

# **NTI**:bio

# BIOSECURITY INNOVATION & RISK REDUCTION INITIATIVE

A Global Initiative to Reduce Biological Risks Associated with Advances in Technology

# **VISION STATEMENT**

Rapid advances in genomics, synthetic biology, and microbiology will prove essential to achieving a safer and more secure society. However, the convergence of disciplines and the accelerated development and dissemination of novel biological **tools** to create and modify biological **agents** or produce new materials that affect living **systems** will also pose new risks of accidents or deliberate misuse. These factors could lead to high-consequence events with a grave impact on the human population. We are unable to predict all the positive and negative consequences of these technical advances, and they have in many instances outpaced effective governmental oversight. These trends suggest a future in which society is more dependent on biotechnology and increasingly susceptible to misuse and unintended consequences resulting from these tools and widespread access to them.

We commit ourselves to urgently catalyze a new norm of evaluating, reducing, and — where possible eliminating risks before new biotechnology innovations are funded, developed, and disseminated. We will foster and publish a set of targeted international actions that can be taken by non-governmental stakeholders to reduce biological risks, and we commit to lead global action to facilitate their adoption and implementation.

We will consider our shared responsibility for reducing risks as we strive toward a safer and more secure pursuit of biotechnology innovation to benefit society.

# BIOSECURITY INNOVATION & RISK REDUCTION INITIATIVE

## A Global Initiative to Reduce Biological Risks Associated with Advances in Technology

Since the 1975 Asilomar Conference on Recombinant DNA and the entry into force of the Biological and Toxins Weapons Convention that same year, stakeholders have been debating mechanisms to maximize societal benefits and mitigate societal risks posed by life sciences research. However, despite continued debate and some progress in developing national policies for oversight, there are still no universally adopted norms for reducing biological risks associated with advances in technology.

Biotechnologies and biological systems pose unique risks because they may include selfreplicating systems, can adapt and grow beyond the original vision of well-intentioned actors, and can have multi-generational and population-wide effects. Therefore, intentional misuse, accidents, and experiments with unintended consequences in the life sciences can have an out-sized impact on humanity.

Taking these factors into account, recent discussions during the United Nations General Assembly, the World Economic Forum Annual Meeting (known as Davos Forum),<sup>1</sup> and the Munich Security Conference<sup>2</sup> have underscored an urgency to develop creative and stakeholder-driven approaches to reduce biological risks. Advances in the life sciences are outpacing the ability of governments to provide effective oversight, and national governments vary widely in their ability to anticipate and mitigate emerging biological risks. This results in an uneven patchwork of security and safety practices across facilities, countries, and regions. Such a lack of comprehensive, coordinated governance creates a pressing need for stakeholders — including academic and private stakeholders who conduct, fund, and publish research as well as those who develop new technologies and insure against risk — to take greater responsibility for identifying risks and taking concrete steps to mitigate them.

The Biosecurity Innovation and Risk Reduction Initiative will engage global field leaders from different sectors — including genomics, synthetic biology, microbiology, security, bioethics, insurance, and science publishing — to develop, promulgate, and incentivize global normative actions that can be rapidly taken to enhance biosecurity innovation, reduce biological risks associated with advances in technology, and, ultimately, protect against harm.

# **GUIDING PRINCIPLES**

The Biosecurity Innovation and Risk Reduction Initiative seeks to identify and develop normative actions and novel approaches that can reduce biological risks, as well as strategies for their global adoption and implementation. The Initiative also seeks commitments from and engagement with additional scientific leaders and experts around the world from the private sector, educational institutions, scientific organizations, and governments. The desired outcome of the Initiative is safer, more secure biotechnology innovations that realize the promise of scientific advances but minimize risks of a deliberate or accidental high-consequence biological event.

Currently, only a handful of countries have adopted legislation or regulations to provide oversight for dual use research. In many cases existing national policies are voluntary and not always inclusive of the private sector. Moreover, there are few incentives and financial resources for scientists and engineers throughout academia and industry to integrate biosecurity into novel tools and technologies. This leaves technical experts, biosecurity leaders, and the general public in a position of reacting to emerging risks rather than proactively designing risk mitigation and/or approaches that incorporate "biosecurity by design" as an integral component of technological advance.

### As guiding principles, the Initiative:

- Promotes safe and secure biosecurity innovation when developing new biotechnologies and embarking on novel life science research, while protecting against harm caused by known or unintended risks.
- Acknowledges there is an urgent need for global commitment to understand and reduce biological risks at all stages (e.g., funding, research, publication) and across all sectors (i.e., academic, commercial, and governmental).
- Seeks to develop a set of targeted international actions that can be advanced by non-governmental stakeholders to reduce biological risks.<sup>3</sup>
- Commits to leading global action toward the publication, adoption, and implementation of these targeted actions.

The desired outcome of the Initiative is safer, more secure biotechnology innovations that realize the promise of scientific advances but minimize risks of a deliberate or accidental high-consequence biological event.

# FOCUS AREAS FOR THE BIOSECURITY **INNOVATION AND RISK REDUCTION INITIATIVE**

To safely and securely realize the promise of continued advances in genomics, synthetic biology, and microbiology, the Biosecurity Innovation and Risk Reduction Initiative will explore a series of global actions. These actions will include contributions to standardizing safe and secure approaches for innovation that incorporate responsible risk identification and evaluation during the technology conceptualization and design of research, technology, and experiments. The end goal for every Initiative concept is the same: mitigate or avoid risks and potential misuse of biotechnology.

#### The Initiative will focus on central norms and actions, including but not limited to:

- Developing and adopting novel financial incentives for biosecurity and biosafety practices and procedures, including both private- and public-sector investors.
- Promoting funding for and investments in technological innovations that emphasize biosecurity by design throughout the research and development lifecycle.
- Improving processes and procedures for evaluating and mitigating biosecurity risk in biological research, development, and commercialization.
- Strengthening and expanding the use of globally accessible tools and techniques to mitigate the potential risks associated with advances in technology.

- Convening disparate technical communities to survey the risk landscape and build consensus on the best ways to continually evaluate emerging risks associated with biotechnology research and development.
- Investigating models and global peerenforced oversight/governance mechanisms to create consistent biosecurity practices around the world.
- Identifying and testing mechanisms to propagate international norms and pilot proposed solutions as proofs of concept.

# **PUBLIC & PRIVATE OUTREACH**

As a core component of the Initiative, NTI seeks to develop an engagement strategy for public discussion. For example, through the Initiative, NTI will socialize concrete ideas for risk mitigation globally with the general public, which remains the steward of biotechnology research and the funding toward it. NTI anticipates the Initiative will also catalyze consultations with the Office of the United Nations Secretary General to develop a plan for a high-level meeting to consider additional pathways to global implementation, involve additional stakeholders, and motivate specific and positive actions to mitigate risk and maximize benefit of future technological advances.

#### Areas of exploration:

- A universal platform to prevent illicit gene synthesis
- Financial incentives for biotechnology investors to improve biosecuri
- Standards for funders and grantees to identify and mitigate biological risks
- Seals of approval for experts and institutions who adhere to biosecurit best practices
- Insurance incentives for reducing biological risks

## **INITIATIVE MEMBERS**

#### Yuhai Bi

Director of Technology Platform for Influenza Virus Research, Chinese Academy of Sciences

#### **Elizabeth Bohm**

Head of International. The Academy of Medical Sciences, United Kingdom

#### **Christian Bréchot**

President, Global Virus Network

#### Patrick Cai

Chair in Synthetic Genomics, University of Manchester, United Kingdom

#### Vanessa Candeias

Head of Global Health and Healthcare System Initiative, World Economic Forum<sup>+</sup>

#### Ash Carter

Director, Belfer Center for Science and International Affairs, Harvard Kennedy School, United States

R. Alta Charo

Warren P. Knowles Professor of Law and Bioethics, University of Wisconsin–Madison, United States

#### **Aaron Ciechanover**

Faculty of Medicine, Technion-Israel Institute of Technology, Israel

#### **Monique Eloit**

Director General, World Organisation for Animal Health

**Jeremy Farrar** Director, Wellcome Trust+

**Douglas Friedman** Executive Director, Engineering Biology Research Consortium

**Tedros Adhanom Ghebreyesus** Director-General, World Health Organization

Margaret A. Hamburg Foreign Secretary, National Academy of Medicine, United States

#### **Christian Happi**

Professor, Department of Biological Sciences, Redeemers' University, Nigeria Visiting Scientist, Harvard T.H. Chan School of Public Health, United States

#### **Richard Hatchett**

Chief Executive Officer, Coalition for Epidemic Preparedness Innovations<sup>+</sup>

#### **Aamer Ikram**

Executive Director, National Institute of Health, Pakistan

#### Wilmot James

Visiting Professor of (non-clinical) Pediatrics and International Affairs, Columbia University, United States

Tom Kariuki Director of Programmes,

## Sang Yup Lee

Dean, Korea Advanced Institute of Science and Technology, Republic of Korea

### Raymond Lin

Head & Senior Consultant, Microbiology Division, National University Health System, Singapore

## CHALLENGES IN GLOBAL BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

OPEN, ACCESSIBLE SYSTEM	<ul> <li>Life scientists and synthetic biologists place a premium on open data sharing, open access to new biological systems and materials, and open publication of methods and results.</li> </ul>
DIVERSE STAKEHOLDERS	<ul> <li>The number of actors and disciplines with a direct stake in biotechnology advances has increased as the bioeconomy has grown, DNA synthesis and gene editing have become commonplace, and synthetic biology has become more widespread.</li> </ul>
FRAGMENTED, LIMITED LEGAL OVERSIGHT	<ul> <li>Only a handful of countries have adopted oversight for dual use research, including research to re-create, enhance virulence, or increase transmissibility of infectious disease agents.</li> <li>Existing national policies are largely voluntary, not always inclusive of the private sector, and disparately applied.</li> </ul>
BIOSECURITY INNOVATION DOORLY INCENTIVIZED	<ul> <li>The field of biosecurity still exists largely among policymakers.</li> </ul>
	• There are minimal incentives for scientists and engineers, including those in the private sector, to develop innovative technical solutions to biosecurity challenges.
	<ul> <li>No universally adopted global oversight mechanisms or bodies exist to provide guidance or set norms for life sciences dual use research.</li> </ul>
	• There are not yet common biosecurity norms among public and private sector creators of biotechnology products.
	<ul> <li>International organizations do not require specific oversight mechanisms for research — or centers conducting research — that could enhance transmissibility or virulence of pathogens that have pandemic potential.</li> </ul>
	<ul> <li>Existing international mechanisms focus on misuse of established technologies but do not include oversight or risk-benefit analysis to determine whether research should or should not be performed — and, if so, how to mitigate associated risks in real-time.</li> </ul>
	<ul> <li>Publication of dual use life sciences research is addressed on a case-by-case basis.</li> </ul>
	• Existing global norms for screening DNA orders and customers may be outdated and are not universally applied.
LACK OF RISK REDUCTION RESOURCES	• There is a lack of financial resources to support new forms of self-governance and technological innovation that reduce biological risks.

African Academy of Sciences

#### Volker ter Meulen

Immediate Past President, InterAcademy Partnership

#### Anne Meyer

Associate Professor of Biology, University of Rochester, United States

#### **Piers Millett**

Vice President of Safety and Security, iGEM Foundation<sup>+</sup>

#### Ernest J. Moniz

Co-Chair and Chief Executive Officer, Nuclear Threat Initiative (NTI)

#### **Indira Nath**

Former Head of Department of Biotechnology, All India Institute of Medical Sciences

#### Sergey Netesov Head of Bionanotechnology

Laboratory, Novosibirsk State University, Russia

#### **Amadou Sall**

Director of Institute, Institut Pasteur in Dakar, Senegal

#### **Pamela Silver**

Elliot T. and Onie H. Adams Professor of Biochemistry and Systems Biology, Harvard Medical School, United States

#### Magdalena Skipper Editor-in-Chief, Nature

**Rakesh Sood** Distinguished Fellow, Observer Research Foundation, India

#### Herawati Sudoyo Deputy for Fundamental Research, Eijkman Institute, Indonesia

## Hans-Joachim Wieden

Professor of Chemistry and Biochemistry, University of Lethbridge, Canada

#### **+ADVISING ORGANIZATIONS**

Wellcome Trust

World Economic Forum

**Coalition for Epidemics Preparedness Innovations** 

International Genetically **Engineered Machine Foundation** 

Members of the NTI Biosecurity Innovation and Risk Reduction Initiative participate in their personal capacities or in their capacities as representatives of advising organizations. The opinions expressed here and the actions supported by the Initiative do not necessarily reflect the views of their respective employers, other affiliations, or governments.

- <sup>1</sup>Klaus Schwab, "The Fourth Industrial Revolution: What It Means, How to Respond," *World Economic Forum* (January 14, 2016), https://www.weforum.org/agenda/2016/01/the-fourth-industrial-revolution-what-it-means-and-how-to-respond/.
- <sup>2</sup> Janosch Delcker, "Risk of Bioweapon Attack Growing, Dutch Defense Minister Says," *Politico* (February 18, 2018), https://www.politico.eu/article/ank-bijleveld-bioweapon-risk-attack-growing-dutch-defense-minister-says/; and Bill Gates, "Speech by Bill Gates at the 53rd Munich Security Conference" (speech, Munich, Germany, February 18, 2017), Munich Security Conference, https://www.securityconference.de/en/activities/ munich-security-conference/msc-2017/speeches/speech-by-bill-gates/.
- <sup>3</sup> Initiative normative actions will be designed for non-governmental advance but be made flexible for governments seeking to address the current lack of governance and effective national policy frameworks.

## About the Nuclear Threat Initiative

The Nuclear Threat Initiative works to protect our lives, environment, and quality of life now and for future generations. We work to prevent catastrophic attacks with weapons of mass destruction and disruption (WMDD) nuclear, biological, radiological, chemical, and cyber.



NTI:bio

1776 Eye Street NW, Suite 600 • Washington, DC 20006

#### WWW.NTI.ORG/BIO