



The following paper is intended for the purposes of framing constructive discussion during the June 20-21, 2018 meeting on biological risk hosted by the Wellcome Trust, NTI, and the World Economic Forum in London. We look forward to your participation.

INTRODUCTION

Since the 1975 Asilomar Conference on Recombinant DNA¹ and the entry into force of the Biological and Toxins Weapons Convention (BTWC) that same year, stakeholders have been debating mechanisms to maximize societal benefits and mitigate societal risks posed by life sciences research. In 2018, despite continued debate and some progress in developing national policies for oversight of life sciences dual use research (largely in the United States and Europe), **there are still no globally accepted or adopted norms² for reducing biological risks associated with advances in technology.**

Recent discussions during the United Nations General Assembly, the Davos World Economic Forum³, and the Munich Security Conference^{4,5} have underscored the urgency to develop creative and stakeholder-driven approaches to reduce biological risks. The purpose of our June 20-21 meeting in London is to convene stakeholders – including leaders and experts in genomics, virology, synthetic biology, security, bioethics, insurance, and science publishing – to identify short and medium-term actions that can be taken to spur both biosecurity innovation and risk reduction.

The world in which we find ourselves

Promise. Rapid advances in biotechnology hold the promise of a future that is resilient to disease, food insecurity, and environmental instability. There is no doubt that advances in genomics, synthetic biology, and virology will continue to prove essential to achieve a safer and more secure society.

Peril. On the other hand, global and democratizing trends in travel, trade, terrorism, and technology are increasing the risk of a deliberate or accidental high consequence biological event. Advances in technology, cheaper DNA synthesis⁶, and widespread access to gene editing tools have made it possible for a wider array of actors to manipulate biological agents and systems. In addition, scientific advances are outpacing the ability of national governments to provide effective oversight, **increasing the relevance of governance by the technical community itself.** New technologies – and the widespread availability

MEETING PURPOSE

From June 20-21 in London: NTI, Wellcome Trust, and the World Economic Forum will convene stakeholders – including leaders and experts in genomics, virology, synthetic biology, security, bioethics, insurance, and science publishing – to identify short and medium-term actions that can be taken to both spur biosecurity innovation and reduce biological risks.

¹ P. Berg et al., "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules.," *Proceedings of the National Academy of Sciences* 72, no. 6 (1975): 1981-1984, <https://authors.library.caltech.edu/11971/1/BERpnas75.pdf>.

² There is general agreement on the definition of a norm as a standard of appropriate behavior for actors with a given identity. See Martha Finnemore and Kathryn Sikkink, "International Norm Dynamics and Political Change." *International Organization* 52, no. 4 (1998): 887-917. <http://www.jstor.org/stable/2601361>.

³ 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/>.

⁴ 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/>.

⁵ 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/>.

⁶ Gigi Kwik Gronvall, *Synthetic Biology: Safety, Security, and Promise* (Health Security Press, 2016), 8.

of them – will make it easier for state and non-state actors to make, modify, and enhance infectious agents, harm agricultural assets, and target people and infrastructure. Wider use of living systems for product development may also increase the risk of an accidental release of agents or materials that could cause harm to people, food sources, or the environment. Yet, very few resources are currently invested in considering concrete mechanisms to identify and curb these biological risks, in real-time, at the same time new technologies are developed.⁷

Biosecurity and Innovation – A Fraught Relationship. In 2004, following the 2001 anthrax attacks in the United States and controversial experiments in Australia with mousepox virus⁸, the U.S. National Academies of Science released the report, “Biotechnology Research in the Age of Terrorism⁹.” The “Fink Report,” so named for Dr. Gerald Fink who chaired it, this seminal report outlined seven specific life sciences experiments of greatest concern for misuse¹⁰ and called for the international policymaking and technical communities to create an international forum focused on biosecurity, “...to develop and promote harmonized national, regional, and international measures...” But, nearly 15 years later, no internationally accepted forum or harmonized norms exist for identifying and reducing biological risks.

There is broad societal consensus that the risk of an intentional or accidental high-consequence biological event has increased over the past decade. However, there is still significant disagreement about the level of that risk and whether it can be effectively mitigated without exacting too high a price on the societal promise of life sciences research. **This lack of consensus may have stymied the development and adoption of international norms and concrete, globally applicable actions to mitigate urgent risks.** And, since stakeholders can’t agree on what constitutes “risky” biological research, there are no consistent national or peer-reviewed accountability mechanisms for scientists who conduct experiments at the cutting edge of both “promise” and “peril”. In addition, there are not defined economic and policy drivers to incentivize a field of study dedicated to creating safer and more secure biotechnology.

Our Hypothesis. Governmental oversight will continue to lag behind biotechnology breakthroughs. Therefore, it is the academic and private stakeholders who conduct, fund, and publish research – as well as those who develop new technologies and insure against risk – who must take greater responsibility for risk identification and concrete steps to mitigate risk. As part of this responsibility, they should also play a key role in developing and incentivizing the adoption of international norms for biological risks associated with advances in technology.

The time is now. While recombinant DNA technology has been available since the early 1970s, the recent synthesis of horsepox virus by Canadian scientists¹¹, with only a reported \$100,000 in funding from a private U.S. biotechnology company, has raised fresh questions about international norms for life sciences research. The principal investigator for this experiment is a member of the World Health Organization

YOUR MISSION

In London from June 20-21, you will explore:

1. The different stakeholders who should be engaged in developing norms and actions to mitigate current and future biological risks.
2. The feasibility of publishing a set of international norms to guide technical experts across different sectors (e.g. genomics, virology, synthetic biology).
3. The potential to develop a suite of concrete, practical, stakeholder-driven actions that might be considered by different relevant sectors to urgently reduce risk and establish norms.

⁷ Todd Kuiken, “U.S. Trends in Synthetic Biology Research Funding,” *Wilson Center*, September 15, 2015, <https://www.wilsoncenter.org/publication/us-trends-synthetic-biology-research-funding>.

⁸ William J. Broad, “Australians Create a Deadly Mouse Virus,” *The New York Times*, January 23, 2001, <https://www.nytimes.com/2001/01/23/world/australians-create-a-deadly-mouse-virus.html>.

⁹ U.S. National Academies National Research Council, “Biotechnology Research in an Age of Terrorism,” *The National Academies Press*, 2004, <https://doi.org/10.17226/10827>.

¹⁰ U.S. National Academies National Research Council, “Fink report’s seven classes of experiments,” *The National Academies Press*, 2004, https://www.ncbi.nlm.nih.gov/books/NBK305030/box/ch2_box7/?report=objectonly.

¹¹ Kai Kupferschmidt, “A paper showing how to make a smallpox cousin just got published. Critics wonder why,” *Science*, January 19, 2018, www.sciencemag.org/news/2018/01/paper-showing-how-make-smallpox-cousin-just-got-published-critics-wonder-why.

(WHO) Advisory Committee on Variola Virus Research that oversees research on the virus that causes smallpox, and his work has raised the specter of a world in which smallpox (eradicated in 1980) can be created from scratch¹². In the wake of this experiment, many have argued that the time is now to set stronger boundaries.

The Situation as We Find It	
System attributes	Open, democratized, and distributed system. <ul style="list-style-type: none"> 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.
Stakeholders	Wide array of stakeholders. <ul style="list-style-type: none"> 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.
Legal oversight	Fragmented, applies in only a handful of countries. <ul style="list-style-type: none"> Only a handful of countries have adopted legislation or regulations that provide oversight for dual use research, including research that would recreate, enhance virulence, or increase transmissibility of an infectious disease agent. Existing national policies are largely voluntary, not always inclusive of the private sector, and disparately applied.
Biosecurity Innovation	Not incentivized, private sector not sufficiently engaged. <ul style="list-style-type: none"> The field of biosecurity still exists largely among policymakers; scientists and engineers are not well-incentivized to develop innovative and technical solutions to biosecurity challenges.
Global Norms	No consensus on how to develop or adopt. <ul style="list-style-type: none"> No formal or informal global oversight mechanisms or bodies exist to provide guidance or set norms for new biotechnologies or life sciences dual use research. There are not yet common biosecurity and biosafety norms among those creating living systems for product development within the public or private sectors. 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. Publication of dual use life sciences research is addressed on an <i>ad hoc</i>, case-by-case basis. Existing global norms for screening DNA orders and customers may be outdated and are not universally applied.
Resources for Risk Reduction	Lacking. <ul style="list-style-type: none"> There is a lack of financial resources for biological risk reduction.¹³

¹² Ibid.

¹³ Kuiken, "U.S. Trends in Synthetic Biology Research Funding."

Norms Challenge #1

NORMS TO ADDRESS THE SYNTHESIS OF EXISTING, NOVEL, OR MODIFIED INFECTIOUS AGENTS

Stakeholders struggle to define both risks and merits associated with research that creates, modifies, or enhances transmissibility or virulence of infectious agents – particularly those with pandemic potential. While this debate continues, international experts have been stymied in their ability to define concrete, globally applicable norms and actions to reduce risks associated with this type of research.

The advent of faster and cheaper technologies for DNA synthesis led to the synthetic construction of poliovirus in 2002¹⁴ and the 1918 H1N1 influenza pandemic virus in 2005¹⁵. In 2012, research in the Netherlands and the United States to enhance the function of H5N1 avian influenza^{16,17} ignited fears over accidental or intentional release of a pandemic agent. And, in 2018, privately funded Canadian research to recreate the horsepox virus¹⁸ – a near neighbor of the virus causing smallpox – sparked new calls for research norms and public discussion about biological risk associated with advances in technology.

Each controversial experiment has ignited public interest in risk reduction, and some progress has been made. The U.S. has been particularly active in launching federal and institutional oversight requirements for federally funded Dual Use Research of Concern¹⁹ and recently enacting the first guidelines²⁰ for research that enhances the transmissibility and/or virulence of a pandemic agent.

However, existing national guidelines to oversee research or businesses that create and modify pathogens are fragmented, generally do not apply to research that is funded by the private sector, and do not adequately take into account the global and changing nature of life sciences research collaborations. Many countries place safety and security controls on dangerous infectious agents but do not provide guidelines for assessing the aims, outcomes, or risks of research experiments conducted to make, modify, or enhance transmissibility or virulence of them. Others recommend self-governance or provide guidance, but do not have laws or regulations in place.²¹ And others, like the United States, use the Fink Report's²² seven specific classes of experiments as a guide and then apply oversight requirements when those experiments are conducted with specific agents. But, there is no oversight mechanism that would require specific guidelines for facilities, including WHO collaborating centers, that create, modify, or enhance the transmissibility or virulence of infectious agents.

Food for thought:

Academic centers and genomics consortia could drive new norms by adopting safe and secure practices as requirements for all members.

Oversight models could be considered for organizations conducting research that enhances transmissibility or virulence.

Incentives from the private sector and funders could drive norms and concrete actions.

¹⁴ Ariella M. Rosengard, Yu Liu, Zhiping Nie, Robert Jimenez, "Variola virus immune evasion design: Expression of a highly efficient inhibitor of human complement," *Proceedings of the National Academy of Sciences* 99, no. 13 (2002): 8808-8813, accessed May 9 2018, <http://www.pnas.org/content/99/13/8808>.

¹⁵ Terrence M. Tumpey et al., "Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus," *Science* 310, no. 5745 (2005): 77-80, accessed May 9 2018, <https://www.ncbi.nlm.nih.gov/pubmed/16210530>.

¹⁶ Martin Enserink, "Scientists Brace for Media Storm Around Controversial Flu Studies," *Science*, November 23, 2011, www.sciencemag.org/news/2011/11/scientists-brace-media-storm-around-controversial-flu-studies.

¹⁷ Masaki Imai et al., "Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets," *Nature* 486, (2012): 420–428, accessed May 9 2018, <https://www.nature.com/articles/nature10831>.

¹⁸ Ryan S. Noyce, Seth Lederman, David H. Evans, "Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments," *Plos One*, January 19, 2018, <https://doi.org/10.1371/journal.pone.0188453>.

¹⁹ "Dual Use Research of Concern," *Science, Safety, Security*, accessed May 9, 2018, <https://www.phe.gov/s3/dualuse/Pages/default.aspx>.

²⁰ U.S. Department of Health and Human Services, "Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens," 2017, <https://www.phe.gov/s3/dualuse/Documents/p3co.pdf>.

²¹ Piers D Millett, "Gaps in the International Governance of Dual-Use Research of Concern," *National Academies*, January 17, 2017, https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pqa_176434.pdf

²² U.S. National Academies National Research Council, "Biotechnology Research in an Age of Terrorism."

As DNA synthesis has become common-place, more focus has been placed on screening orders and customers. DNA synthesis screening guidelines in the United States²³ and voluntary guidelines through the International Gene Synthesis Consortium (IGSC)²⁴ have been developed to guard against the creation of dangerous pathogens by nefarious actors. However, most countries do not require companies that operate within their territory to screen orders or customers.²⁵

Significant discord also remains among experts regarding the need for researchers to conduct certain types of experiments,²⁶ including those that could create new and more harmful agents. For example, some experts have argued that research that enhances the transmissibility or virulence of pandemic influenza virus is not necessary to make gains in countermeasure development, does not justify the potential risk²⁷, or should require oversight from an international (e.g. UN) body. Others have argued against limitations on peaceful life sciences research or its publication, whatever the potential involved risks.

Existing oversight models – such as prequalification of certain types of laboratories or the existing structure for oversight for smallpox research – could serve as a guide for research that would enhance virulence or transmissibility of other potentially pandemic agents.²⁸ Insurance models to incentivize norms and actions related to the synthesis or modification of infectious agents with pandemic potential could also be considered.²⁹ Reinsurers that focus on terrorism risk, including CBRN risk,^{30,31} as well as pandemic risk,³² should be involved in developing these options.

Norms Challenge #2

NORMS TO REDUCE RISKS POSED BY RAPID ADVANCES IN GENE EDITING AND SYNTHETIC BIOLOGY IN THE CONTEXT OF A GROWING BIOECONOMY

Synthetic biology, defined by the Engineering Biology Research Consortium as, “...the design and construction of new biological entities or the redesign of existing biological systems”³³, will continue to bring the tools of biotechnology to more people in more facilities. The use and modification of living systems to create new materials will certainly make a positive impact on people, agriculture, the environment, and infrastructure, but may simultaneously create both future opportunities for peace and security and new ways for state and non-state actors to cause harm.

Meanwhile, the bioeconomy^{34,35} has gone global. In 2014³⁶, the global bioeconomy was responsible for exports valued at 13% of world trade and societal benefits in energy, food production, health, and other sectors vital to sustainable development. China’s Minister of Health has pledged \$11.8 billion annually

²³ U.S. Department of Health and Human Services, “Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA,” Public Health Emergency, accessed May 9, 2018, <https://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/default.aspx>.

²⁴ “International Gene Synthesis Consortium,” International Gene Synthesis Consortium, accessed May 09, 2018, <https://genesynthesisconsortium.org/>.

²⁵ Gronvall, Synthetic Biology: Safety, Security, and Promise, 40.

²⁶ Marc Lipsitch and Thomas V. Inglesby, “Moratorium on Research Intended To Create Novel Potential Pandemic Pathogens,” *MBio* 5, no. 6 (2014), <http://mbio.asm.org/content/5/6/e02366-14.full>.

²⁷ Daniel J. Rozell, “Assessing and Managing the Risks of Potential Pandemic Pathogen Research,” *MBio* 6, no. 4 (2015): 1-4, <http://mbio.asm.org/content/6/4/e01075-15.full>.

²⁸ National Academies of Sciences, Engineering, and Medicine, “Gain-of-Function Research: Summary of the Second Symposium, March 10-11, 2016,” *The National Academies Press*, (2016): 59, <https://www.nap.edu/read/23484/chapter/5>.

²⁹ Sebastian Farquhar, Owen Cotton-Barratt, and Andrew Snyder-Beattie, “Pricing Externalities to Balance Public Risks and Benefits of Research.” *Health Security* 15, no. 4 (2017): 401-08, <https://www.liebertpub.com/doi/pdfplus/10.1089/hs.2016.0118>.

³⁰ “Pool Re Hails Government Action to Close the Terrorism Insurance Gap,” Pool Re insurance, March 22, 2018, , accessed May 09, 2018, <https://www.poolre.co.uk/pool-re-hails-government-action-close-terrorism-insurance-gap/>.

³¹ “Pool Re and the Nuclear Threat Initiative Highlight Radiological Material Security Efforts,” Nuclear Threat Initiative, April 5, 2017, <http://www.nti.org/newsroom/news/pool-re-and-nuclear-threat-initiative-highlight-radiological-material-security-efforts/>.

³² “Swiss Re Helps Establish the Pandemic Emergency Financing Facility,” Swiss Re, accessed May 09, 2018, http://www.swissre.com/global_partnerships/swiss_Re_helps_establish_the_pandemic_emergency_financing_facility.html.

³³ “What Is Synthetic Biology?” Engineering Biology Research Consortium, accessed May 09, 2018, <https://www.ebrc.org/what-is-synbio>.

³⁴ “What Is the Bioeconomy?” European Commission, accessed May 09, 2018, <https://ec.europa.eu/research/bioeconomy/index.cfm>.

³⁵ “National Bioeconomy Blueprint,” Obama White House, April 2012, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf.

³⁶ Beate El-Chichakli et al., “Policy: Five Cornerstones of a Global Bioeconomy,” *Nature* 535, no. 7611 (2016): 221-223, <https://www.nature.com/news/policy-five-cornerstones-of-a-global-bioeconomy-1.20228>.

toward biotechnology innovation from 2015-2020. India's bioeconomy was valued at greater than \$4 billion in 2013, and the European Union bio-based economy was reported to generate more than \$2 trillion and 17 million jobs. In many countries, including the U.S., UK, China, Singapore, and Denmark, bio "foundries" are being created³⁷ to develop new technologies and advance product development in living systems. New and global academic consortia have also developed around synthetic biology challenges.

Synthetic biology companies and citizen scientist collectives – such as the BioNet³⁸, which provides for free gene swapping – could serve as test-beds for norms development and for incentivizing, propagating, or requiring safe and secure practices as a requirement for admission. Funders can also create demands among researchers for safer and more secure actions and technologies. One recent example is the 2017 "Funding Principles for Sponsors and Supporters of Gene Drive Research³⁹," which brought together thirteen organizations and could serve as a model for other types of stakeholders to drive behavior across emerging areas of technology.

Food for thought:

Synthetic biology companies and academic consortia focused on synthetic biology challenges could develop and catalyze adoption of norms and actions to reduce risk among involved institutions.

Systems could be considered that would identify and mitigate risk at the same time new technologies are developed.

Incentives from the private sector and funders could drive norms and actions.

Norms Challenge #3

BIOSECURITY BY DESIGN – INCENTIVIZING A TECHNICAL DISCIPLINE TO REDUCE BIOLOGICAL RISK ASSOCIATED WITH ADVANCES IN TECHNOLOGY

With each major biotechnology breakthrough – such as the discovery and widespread use of advanced gene editing technology (e.g. CRISPR) or the development of gene drives⁴⁰ – there are new calls for national policies and governance to mitigate risk⁴¹. On the one hand, there are growing public and private concerns regarding emerging biological risks that need to be addressed. On the other hand, new standards – or even norms – that are only adopted in one country or region could drive risk (and technical advances) to emerging leaders and markets and away from countries that implement and enforce stringent oversight policies. These dynamics argue for stakeholder-driven risk reduction approaches that can cross borders.

One way to mitigate risk associated with advances in technology is to develop and incentivize technical solutions that decrease the likelihood that the technology could cause societal harm. In today's world, technical innovation targeted at improving security is a major business. However, unlike some other fields (such as cybersecurity) the field of biosecurity remains largely confined to discussions about policies and best practices – not technical solutions. Experts working with agents that are immediately hazardous to human or animal health are trained to implement safe and secure practices to protect materials and the people working with them. But, there is no real technical profession surrounding biosecurity, which would aim to develop safer and more secure technologies. Hacking competitions in the life sciences are generally designed to develop new modes of solving societal challenges – not safer and more secure ways of achieving those goals.

³⁷ Beth Baker, "Synthetic Biology and the Marketplace: Building the new bioeconomy," *BioScience* 67, no. 10 (2017): 877–883, <https://doi.org/10.1093/biosci/bix101>.

³⁸ "A Free Biological Inventory Management System And Browser," BioBricks Foundation, accessed May 09, 2018, <https://biobricks.org/bionet/>.

³⁹ "Science Publishes Guiding Principles for Sponsors and Supporters of Gene Drive Research," Foundation for the National Institutes of Health, November 30, 2017, <https://fnih.org/news/announcements/guiding-principles-for-sponsors-supporters-gene-drive-research>.

⁴⁰ Heidi Ledford, "CRISPR, the Disruptor," *Nature* 522, no. 7554 (June 3, 2015): 20-24, <https://www.nature.com/news/crispr-the-disruptor-1.17673>.

⁴¹ National Academies of Sciences, Engineering, and Medicine, "Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies," *The National Academies Press*, 2017, <https://doi.org/10.17226/24761>.

A recent positive step forward has been the advent of the Defense Advanced Research Projects Agency (DARPA) Safe Genes Program⁴², which was launched to address risks posed by gene editing technologies, including by developing ways to, “...restrict or reverse propagation of engineered genetic constructs.” Safe Genes has created a mechanism – and hopefully someday a market – for leading researchers to consider innovative mechanisms to reduce or counter biological risks associated with technologies that they (or other researchers) create.

The annual International Genetically Engineered Machine Competition (iGEM)⁴³ also provides an opportunity to engage broader and next generation community in best practices that can be propagated. The iGEM competition seeks to not only bolster safe and secure practices among competitors in its annual competition, but also could serve as a test-bed for developing new technical approaches to countering biotechnology risks. In 2017, iGEM included over 295 teams from around the world.⁴⁴

Academic challenges focused on designing safe and secure biotechnologies could serve as one way to incentivize scientists and engineers to pursue risk mitigation as an integral piece of the discovery process. There are some risks associated with incentivizing experts to consider all the ways in which specific biotechnologies could be misused – even for the purpose of mitigating those risks. However, incentivizing a cadre of scientists and engineers who are focused on countering negative outcomes associated with new biotechnologies might also dissuade or deter those with harmful intent.

Food for thought:

Grand challenges to improve biosecurity should be fostered and funded on a global scale.

A new cadre of biosecurity innovators could be nurtured.

Entities that fund and invest in biotechnology could require awardees to invest in biosecurity innovation and best practices.

WAY AHEAD

For the past 20 years, global discussion surrounding development of policies and practices for reducing biological risk has focused largely on securing and accounting for specific dangerous agents, implementing biosafety practices in facilities working with those agents, and developing national governing strategies for research deemed to carry greater societal risk. During the timeframe in which these conversations have occurred, a new, open, global, and transparent economy has emerged that focuses on creating and manipulating biological systems.

As the private sector emerges as a larger player in biotechnology, synthetic biology companies begin to develop a new culture of practice for the future, and the public demands more attention to risk, a new opportunity exists – now and for new actors such as companies, insurers, foundries, genomics consortia, and academic leaders – **to set international norms, take a hard look at the future benefits of biology, and take concrete actions to ensure that society can enjoy them.**

NTI, the World Economic Forum, and the Wellcome Trust are determining next steps toward incentivizing norms and concrete actions across the technical community. Your participation will be directly relevant to our future work, including the stand-up by NTI later this year of a global senior leaders group focused on biosecurity innovation and risk reduction, which will be asked to identify and publish international norms and concrete options for adopting them.

We look forward to your perspectives and inputs in June.

⁴² “Setting a Safe Course for Gene Editing Research,” Defense Advanced Research Projects Agency (DARPA), September 7, 2016, <https://www.darpa.mil/news-events/2016-09-07>.

⁴³ “Safety & Security at iGEM,” International Genetically Engineered Machine Competition, accessed May 09, 2018, <http://igem.org/Safety>.

⁴⁴ “Web Sites for iGEM 2017 Teams,” iGEM, accessed May 10, 2018, http://igem.org/Team_Wikis.

IDEAS TO CATALYZE YOUR THOUGHTS

WHAT ARE THE MERITS OF THE FOLLOWING APPROACHES?

1. Publish a set of forward thinking global norms with the involvement of senior leaders from across a range of stakeholders.
2. Launch global challenges to fund biosecurity-by-design and foster a new discipline of biosecurity innovators among synthetic biology leaders, biotechnology developers, and academic universities.
3. Incentivize researchers to only work with DNA synthesis companies that conduct rigorous and updated screening and incentivize pledges from governments and companies to adopt norms and enforce DNA synthesis screening as a condition for DNA synthesis companies to operate in country.
4. Explore mechanisms of oversight for conducting research that synthesizes or modifies pathogens with pandemic potential.
5. Spur foundries to develop and incentivize common safety and security practices.
6. Explore risks reduction models that have been applied in other areas, in partnership with the private sector and insurance industry.
7. Explore adoption of specific actions as a prerequisite to participation in scientific collaboration by existing academic and community synthetic biology and genomics consortia.
8. Develop and adopt standards among leading journals for review and publication of dual use research.
9. Develop and adopt principles among funders focusing on advances in biotechnology.
10. Launch a United Nations high-level event on biological risk that highlights concrete options for stakeholder and government action.
11. Hold a public-facing event in 2019 or 2020 to pose concrete norms and actions to a large group of public and community stakeholders.