has developed.

As technological capabilities evolve and boundaries blur between disciplines, we should anticipate that traditional approaches to biosafety and biosecurity may prove inadequate to address emerging threats.

To prevent that, it will be imperative for stakeholders across civil society, industry and government to collaborate closely, anticipate potential risks, and develop agile response mechanisms to promote responsible use in ways that appropriately balance risks and benefits. One of the roles CEPI can play is in catalysing cooperation among stakeholders, investing in research and development and prioritizing the integration of innovative technologies into existing frameworks. In doing so, we can strengthen the global health and security ecosystems, thereby enhancing our ability to mitigate risks and accelerate global progress toward 100 Days Mission goals.

"*The very act of trying to look ahead to discern possibilities and offer warnings is in itself an act of hope*" – Octavia Butler, "A few Rules for Predicting the Future" (2000).

CEPI's work in this space will undoubtedly continue to evolve and we want to define implementation approaches that neither unnecessarily impede the pace of research nor conflict with national priorities. We are especially attuned to the need to reduce risks across both the Global North and South, in the interest of enhancing research capacity globally and in an equitable fashion and we welcome your input to this process.

Dr. Richard Hatchett,
CEO of CEPI

"Security and equity are at the heart of CEPI's 100 Days Mission – a strategy for the world to develop new vaccines against any emerging epidemic threat, regardless of whether it arises naturally, accidentally or due to deliberate misuse, and to do that quickly enough to prevent or mitigate deadly pandemics. To underpin that strategy, and to ensure the world can achieve the 100 Days Mission goal safely and securely, we need a robust, collaborative approach to maximising the benefits of new technologies and reducing their potential threats to human health."

Jane Halton,
Chair of CEPI's Board

Executive Summary

As a leading global funder of vaccine research, development, and manufacturing (R&D&M) with up to 3.1B USD invested in projects since CEPI's launch (Figure 1), CEPI has a critical responsibility to ensure its investments in vaccine and biologics R&D&M do not inadvertently cause the next epidemic or pandemic due to an accident or deliberate misuse. Given the heightened attention to biosafety and biosecurity risks in the wake of the COVID-19 pandemic, rapid advances in synthetic biology and biotechnology, and powerfully expanding biological applications of Artificial Intelligence (AI), CEPI also has an opportunity, beyond meeting this threshold obligation, to serve as a global thought leader and influencer on biosafety and biosecurity, particularly related to vaccine research, development, and manufacturing.

CEPI's biosecurity strategy outlines its understanding of urgent global vulnerabilities in this area and identifies concrete ways that CEPI will work to address them. In support of CEPI's vision for "a world in which epidemics and pandemics are no longer a threat to humanity," CEPI has defined a biosecurity focus to "**protect society from epidemic and pandemic threats, with an emphasis on preventing accidental and deliberate misuse of pathogens associated with CEPI-sponsored research**."

To advance this, CEPI will prioritize activities that:

1) Strengthen biosafety and biosecurity risk identification, mitigation, and oversight by CEPI and encourage similar efforts by other life science research funders;
2) Enhance global biosafety and biosecurity capabilities of CEPI partners for achieving the 100DM safely and securely, and promote health-security partnerships;
3) Drive biosecurity and biosafety in support of equity;
4) Monitor and reduce emerging biotechnology and converging technology risks across CEPI's vaccine research, development, and manufacturing (R&D&M) portfolio; and
5) Accelerate biosafety and biosecurity innovation for vaccine R&D&M.

Inherent to CEPI's mission is creating the capacity for the world to develop, test, and produce vaccines at population scale to stop epidemics and pandemics, which at its core is an inherently biosecurity function. While the 100DM has been embraced by the global health community, the benefits of 100DM capabilities are inadequately recognized by the global security community. The capabilities to enable rapid vaccine, therapeutic, and diagnostics development within 100 days will help stop epidemics and pandemics, regardless of whether they originate naturally or due to the deliberate development of bioweapons. As such, the 100DM capabilities are also fundamentally security capabilities, and CEPI can play an important role in bridging the health and security communities to strengthen whole-of-society approaches for neutralizing future emergent threats. CEPI is committed to cultivating an international pandemic preparedness and response ecosystem that prioritizes biosecurity and biosafety, and where research funders support biosafety and biosecurity as core business components, much like other areas such as human clinical trials, animal welfare, and genomic privacy.

To support and inform biosecurity strategy development, CEPI established a Biosecurity Strategy Group (BSG) of external advisors in March 2024, with group members appointed by CEPI CEO Richard Hatchett. The BSG members possess a diverse range of experiences and expertise across sectors from around the world, related to vaccine R&D&M and biosecurity. Over several months, CEPI convened

meetings to solicit feedback on CEPI-identified global biosecurity vulnerabilities and CEPI's biosecurity focus and priorities, which the BSG enthusiastically supported. Additionally, CEPI engaged more than 150 entities representing global health and security stakeholders across governments, industry, and civil society during the strategy development process. CEPI Management and Board approved the biosecurity strategy.

The strategy does not include detailed information on specific actions, milestones, and timelines in priority areas, and CEPI intends to use this strategy document to broaden and deepen engagement with global health and security stakeholders. Based on feedback received and additional discussions, CEPI will develop an implementation plan for the biosecurity strategy, which will be published in early 2025.

CEPI's vision is of a world in which epidemics and pandemics are no longer a threat to humanity.

CEPI's biosecurity focus is to protect human populations from epidemic and pandemic threats, with an emphasis on preventing accidental and deliberate misuse of pathogens associated with CEPI-sponsored research.

Introduction

Vaccines are at the heart of how societies counter infectious disease threats. They are our most potent tool against epidemic and pandemic risks and critical to any future response. The faster an effective vaccine is developed and deployed, the faster an incipient pandemic can be contained and controlled.

CEPI was created in the aftermath of the 2014–2016 West Africa Ebola epidemic to develop new vaccines to prevent future epidemics. CEPI's objectives further expanded upon the adoption of its 2.0 Strategy, including the call for the world to be able to respond to the next "Disease X" with a new vaccine in just 100 days. This 100 Days Mission (100DM), supported by G7 and global partners, aims to give the world the capability to design, test, and make available, safe and effective vaccines within 100 days of identification of a viral threat. Ultimately, the bold 100DM ambition is to eliminate the threat that epidemics and pandemic pose to people and society.

Advancing research, development, and manufacturing (R&D&M) to deliver safe and effective vaccines to counter novel infectious threats inherently must include investments in research involving epidemic and pandemic pathogens, and therefore requires laboratories capable of handling and storing pathogens and/or genomic data for current and future use. **As stewards of global public funds, CEPI has a critical responsibility to ensure its investments in vaccine and biologic R&D&M do not inadvertently cause the next epidemic or pandemic due to an accident or deliberate misuse**. This is particularly salient given an ongoing reassessment by many policymakers in the wake of the COVID-19 pandemic of social tolerance for biosafety and biosecurity risks associated with research on high consequence pathogens. Given most of CEPI's priority pathogens are zoonotic, the risk of accidental or deliberate release into communities or the environment may pose threats to wildlife, companion animals, and livestock, making biosecurity also fundamentally a One Health issue. Furthermore, as the world grapples with trust in science and particularly vaccines, CEPI's work to be clear and transparent about how it is ensuring the safety and security of research it funds is imperative.

Additionally, rapid advances in biotechnology and other converging technology areas are simultaneously creating extraordinary new opportunities to accelerate global progress toward 100DM goals while leading to new and evolving biosafety and biosecurity risks. Recently, tremendous progress in Artificial Intelligence (AI) and machine learning technologies have been an area of intense interest given the transformative potential of AI on society, including in the areas of biosecurity, pandemic preparedness, and health security. While AI holds great promise in improving capabilities to achieve the 100DM, there are also risks that AI could be misused to cause harm. Over the last year, CEPI has been at the forefront of driving efforts by the scientific and biosecurity communities to promote responsible and equitable development of AI technologies in support of 100DM goals. CEPI and partners must remain committed to unleashing emerging technologies in support of 100DM vaccine goals, particularly against the backdrop of other anthropogenic drivers of disease emergence and pandemic threat, such as climate change, conflict and migration, while working simultaneously and with equal conviction to identify and mitigate biosafety and biosecurity risks. Beyond this threshold obligation to reduce biosafety and biosecurity risks across its research portfolio, CEPI is uniquely positioned to elevate attention to the important role of biosafety and biosecurity in vaccine development and across the end-to-end preparedness ecosystem (i.e., from pathogen detection to vaccine design, clinical testing, manufacturing, and distribution/delivery) while accelerating global progress toward reducing urgent biosecurity vulnerabilities and achieving the 100DM safely and securely (Figure 2).

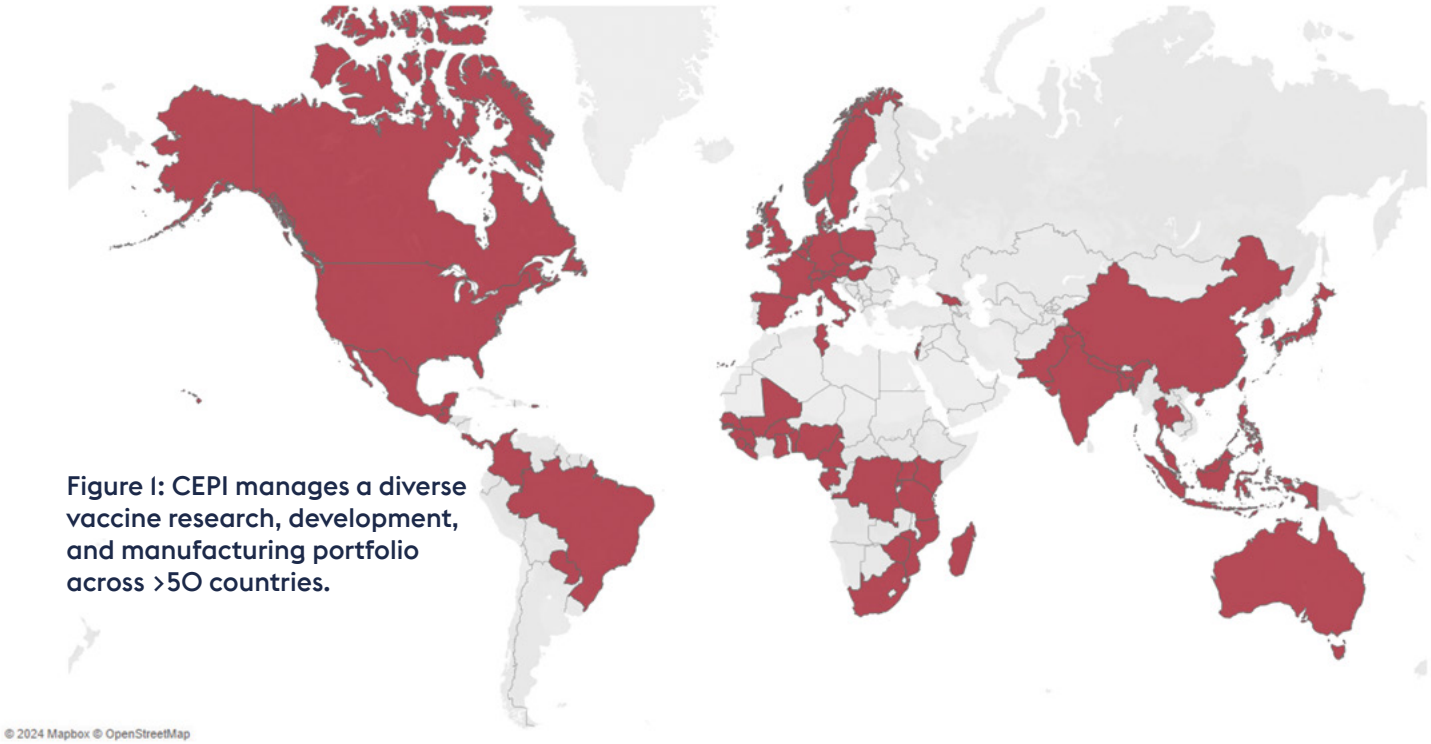


Figure 1: CEPI manages a diverse vaccine research, development, and manufacturing portfolio across >50 countries.

Over the years, the terms biosafety and biosecurity have evolved to possess different meanings globally among different international constituencies[1]. For instance, WHO[2] defines biosecurity as preventing the intentional or accidental unauthorized access to biological material, technology, and information while FAO employs the term to refer to managing relevant risks to human, animal and plant life and health[3]. CEPI acknowledges the urgent need to protect human populations from infectious disease threats regardless of whether they arise naturally, accidentally, or due to deliberate misuse. CEPI's new, dedicated biosecurity function will emphasize efforts to reduce the risk that CEPI-supported research leads to the next epidemic or pandemic due accidental or deliberate misuse.

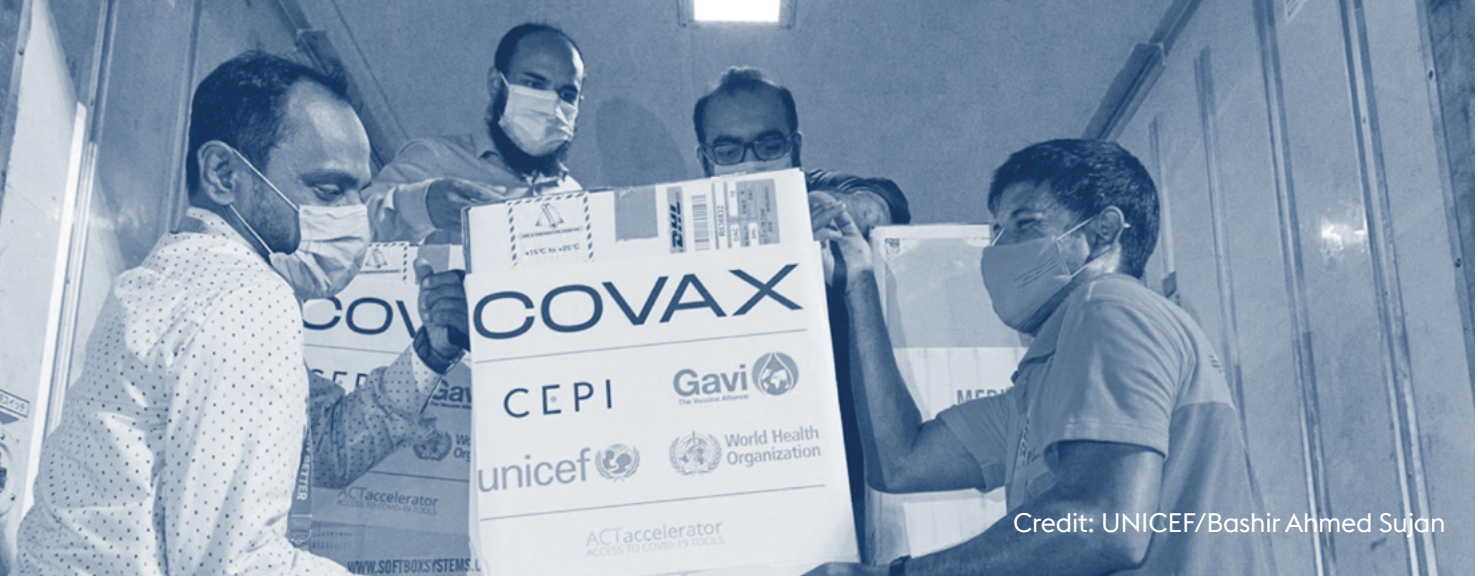
It's critical that CEPI's biosecurity and biosafety priorities are not seen as conflicting to CEPI's mission to accelerate vaccine development towards the 100DM. The ability of CEPI and other life science research funders to move quickly in the event of an outbreak is essential. Therefore, this strategy demonstrates how an innovative approach to biosecurity and biosafety, frontloaded towards preparedness, will in fact serve to enable the safe and secure delivery of the 100DM. The more we can mitigate safety and security risks, and balance with benefits, in R&D&M in advance of an outbreak, the greater the ability the world will have to respond to it quickly. CEPI can also be a thought leader in outlining the key checkpoints along the end-to-end vaccine development cycle where researchers do need to pause to consider risk mitigation, to enable rapid progress over the rest of the timeline.

Ultimately, the world needs the ability to respond to outbreaks no matter their origin, and this will require using the same systems and capabilities developed for the 100DM. That's why health-security partnerships are key - so the sectors can cooperate to leverage their joint capacities and build a more resilient and equitable global health security ecosystem.

[1] Renault V, Humblet M.-F., and Saegerman C. Biosecurity Concept: Origins, Evolution and Perspectives. Animals (Basel). 2022 Jan; 12(1): 63..

[2] WHO Laboratory Biosecurity Guidance (2024) defines biosafety as Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

[3] The FAO Biosecurity Toolkit (2007) defines biosecurity as a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analysing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment.



Credit: UNICEF/Bashir Ahmed Sujan

CEPI-identified Global Biosecurity Vulnerabilities

In the wake of the COVID-19 pandemic, and in the midst of a global biotechnology revolution that is poised to transform society, there is an urgent need to ensure that biosafety and biosecurity risk identification and mitigation approaches keep pace with the evolution of the ways in which biological tools could accidentally or deliberately be misused to cause harm. Incidents of laboratory breaches and failures of biorisk protocols over the last 25 years, including the 2001 Amerithrax attacks and 2014 CDC anthrax exposure as well as questions relating to the origins of COVID-19, underscore the need for stronger approaches to identify and reduce biosafety and biosecurity risks in research facilities worldwide. In parallel, there has been a well-documented proliferation of high containment biosafety labs across the world that will require a long-term approach to ensure sustained maintenance and secure operations to minimize biosafety incidents, accidental release and/or security failures. Robust risk assessment frameworks, rapid early warning systems, proactive, agile, and effective mitigation practices, and transparent bio incident reporting are critical.

While traditional pathogen-based systems are helpful in informing safety and security risk assessment, pathogen endemicity varies by region and laboratory work involving endemic pathogens might pose a lower relative risk to the general public in particular geographies. Additionally, powerful new bio design tools, powered by AI technologies, are rapidly rendering pathogen-based risk regimes obsolete as they more accurately design biological molecules with specific functions that are encoded by sequences not found in nature. As such, we must work toward a future of function-based risk identification and assessment, despite the challenges this will pose for CEPI, other life science research funders, and the broader scientific community. Moreover, recent public health emergencies, such as H5N1 and mpox outbreaks, continue to highlight the critical need for diverse and interdisciplinary collaboration and knowledge sharing to enhance preparedness and response capabilities against infectious disease threats. As life science research funders and practitioners, we must work with urgency to reduce global biosecurity vulnerabilities, fortify our defenses against future epidemics and pandemics, safeguard public health on a global scale (including disproportionately vulnerable communities), and enable the success of the 100DM.

To ensure CEPI's biosecurity strategy is grounded in the current key gaps in the ecosystem, CEPI has carried out an extensive mapping exercise of the global biosecurity landscape, in consultation with nearly 150 stakeholders across a range of sectors, geographies, and disciplines. Discussions with civil society, governments, and industry stakeholders, across the health and security enterprises, revealed significant vulnerabilities in the global ecosystem, and partners showed enthusiasm for CEPI's efforts to elevate these issues. While there are dedicated organisations in the security sector focused on biosecurity, there are few dedicated health organisations engaging in this space. Normative organizations, like the WHO and the International Organisation for Standardisation (ISO), are playing a critical role in setting out guidance documents and frameworks for laboratories working with high consequence pathogens around the world, and commitment from countries has been underscored by the recent adoption of the resolution, "Strengthening

laboratory biological risk management (EB154(10))" at the 77th World Health Assembly in May 2024. CEPI and other funders of life science research have an important role to play in the implementation of these efforts and can be instrumental in ensuring that high standards are deployed in the research and capabilities they fund. That's why CEPI, along with the Nuclear Threat Initiative (NTI), has already launched the Bio Funders Compact. CEPI is a founding signatory of this important initiative – along with philanthropies Sentinel Bio and Global Health Security Fund - demonstrating our mutual commitment and leadership to prioritizing biosecurity and biosafety as a critical component of R&D&M in life sciences and pandemic preparedness and response.

There is a clear gap in leadership on biosecurity from organisations dedicated to vaccine development and innovation prioritizing biosecurity, and CEPI can play a unique role in bridging between communities and serving as a thought leader and leader-by-example on this critical intersection. CEPI is committed to working with existing partners and leaders in biosecurity, to ensure our efforts are complementary, mutually supportive, and wherever possible advancing internationally-recognized approaches and solutions.

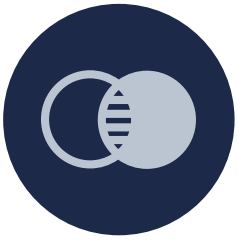
It is clear the world continues to lack the necessary preparedness capabilities to enable a more rapid and equitable response to the next pandemic, regardless of whether the next global emergency originates naturally, accidentally, or due to deliberate misuse.

Key global biosecurity and biosafety vulnerabilities identified by, and relevant for, CEPI include:

1. **Variable biosafety and biosecurity oversight, risk identification, and management practices among life science funders for research involving high consequence pathogens, including CEPI.** There is a wide breadth of oversight approaches employed by R&D&M funders to biosafety and biosecurity risk identification, assessment, mitigation, and oversight. The range spans from funders that have defined policies and practices in place, to others that employ limited (or no explicit) approaches to mitigating biosafety and biosecurity risks. Oftentimes research funders rely on national and institutional regulations, policies, and practices that can vary substantially across countries and among institutions. Transparent biosafety and biosecurity oversight by funders can create an important layer of defense to reduce the risk that research is conducted in institutions with inadequate biosafety and biosecurity competence and also holds the potential to incentivize the implementation of consistent, globally-recognized best practices.

2. **Substantial variations in biosafety and biosecurity policies, regulations, practices, and competencies where CEPI-funded research takes place, and insufficient health and security collaboration.** The Global Health Security Index reveals that fewer than 6% of countries around the world provide oversight of dual use research, and there is a patchwork of national, regional, and global norms, guidance, and standards governing laboratory biosafety and biosecurity. This is exacerbated by a common siloing between the health and security policy, implementation, and financing communities, whereby biosafety and biosecurity are responsibilities for many but priorities for none. Following the COVID-19 pandemic, many countries are increasingly investing in the creation of high-performance lab infrastructure (including at the biosafety level 3 and above); however, varying approaches to managing and maintaining these laboratories in the long-term represents a

key vulnerability. As well as research institutions, attention is also needed at manufacturing facilities, where inadequate biosafety and biosecurity can also have significant potential impacts. The global R&D&M community, including CEPI, would benefit from clarity on criteria and performance monitoring approaches that can be applied to ensure that biological laboratories, across the One Health spectrum, are able to conduct their work in a safe, secure, and responsible manner.

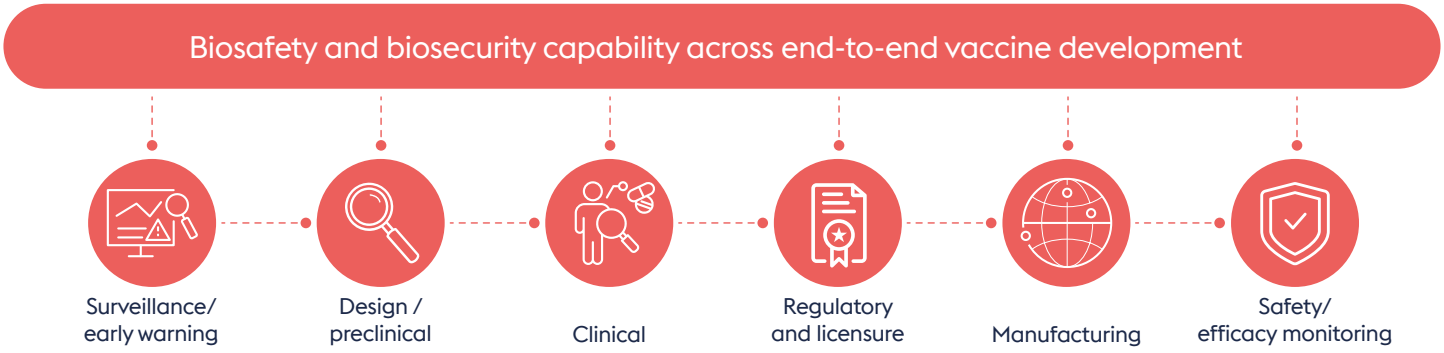


3. **The intersection between biosecurity and equity is insufficiently recognized, which threatens progress towards the 100DM and future responses to epidemic and pandemic threats.** Identifying and utilizing clear, objective, and transparent biosafety and biosecurity criteria can level the playing field for broad international scientific collaboration on vaccine R&D&M, including between the global North and South. As a research funder, with equity as a core mission, CEPI is well-positioned to incentivize the application of consistent, globally-recognized biosafety and biosecurity norms, principles, and best practices for research involving high consequence pathogens while working to build biosecurity and biosafety capabilities in low- and middle-income countries (LMICs). This can help accelerate diverse, equitable, and merit-based participation across the vaccine R&D&M continuum, foster broader adherence to biosafety and biosecurity guidance from WHO and global stakeholders, and drive equitable development of vaccine products, platforms, and capabilities. Global scientific participation is critical to the success of the 100DM and will enable vaccine R&D&M to take place in communities that need it, led by communities that need it, and informed by priorities of the vulnerable communities that are disproportionately impacted by epidemics and pandemics. Funders of life science research need a way to ensure that biosecurity and biosafety requirements do not inadvertently create barriers for responsible scientists in low-resource settings to participate in cutting-edge research. Furthermore, this is an under-explored area of intersection, and there is no unifying vision for a cost and accountability sharing structure for biosecurity and biosafety that has equity at its heart and demonstrates the cross-sectoral responsibility that these efforts require.

4. **Emerging biotechnology and converging technologies present dynamic and evolving biosecurity risks that threaten 100DM progres.** The rapid pace of innovation in fields such as synthetic biology and AI present unprecedented opportunities for vaccine and biologic development, but also introduces new avenues for accidents and deliberate misuse. As technological capabilities evolve and boundaries blur between disciplines, traditional approaches to biosafety and biosecurity may prove inadequate in addressing emerging threats. It is imperative for stakeholders across civil society, industry, and government to collaborate closely, anticipate potential risks, and develop agile response mechanisms to promote responsible use in ways that appropriately balance risks and benefits. Global dialogues around balancing emerging and converging biosecurity benefits and risks – and trade-offs associated with various mitigation approaches - tend to take place with insufficient global representation, which is vital to building a more resilient and equitable preparedness ecosystem.

5. **The world is insufficiently harnessing technological innovation to reduce safety and security vulnerabilities of the 100DM.** Despite the rapid advancement of technology across domains, there remains a significant gap in integrating these innovations into comprehensive strategies aimed at enhancing biosafety and biosecurity. Key challenges include fragmented information sharing (including of evidence-based outcomes), inadequate interoperability, and limited adoption of emerging technologies for real-time monitoring and response. To address these shortcomings, a concerted effort is needed to leverage cutting edge technological solutions such as AI and predictive analytics to bolster safety and security risk management in support of the 100DM. Innovation may also take more mundane but equally impactful forms, such as creative new approaches to process or design challenges that could still have a significant impact on R&D&M biosafety and biosecurity. By catalyzing cooperation among stakeholders, investing in R&D, and prioritizing the integration of innovative technologies into existing frameworks, we can strengthen the global health and security ecosystems, thereby enhancing our ability to mitigate risks and accelerate global progress toward 100DM goals.

Figure 2: Biosecurity and Biosafety capabilities are critical to achieving the 100 Days Mission safely and securely, required during every stage of the end-to-end vaccine development cycle, during both preparedness and response.



CEPI Biosecurity Focus and Priorities

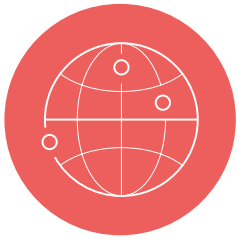
In support of CEPI's vision for "a world in which epidemics and pandemics are no longer a threat to humanity", and its organizational mission and the CEPI 2.0 strategy, CEPI's biosecurity focus is to "**protect society from epidemic and pandemic threats, with an emphasis on preventing accidental and deliberate misuse of pathogens associated with CEPI-sponsored research.**" To this end, the biosecurity strategy addresses global biosecurity vulnerabilities to accelerate CEPI's current strategic goals and in areas aligned with CEPI's mission and mandate (Figure 3).

Informed by identified vulnerabilities, CEPI biosecurity priorities are to:

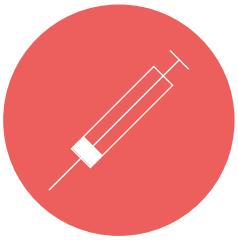
1. **Strengthen biosafety and biosecurity risk identification, mitigation, and oversight by CEPI and encourage similar efforts by other life science research funders.** To maximize current pathogen-specific and pathogen-agnostic vaccine R&D&M investments, CEPI will strengthen its internal risk frameworks and oversight processes across the R&D&M continuum (e.g., from sample acquisition/sharing through research, development, and manufacturing) to support funding decision-making (i.e., pre-award) as well as research monitoring and evaluation frameworks (i.e., post-award). CEPI will leverage its unique role in the global health ecosystem to catalyze action by other funding partners to prioritize biosafety and biosecurity and encourage other funders, for example, to become Bio Funders Compact signatories and participants in the Bio Funders Forum, and take concrete steps to strengthen and coordinate biosafety and biosecurity risk mitigation and oversight.

2. **Enhance global biosafety and biosecurity capabilities of CEPI partners for achieving the 100DM safely and securely, and promote health-security partnerships.** CEPI is in a unique position to cultivate broader health-security partnerships and collaborations and catalyse the two sectors to leverage joint capabilities to respond to outbreaks no matter their origin. CEPI is also uniquely positioned to accelerate global adoption of internationally-recognized standards and related approaches to reducing biosafety and biosecurity vulnerabilities. To forge common approaches to vaccine pre-clinical development, clinical testing, and manufacturing, CEPI has established geographically diverse lab networks, including the Animal Model Network, Centralized Lab Network, and Manufacturing Network. With an emphasis on these networks, CEPI can accelerate common global biosafety and biosecurity approaches, including for adoption of performance-based standards like ISO 35001 and strengthening bioincident identification at high performance laboratories to support biosafety and biosecurity risk management performance monitoring. CEPI can also partner with key regional leaders to build biosecurity and biosafety capacities, including under the renewed CEPI Memorandum of Understanding with the Africa Centres for Disease Control and Prevention.

3. **Drive biosecurity and biosafety in support of equity.** CEPI and partners are expanding global R&D&M efforts, so that research is done in communities that need it, for communities that need it, with more equitably shared economic, health, and development benefits – an imperative for science that is inclusive and relevant for all. In partnership with a broad range of stakeholders, including from scientific communities in LMICs, CEPI can identify and encourage development of, as appropriate, clear, objective, and transparent biosafety and biosecurity criteria for scientific participation, to level the playing field for broad and equitable international collaboration during public health emergencies and in support of the 100DM. CEPI will support its laboratory network partners in implementation, so new expectations do not create barriers to partnership or collaboration. CEPI can also use its funding, networks, and access to mobilise under-represented voices in global biosecurity engagement, and support development of enduring biosafety and biosecurity capabilities. CEPI recognizes that there are many ways to think about the nexus between biosecurity and equity and will bring together experts to explore how to clearly articulate the intersection and shifts required, concrete areas to drive progress, and nurture a community of advocates who are aligned in thinking on bolstering biosafety and biosecurity capacity to produce a more equitable global preparedness and response ecosystem. Equity is also embedded throughout the other biosecurity strategy priorities, which will focus on ensuring CEPI enables global scientific collaboration and considers how to reduce emerging risks and accelerate innovations across resource contexts and alongside partners.

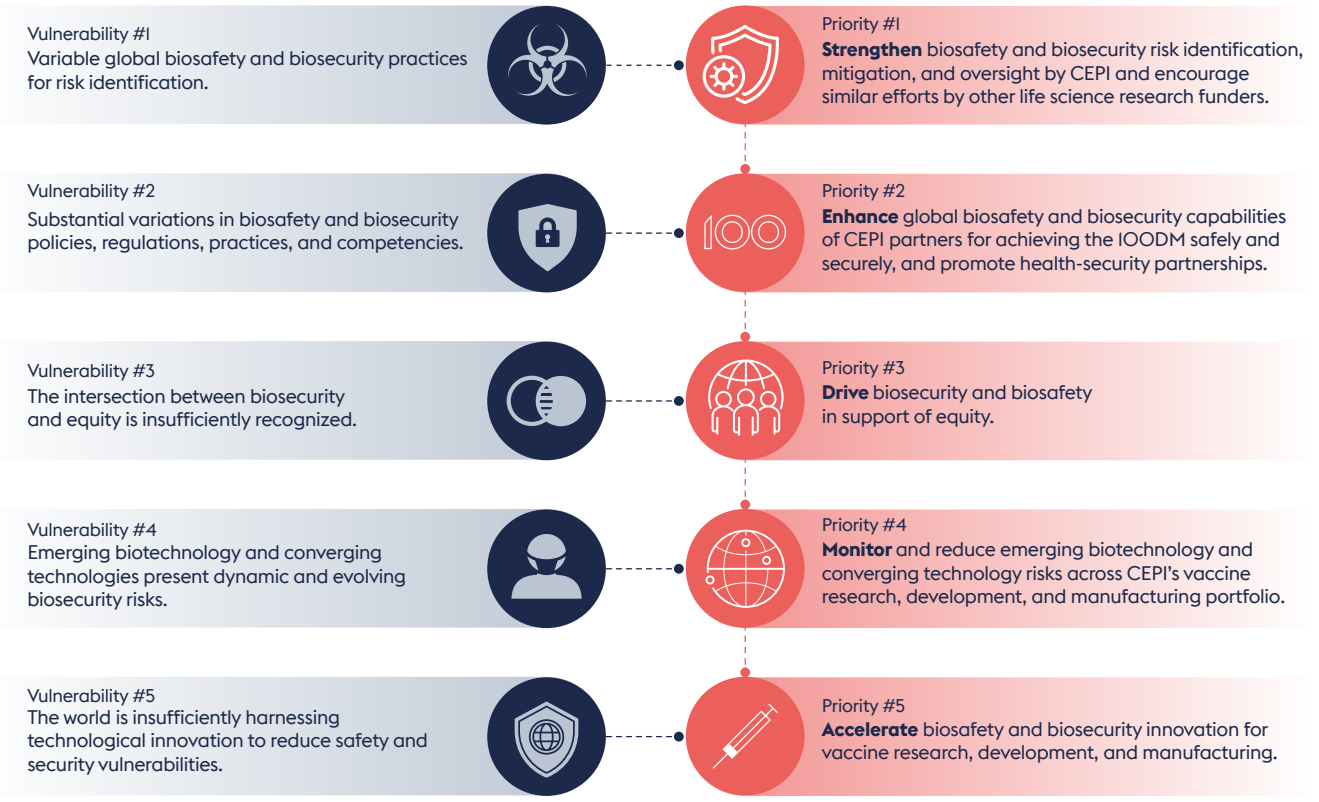


4. **Monitor and reduce emerging biotechnology and converging technology risks across CEPI's vaccine research, development, and manufacturing portfolio.** CEPI has a critical responsibility as a funder of research involving high consequence pathogens to continuously monitor advancements in biotechnology and converging technologies, identify potential biosafety and biosecurity risks, and develop and implement proactive mitigation strategies across its research portfolio that balances benefits and risks. CEPI is uniquely positioned to raise awareness regarding new and emerging technology risks in vaccine R&D&M and develop and implement new mitigation approaches for technologies like AI and in areas like bio-cybersecurity to reduce biosecurity risks and drive safe and secure progress to achieve 100DM goals.



5. **Accelerate biosafety and biosecurity innovation for vaccine research, development, and manufacturing.** CEPI is uniquely positioned to catalyse the innovator community in this area. Through targeted funding opportunities in coordination with our research funders and venture firms as well as sharing of evidence and outcomes, CEPI can drive the development of safer and more secure vaccine R&D&M technologies and approaches and facilitate uptake and adoption by R&D&M facilities. For example, as platform technologies are largely pathogen agnostic, they represent an opportunity for widely applicable biosecurity innovation, including new approaches that would be applicable to vaccine development for disease X. Recently, CEPI demonstrated its global leadership capacity in this area by working in concert with scientific and security partners to articulate principles to guide responsible AI development for vaccine design. These innovations could catalyze new approaches to biosafety and biosecurity risk management that springboard institutions across the Global South and North to the forefront of responsible, safe and secure cutting-edge R&D, in support of CEPI's equity vision.

Figure 3: CEPI's biosecurity focus is to protect society from epidemic and pandemic threats, with an emphasis on preventing accidental and deliberate misuse of pathogens associated with CEPI-sponsored research. CEPI identified global biosecurity vulnerabilities that are relevant to CEPI's mission, and used those to develop the five priorities of its biosecurity strategy.



The Way Forward

Following the publication of this strategy CEPI will develop and publish an implementation plan to describe our planned activities, goals and timelines in greater detail. This will include how CEPI's biosafety and biosecurity priorities will be integrated into CEPI's mission and mandate and CEPI's existing vaccine R&D&M activities to provide a sustainable set of capabilities. These will likely fall into three major categories of effort:

- **Catalyzing strategic partnerships and coalitions.**CEPI's position within the global R&D&M landscape has led to significant partnerships with governmental, non-governmental and other entities across the world, which can be leveraged to advance biosecurity and biosafety objectives, as well as ensure our efforts are complementary to those of existing organisations acting in this space. As an example, CEPI renewed a Memorandum of Understanding with the Africa CDC, which includes a plan for collaborative activities. Biosecurity has been included as a core thematic activity linked to laboratory capacity strengthening and also touching on shared priorities such as innovation and emerging technologies. CEPI has also concluded a partnership agreement with the Munich Security Conference, CEPI's first security-focused partnership to advance the 100DM safely and securely.

- **Advocacy and coordination:** CEPI's status as a large, independent, and international research funder provides substantial leverage to fund, convene, and facilitate activities that reduce global biosafety and biosecurity vulnerabilities and promote safe and secure vaccine R&D&M in support of the 100DM. For example, CEPI and Global Affairs Canada hosted a panel discussion on biosafety and biosecurity performance-based standards at the 2024 Global Health Security Conference in Sydney, which is catalyzing development of a roadmap to make it easier for interested institutions to implement ISO 35001, the world's only internationally recognized performance-based standard for biosafety and biosecurity.

- **Supporting biosafety and biosecurity capabilities development:** In addition to thought leadership and policy influence in the realm of biosecurity, CEPI could make direct investments in biosafety and biosecurity operations and implementation that harmonize global biosecurity practices and boost biosecurity capabilities globally. Through targeted support to CEPI lab networks and other CEPI-sponsored R&D&M partners, CEPI can accelerate global implementation of performance-based standards for laboratory biosafety and biosecurity, support applied implementation research for biosecurity innovation and biosafety and biosecurity performance monitoring, and strengthen coordination and capacity for biosecurity in support of vaccine equity.

CEPI

With thanks to CEPI's Biosecurity Strategy Group of external advisors

ELIZABETH CAMERON

Professor of the Practices of Health Services, Policy and Practice, Brown University

UNA JAKOB

Head of Research Group, Biological and Chemical Weapons Control, Peace Research Institute Frankfurt (PRIF)

PIERS MILLETT

Executive Director, International Biosafety and Biosecurity Initiative for Science

LYNDA STUART

Executive Director Institute of Protein Design, University of Washington

WEIWEN ZHENG

Baiyang, Professor and Director, Tianjin University Center for Biosafety Research and Strategy

NIVEDITA GUPTA

Head of Virology, Indian Council for Medical research

CLAUDIO MAFRA

Chair, International Federation of Biosafety Associations; President, Brazilian Biosafety and Biosecurity Society

TREVOR SMITH

Senior Program Manager, WMD Threat Reduction Program, Global Affairs Canada

YENEW KEBEDE TEBEJE

Head, Division of Laboratory Systems and Networks, Africa CDC