The United Nations Institute for Disarmament Research (UNIDIR) is a voluntarily funded, autonomous institute within the United Nations. One of the few policy institutes worldwide focusing on disarmament, UNIDIR generates knowledge and promotes dialogue and action on disarmament and security. Based in Geneva, UNIDIR assists the international community to develop the practical, innovative ideas needed to find solutions to critical security problems.

Support from UNIDIR’s core funders provides the foundation for all the Institute’s activities. The 2020 Innovations Dialogue was the second edition of one of UNIDIR’s flagship events organized by its Security and Technology Programme, which is funded by the Governments of Germany, the Netherlands, Norway, and Switzerland, and by Microsoft.

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Design and layout by Eric M. Schulz.

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Contemporary developments in science and technology present new opportunities as well as challenges to international security and disarmament. UNIDIR’s Security and Technology Programme (SecTec) seeks to build knowledge and awareness on the international security implications and risks of specific technological innovations and convenes stakeholders to explore ideas and develop new thinking on ways to address them.

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ACRONYMS & ABBREVIATIONS

<table>
<thead>
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<th>Acronym</th>
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<tr>
<td>BTWC</td>
<td>Biological and Toxin Weapons Convention</td>
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<td>CWC</td>
<td>Chemical Weapons Convention</td>
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<tr>
<td>CRISPR</td>
<td>Clustered Regularly Interspaced Short Palindromic Repeats</td>
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<td>DIY</td>
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Launched in 2019, the Innovations Dialogue is one of UNIDIR’s flagship events. The conference series was established pursuant to the 2018 General Assembly resolution on the “Role of science and technology in the context of international security and disarmament.” The Innovations Dialogue provides a unique multi-stakeholder forum—convening experts from the diplomatic and policy community, technical and scientific community, industry groups, and academia and civil society—to collectively examine developments in science and technology that have potentially radical and novel implications for international security and disarmament. Through fact-based and balanced discussions, the dialogue aims to dispel myths about scientific and technological innovations and build a shared understanding of the potential benefits, risks and policy challenges posed by such innovations.

The Secretary-General’s May 2018 Agenda for Disarmament, “Securing Our Common Future”, and his report on “Current developments in science and technology and their potential impact on international security and disarmament efforts” recognize UNIDIR’s role as a source of knowledge and ideas, as well as a convener of multi-stakeholder dialogues, on the nexus of technology and security.

The key objectives of the Innovations Dialogue are:

To collaboratively examine beneficial applications as well as new and converging challenges or risks presented by advances in science and technology for international peace and security.

To promote multi-stakeholder engagement and build new relationships among a range of actors and tools that can contribute to mitigating potential harms, harnessing potential benefits, and promoting responsible innovation.

To explore how multi-stakeholder dialogue can facilitate policy responses to developments in science and technology that have potentially radical and novel implications for international security and disarmament, with a view to identifying gaps or opportunities where early thinking on strategies for risk mitigation may be beneficial.

1 UNGA (2018b).
2 UNGA (2018a).
The 2020 Innovations Dialogue examined technological advancements and trends that could radically affect the creation, production, and delivery of biological weapons: gene editing techniques, DIYbio, cloud labs and nanobiotechnology. The Dialogue provided a multi-stakeholder forum for a balanced discussion on the potential positive applications of these technologies for societies as well as their risks and opportunities for arms control, international security, and disarmament. In light of the current COVID-19 crisis, the discussions also explored the extent to which these technologies can aid public health response measures.

The Dialogue explored the challenges to existing governance and arms control approaches arising from the dual-use nature of technological innovations in the life sciences and considered what new instruments, if any, are needed and how existing ones can improve and adapt to safely and securely support the peaceful exploitation of twenty-first century biotechnology.

This report provides a summary of the key themes, issues, and takeaways that emerged from the two-day discussions at the 2020 Innovations Dialogue. Part I provides an overview of the past, present, and future of technological advancements and trends in different fields related to the life sciences and discusses their implications for international security and disarmament, particularly for the Biological and Toxin Weapons Convention (BTWC) and the biosecurity and arms control communities. Part II provides a summary of each expert panel dedicated to technological advancements and related dual-use governance challenges examined at the 2020 Innovations Dialogue.

3 Gene editing is also referred to as genome editing or genome engineering.
PART I: REFLECTIONS FOR ARMS CONTROL AND DISARMAMENT

LIFE SCIENCES, INTERNATIONAL SECURITY AND DISARMAMENT

Scientific and technological advances in different fields related to and outside of the life sciences are accelerating and converging to create novel tools that can offer considerable potential to address some of humanity’s greatest challenges. From addressing climate change to detecting and mitigating the effects of infectious diseases and supporting economic development goals, innovations in the life sciences have the potential to transform society and the global economy. Research and development in fields related to the life sciences is “overwhelmingly undertaken for peaceful purposes”. This year, in particular, has proven to be a defining moment for the life sciences as humankind is facing a public health and economic crisis of unprecedented magnitude and global scope. The COVID-19 pandemic has served as an innovation catalyst as scientists around the world turn to the life sciences to find solutions for the detection, diagnosis, and management of COVID-19. For example, using the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) gene editing technique, researchers have developed a faster, simpler, and cheaper diagnostic kit that can deliver a 20-minute test for COVID-19. Meanwhile, nanotechnology is being applied to the development of coronavirus vaccines and improved protective equipment.

However, advances in biotechnology are also revolutionizing tools for the potential creation, production, and delivery of biological weapons. These advances can potentially be exploited for hostile purposes, particularly for the development of more lethal and destructive biological weapons. While naturally emerging novel pathogens can cause severe damage—as we are currently experiencing with SARS-CoV-2—the genetically engineered or synthesized pathogens may have the potential to pose even greater risks to human health and economic stability.

Against this backdrop of scientific and technological advances, there are emerging trends in life sciences research, development, and innovation: the digitization of biology; a changing research landscape that has seen the emergence of new actors as a result of the growth in ‘do-it-yourself’ (DIY) biology; and the decreased cost of biological research and development. Such trends are accelerating the pace of technological exploration and innovation and reducing the barriers to entry for a wider range of actors to tackle global challenges. However, the growing access to advanced biotechnology is also raising concerns among the disarmament community regarding potential ease in misuse of capabilities for offensive and defensive purposes.

The dual-use nature of life science innovations and the speed of advances in this area pose a considerable challenge for existing governance approaches and frameworks that seek to reduce the risk of biological weapons proliferation. The biosecurity, disarmament, and arms control communities will need to consider how best to mitigate the risks and harness the opportunities presented by advancements in the life sciences, while at the same time

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4 Warmbrod et al. (2020, 1).
5 Sheridan (2020).
6 UnderstandingNano.com (n.d.).
7 The pathogen that causes the coronavirus or COVID-19 disease.
8 Johnson and Prosnitz (2017).
managing multiple emerging trends in this field. This raises the question of whether new governance mechanisms are needed and how existing ones can improve and adapt to support the peaceful exploitation of twenty-first century biotechnology.

A REVOLUTION IN EVOLUTION⁹

The world today is undergoing unprecedented technological, economic, and social change due to digitization. The digital revolution is transforming every aspect of our lives, societies, and economies.¹⁰ Life itself is being digitized.

This digital revolution in the life sciences was accelerated by the Human Genome Project in 1990, an effort led by an international team of researchers to determine and map the DNA¹¹ sequence of the entire human genome—the structure, organization and function of the complete set of human genes.¹² This gave the world “the ability, for the first time, to read nature’s complete genetic blueprint for building a human being.”¹³ Since its completion in 2003, the project has unlocked processes, tools and technologies that have enabled unprecedented understanding and manipulation of biology. The project has brought automation to genomics and made the process of reading DNA code run by high performance automated machines. This has helped catalyse one of the most remarkable technological advances—the increased speed and lowered costs of DNA sequencing¹⁴ technology to the point where individual genes could be sequenced routinely for just a few thousand dollars.¹⁵ Today, about 55,000 different organisms have been sequenced,¹⁶ and some of this information is organized in freely accessible online databases, such as the Kyoto Encyclopedia of Genes and Genomes.¹⁷

Along with sequencing DNA, we have the ability to write and edit DNA. While the capability has existed for the last 40 years, it has dramatically advanced and become easier to perform. In the early days, what is understood as gene splicing, was complex and difficult. Scientists had to work with special naturally occurring enzymes that act like scissors to cut the DNA and other enzymes that behave like glue to stitch the spliced sequences together. Writing just a small sequence of genetic code using these types of technologies meant working with microscopic molecules and required extensive training, proper facilities, access to particular enzymes and validation technologies to read the code that was being written. Even so, scientists were able to leverage the technology to synthetically make proteins and lay the foundation of the biotechnology industry. Human insulin was one of the first proteins to be genetically engineered and synthetically made, changing the life of diabetic patients around the world.¹⁸

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⁹ This section is based on the Keynote Address by Andrew Hessel, President, Humane Genomics Inc. and Co-founder and Chairman, Genome Project-Write.
¹⁰ UNIDIR (2019).
¹¹ “DNA is a digital programming language that directs cell form and function. This digital code is written in physical atoms and executed by universal molecular machinery. The diversity that we see in nature results from different genetic software” which is made up of physical atoms instead of electronic bits (Hessel, 2020).
¹² National Human Genome Research Institute (n.d.(d)).
¹³ Ibid. (n.d.(c)).
¹⁴ DNA sequencing means determining the order of the four chemical building blocks that make up the DNA molecule. It has profound implications for understanding life at the lowest levels possible because it tells scientists the kind of genetic information that is carried in a particular DNA segment. The overall process of sequencing starts with an organism, whether it human, plant or a microbe. If not a single-celled organism, it is reduced to single cells, following which the genetic material is pulled out and run through automated sequencers through which a digital file for each sequenced organism is created. To learn more about DNA sequencing, see National Human Genome Research Institute (n.d.(a)) and Hessel (2020).
¹⁵ National Human Genome Research Institute (n.d.(a)).
¹⁶ Hessel (2020).
¹⁷ KEGG (n.d.).
¹⁸ American Diabetes Association (2019).
Today, **this type of editing and manipulation has been digitized**, making it much easier to search for a string of genetic letters, recombine it and ‘move things around.’ In order to physically create the artificial gene sequence, a biological process known as DNA synthesis employs DNA molecule printers akin to 3-D printers\(^{19}\) that can string together around 7,000 bits of genetic code, enough to build almost any protein. This is the foundation of the technology of synthetic biology. Writing a complete genome effectively means building an organism from scratch. As DNA synthesis capabilities continue to evolve, they have unlocked the ability to write any protein, from antibodies to enzymes, and do so in a way that is more precise and scalable. We are now starting to be able to write complete genomes of single-celled organisms and can theoretically make any virus from scratch. In principle, someday it may be possible to design and build complex organisms such as natural plants and animals. To this end, one group of researchers called the Genome Project-Write,\(^{20}\) akin to the Human Genome Project, is working to push the limits of existing synthetic biology capabilities.

**These technologies are being used to tackle some of humanity’s greatest challenges in agriculture, manufacturing, and medicine.** They have opened the door to developing new vaccines and gene therapies that would have been difficult to produce in the past. For example, Humane Genomics Inc., a company based in the United States, is using digital synthetic biology tools to build viruses that are custom designed to hunt down and kill cancer cells.\(^{21}\) In response to the COVID-19 crisis, the same digital synthetic biology tools were used to reconstruct the SARS-CoV-2 virus after it was sequenced and put into the public domain. The process of reconstructing the virus took less than a month, which allowed scientists to start the development of vaccines and diagnostics at an unprecedented rate. Although still in their infancy, synthetic biology and genome engineering technologies may bring about a ‘revolution in evolution’ by enabling us to understand and engineer life, build original organisms and possibly modify and enhance the capabilities of nature by being able to mix and match features from the natural world.

Current trends of innovation in synthetic biology and genome engineering point towards a future characterized by increased democratization of gene sequencing and synthesis technologies, a resultant reduction in costs of exploration of biology and an **emergence of new actors that may not always operate in traditional laboratory settings**. The convergence of advances in artificial intelligence and automation with digitization of biology will enable the development of more automated and portable cloud labs that offer promising benefits, particularly in the area of scientific testing. As with all digital technologies, the rapid rate of technological advancements will continue to drive entrepreneurship in the life sciences thereby fuelling the growth of the bio economy. Young people will play a key role in the growing bio economy as they are at the forefront of cutting-edge innovation in the life sciences in university settings and beyond.\(^{22}\)

These advances also **present considerable risks of unintentional harm due to unpredictable accidents or exploitation**. As a growing body of research and innovation is now taking place outside of traditional laboratory settings, the innovation landscape in the life sciences is not transparent—most labs work in silos making it difficult to understand the research and development being conducted as well as carry out continuous oversight and international coordination on developing regulation. The effects of the COVID-19 pandemic have demonstrated the need for greater transparency and robust biosecurity and biosafety systems within the innovation landscape in the life sciences to mitigate or prevent future

\(^{19}\) Sanders (2018).
\(^{20}\) Center of Excellence for Engineering Biology (n.d.).
\(^{21}\) Humane Genomics (n.d.).
\(^{22}\) Hessel (2020).
outbreaks, whether they be natural, accidental or deliberate. Comprehensive education on the potential ethical, safety, and security risks for young scientists and innovators should start at early stages of their career. **Our ability to understand and engineer life will define this century**, therefore the international community must work collaboratively to fully harness the potential of innovation in the life sciences while mitigating the risks.

**GOVERNANCE IN ACTION: KEY TAKEAWAYS FOR ARMS CONTROL AND DISARMAMENT**

Advances in science and technology have shaped the development of weapons and the ways in which war is waged over millennia. However, technological advances have also been central to the development of effective national and multilateral regulation of weapons—they have shown potential to achieve the transparency, verifiability and ‘reportability’ that are the foundations of cooperative arms control. Today the arms control and disarmament machinery finds itself in a fundamentally new moment with the pace of technological change, particularly in the life sciences and the expansion that it represents for the thinking of the concept of security as well as security threats and challenges.

Rapid advances in the life science and biotechnology are critical for reducing public health emergencies, addressing public health challenges, and supporting economic development goals. However, they also pose unique risks and threats that have the potential to undermine global progress toward the very same goals. **These advances are also taking place at the convergence of other technologies** including artificial intelligence and nanotechnology, thereby expanding the consideration of dual-use and biosecurity concerns beyond the life sciences. While technology convergence may increase risk, it also offers an opportunity to build more responsive and adaptive governance systems. **Broader implications thus need to be taken into account while assessing risks and the impact of science and technology developments on arms control, non-proliferation, and disarmament.** How can the multilateral arms control and disarmament machinery adapt? Do we need fundamentally new approaches, or can we build on what we already have?

The BTWC of 1972, agreed by 183 States Parties, comprehensively prohibits the use of viruses, bacteria, and their components for non-peaceful purposes. **It covers all viruses, bacteria, toxins, fungi, and rickettsia whether they are natural or artificially created or altered.** The Convention also enshrines the norm against the use of disease as a weapon as well as the broader norm against using science and technology to deliberately cause harm.  

However, **developments in and beyond the life sciences raise the question as to whether the current Convention adequately addresses all the risks they may present.** Advances in synthetic biology are allowing for the creation of novel biological agents with entirely synthetic base structures that are inspired by DNA or RNA but are different from any known naturally occurring nucleic acid. Furthermore, these biological agents may not necessarily be directed to cause general detrimental effect on the human body. They may instead be intended to target particular biological processes.

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23 This section is based on the discussions that took place during the Innovations Debrief session and the Multilateral Governance in Action: Channelling Reflections into Multilateral Agendas panel.

24 UNOG (n.d.).
such as the human immune or nervous system. It is debated whether such synthetic constructs are covered by the BTWC. If militaries find novel biological agents and related science and technology developments attractive, the balance of incentives and disincentives that determine compliance with the BTWC could be affected.

In order for the BTWC to stay abreast with the evolving biological threat landscape, it **must systematically consider how biological weapons may look and behave differently in the future**. An explicit obligation under Article XII of the BTWC,\(^{25}\) it is essential that the BTWC regularly and systematically reviews science and technology advances in terms of their security implications and beneficial applications. Currently, the conduct of such reviews is the responsibility of individual States Parties. However, a collective dedicated review process for the Convention could provide a common comprehensive technical foundation on which more forward-looking and proactive polices can be built.

The continued democratization of the life sciences and biotechnology has enabled a range of non-State actors—including citizen scientists, DIYbio community labs, students and young scientists, and biotechnology start-ups—to steer trajectories in global research and development. The BTWC needs to engage with this complex networked ecosystem that thrives on organic governance mechanisms. Some of the prominent governance instruments coming out of the life sciences fields are embedded in industry codes of conduct, standards, and research and data-sharing protocols. **The multilateral arms control and disarmament machinery could leverage this web of self-governance initiatives and complement it with top-down governance tools.** Developing effective and scientifically informed policies will require building strong partnerships and continuous open dialogue with the scientific and research communities and the biotechnology industry. A dedicated science and technology review process can provide an opportunity to bring the knowledge and expertise of multiple stakeholders into intergovernmental deliberations on addressing security implications of advances in science and technology. However, a multi-stakeholder approach to multilateral governance in a traditionally State-based disarmament regime will be unachievable without the political willingness to engage non-State stakeholders.

As the arms control and disarmament machinery is increasingly being challenged by a complex and polarized environment strained by competing and converging security challenges, **the United Nations through its thought leadership and strategic coordination role can help the machinery improve and adapt.** The organization has a unique convening power and legitimacy to be a platform for States and other stakeholders to engage in sincere, informed, and proactive dialogue that can stimulate new thinking about disarmament and the arms control toolbox.

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\(^{25}\) Ibid.
PART II: SUMMARY OF EXPERT PANELS

CREATION, PRODUCTION AND DELIVERY

Through three expert panels, panellists and participants examined specific innovations and trends in the life sciences that are revolutionizing tools for the potential creation, production, and delivery of biological weapons: gene editing techniques, DIYbio, cloud labs, and nanobiotechnology. What are they? How do they work? What beneficial applications do they offer, and what risks do they present for international security and arms control? How realistic are the risks of misuse?

CREATION—GENE EDITING TECHNOLOGIES/CRISPR

In the past decade, rapid advances in genome editing techniques have led to significant progress in the biotechnology field. They have enhanced and expanded the toolbox of synthetic methods for making precise additions, divisions, and alterations to an organism’s genetic makeup. The most prominent and versatile of those tools is the CRISPR-Cas9 system—a novel genome editing platform that has brought unprecedented ease, accuracy, and efficiency to the process of adding or deleting small stretches of DNA in the genome.\(^27\) While both synthetic biology and genome editing are similar approaches to changing an organism’s genetic code, they differ in how that alteration is made. In synthetic biology, scientists typically stitch together long stretches of DNA that could be entirely novel or found in other organisms and insert them into an organism’s genome. On the other hand, in genome editing scientists use techniques to make changes directly in an organism’s DNA.\(^28\) However, both synthetic biology and genome editing operate at the level of biological ‘parts’—that is, DNA sequences with specific functions\(^29\) that are found at levels below that of the organism as a whole.

The technology of genome editing is about cutting and pasting DNA, a process that has progressed over time. \textit{Recent advances have enabled much more precise cutting and pasting at predefined locations in the DNA segment}, which has provided new ways to test and predict genomic functions within a biological substrate. Moreover, the convergence of genome editing technologies with artificial intelligence in core functional genomics has enabled the capacity to assess how genetic sequences are meant to function before they are assembled or even exist in their physical form in nature. A promising technology, it has \textit{many beneficial applications, particularly in the treatment of diseases like cancer, or genetic defects, or even COVID-19}.\(^30\) For example, scientists were able to use CRISPR to effectively reduce the transmission efficiency of malarial parasites in mosquitoes.\(^31\) Currently, scientists at Stanford University are experimenting with how CRISPR technology can be used to fight the novel coronavirus by investigating the genetic component of the virus that enables it to penetrate human cells.\(^32\) However, CRISPR tools still have limitations. Many CRISPR applications are in

\(^{26}\) This section is based on the presentations made by the speakers and the reflections provided by the moderators during the Creation—Gene editing technologies/CRISPR, Production—DIYbio and Cloud Labs, and Delivery—Nanobiotechnology Applications for Delivery panels.

\(^{27}\) Spiez Laboratory (2018).

\(^{28}\) National Human Genome Research Institute (n.d.(b)).

\(^{29}\) In biology, “for most evolutionary biologists, function relates to selection (that is, the effect for which the gene was selected in the past at the organismal level),” See Keeling et al (2019, 1).

\(^{30}\) Levy (2020) and Hurlbut et al. (2015).

\(^{31}\) Dhar (2020).

\(^{32}\) Levy (2020).
their infancy and practical challenges, including delivery and off-target effects, remain to be overcome.33

The innovation landscape in synthetic biology and genome engineering is constantly evolving with emerging actors. Along with the biotechnology industry and the scientific and research communities, a global community of young citizen-scientists are at the heart of rapid advances in gene editing technologies. A prominent example of this is the International Genetically Engineered Machine Foundations’ iGEM competition.34 This annual worldwide competition brings together high school, undergraduate, and graduate students that work collaboratively in teams to design, build, and test genetically engineered systems using standard biological parts to solve real-world problems. The competition gives young practitioners the opportunity to push advancements in synthetic biology and to educating them about good biosafety practices and the real world ethical and biosecurity implications their research may have. Today, it has produced close to 45,000 alumni who are going on to become players in the synthetic biology industry. For example, during the iGEM competition in 2011, a team conducted cutting-edge foundational research to develop therapy for celiac disease. The team went on to form a start-up and in 2017 was rewarded a funding of $35 million to develop novel therapeutic for celiac disease.35

Novel gene editing techniques like CRISPR could enable a new generation of biological weapons and challenge existing export control regimes. While offering indisputable powerful benefits, developments in synthetic biology and gene editing methods such as CRISPR have also raised many ethical, biosafety, and biosecurity concerns. From an international security and arms control perspective, novel gene editing techniques like CRISPR could enable a new generation of biological weapons and challenge existing export control regimes in three distinct ways. First, they make it cheaper, faster, and easier to modify biological warfare agents. Second, they allow for

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33 Spiez Laboratory (2018).
34 iGEM (n.d.).
the resurrection or recreation of old pathogens that are already known to be dangerous. For example, smallpox only exists in two laboratories in the Russian Federation and in the United States. However, Canadian researchers recently proved that it is now possible to synthesize a very close relative of smallpox.\(^{36}\) Similarly, scientists have shown that is possible to create the poliovirus from scratch by using genetic sequence information from public databases and readily available technology.\(^{37}\) This ability to produce old and novel viruses and bacteria (to some extent) could be exploited for the development of biological weapons. Third, they allow for the creation of new pathogens with specific functions that have not been seen before, which, for example, could be used to target specific individuals, or ethnic and racial groups.

Export controls on listed plant, animal, and human pathogens; toxins; and related dual-use equipment and technologies have been the most prominent arms control tool to prevent the proliferation of biological weapons. However, synthetic biology and genome editing tools are challenging this approach as most national control lists, along with that of the Australia Group, control organisms and not biological parts with specific functions that are found at levels below the organism. Forward-thinking regimes sometimes do address parts, but they largely only focus on parts that are solely found in pathogens on the control list. However, what happens when there is a biological part that is found in multiple organisms? Furthermore, there are viruses that are not controlled, but are nevertheless similar to some of the most feared pathogens on the planet. The same is true for individual genes. For example, there is similarity between the genetic material of different poxviruses, the family of viruses that include smallpox. Researchers have been able to identify pathogenic genes in non-controlled pathogens that were nearly identical to those found in smallpox. **Genome editing tools make it relatively straightforward to edit the sequences from a non-controlled virus into a sequence from a controlled virus.**

The arms control and disarmament communities need to build control regimes that can deal with biological parts that are ‘functionally’ the same as those on the control lists as genes (biological parts) that have the same controlled function can come from a non-controlled pathogen. Some control lists do address functions like toxins that would pose a significant hazard to human animal or plant health or functions that could enhance pathogenicity, but these only apply to listed pathogens. Currently, it is not clear whether a biological part is covered under export control lists if it is ‘functionally’ the same as the one being controlled. **Often the determination of whether a specific biological part is controlled or dangerous is left to the companies that supply that part.** For example, there are companies that can print any gene sequence you order. Many of those companies have come together to form the International Gene Synthesis Consortium to help them screen their orders and customers in order to make sure that potentially hazardous gene sequences do not fall into the wrong hands.\(^{38}\) However, it is possible to circumvent these screening systems. For example, in 2017 an iGEM team demonstrated that it was able to place an order that obscured hazardous sequences from the screening software.\(^{39}\) Moreover, biosecurity and export control regimes tend to focus exclusively on pathogens and toxins that harm humans or other organisms. However, there are other threats that may need to be addressed. For instance, an iGEM team in 2018 learned that a microbe they were engineering was capable of degrading electronics, an example of a biological part that could be deliberately misused to cause harm other than disease.\(^{40}\)

\(^{36}\) Kupferschmidt (2017).

\(^{37}\) Orwant (2002).


\(^{39}\) iGEM (2020).

\(^{40}\) Ibid.
Thus, **it is critical for the arms control and disarmament communities to rethink and redefine biosecurity threats when developing biosecurity frameworks and regulations.** Additionally, increased participation of key private stakeholders in governance regimes may be necessary to keep regulators abreast of relevant advances in synthetic biology and genome engineering. Further, existing control regimes may need to be constantly tested and improved to address evolving synthetic biology and genome engineering tools that are challenging core arms control concepts, such as the notion of ‘dual-use technology.’

**SUMMARY**

- The last few years have seen major advances in gene editing technologies. The most prominent of these advancements is CRISPR. CRISPR is a gene editing platform that enables cheaper, faster and more precise DNA editing.
- These advances have many beneficial applications, particularly in the treatment of diseases like cancer as well as genetic defects and COVID-19.
- However, novel synthetic gene editing techniques like CRISPR could enable a new generation of biological weapons and challenge existing export control regimes by allowing for the modification of biological warfare agents, resurrection or recreation of old pathogens, and the creation of new pathogens.
- It is critical for the arms control community to continuously test and improve existing export control regimes and to rethink and clearly define biosecurity threats of concern when developing biosecurity frameworks and regulations.
The research and development landscape in the life sciences is constantly evolving with the growing ‘DIYbio’ community and the emerging ‘cloud lab’ industry. Both communities are democratizing and accelerating the design–build–test cycle in biology and lowering the barriers to advanced biological research, which could foster new positive innovations but also provide new avenues for malicious actors to exploit biology to cause harm.

DIYbio
The DIYbio lab community is a movement of biologists that is encouraging open and inclusive exploration of biology outside traditional laboratory settings. The origins of this movement can be traced back to 2008. As biotechnology tools were becoming more accessible and the costs of conducting advanced biological research were decreasing, citizen-scientists and bio-enthusiasts began to form discussion groups exploring how they could utilize these tools and contribute to advancing biology research. The first community biotechnology lab was established in the United States in 2010, and since then more than 100 community labs have emerged across the globe. At the second global bio summit hosted by the MIT Media Lab, over 200 individuals from multiple community labs and groups from around the world developed a shared vision statement that articulated the shared purpose of the DIYbio community which is to fundamentally transform life sciences and democratize biotechnology to both inspire creativity and improve lives by building an inclusive global network, cultivating an accessible ‘commons of knowledge’ and resources, launching community labs and projects, and enabling local educators.

DIYbio is opening doorways to new and different innovation pipelines as individuals who previously might not have had access to biotechnology tools are now able to collaboratively participate in the world of biotechnology, particularly in citizen community spaces. Many start-up companies have also begun to spin out of these spaces as they are becoming the cradle
for innovation in the life sciences. Amidst the COVID-19 pandemic, an open platform called Just One Giant Lab launched an open COVID-19 initiative that has allowed groups around the world to work collaboratively on everything from personal protective equipment, to diagnostic tests to vaccines.\(^{43}\) However, this work has also raised some questions regarding how research around COVID-19 vaccines can be ethically, safely, and securely conducted by an open, virtual, and disconnected community of individuals working in separate locations.

While the DIYbio movement encourages open and inclusive exploration of biotechnology, its open source nature transcends international boundaries and governance mechanisms and could potentially be exploited for the development and production of biological weapons. Recently, a group calling itself the Rapid Deployment Vaccine Collaborative, comprising traditionally trained scientists from various institutions, came under scrutiny when it announced that it had developed a COVID-19 vaccine in its garage lab and disseminated the information for others to replicate its work. Moreover, the group not only took the ‘vaccine’ themselves but also conducted a pseudo-trial by inviting friends and colleagues to take it without seeking the required authorization from the US Food and Drug Administration.\(^{44}\)

The emergence of community biotech labs and garage labs has raised considerable concerns regarding the management of biosafety and biosecurity risks, given that these actors are currently not explicitly captured by any top-down governance mechanisms. Recognizing the responsibility that is required for a sustainable open and accessible research ethos, the DIYbio community has taken some self-governance initiatives to minimize the biosafety and biosecurity risks that could arise from its work. In 2011, community labs in the United States and Europe came together to develop a code of conduct for safety and security.\(^{45}\) This code of conduct is evolving through new initiatives, including the Association for Biosafety and Biosecurity International’s biosafety and biosecurity training course\(^{46}\) that trains lab workers on the various types of safety and security measures for laboratories.

When the code of conduct was created, there were only a handful of actual labs. Now, as the DIYbio community is rapidly expanding across multiple locations with different capacities and facilities, it is increasingly challenging to keep track of the many actors operating in this space. While citizen community labs are easy to identify as they participate in community practices, garage labs can be hard to track as they do not necessarily engage in community initiative or practices. This therefore makes the prospects of developing a universal code of practice for the whole DIYbio community largely unfeasible. As top-down national and global governance frameworks are unable to match the pace of this dynamic community, bottom-up governance initiatives that can instil biosafety and biosecurity norms, ethics, and philosophy in the community may have to be supported and strengthened. Moreover, fostering relationships and an open channel of communication between the biosafety and biosecurity communities and the DIYbio community so that they can jointly understand and mitigate risks would be essential to the establishment of any governance system moving forward.

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\(^{43}\) Kuiken (2020).

\(^{44}\) Kuiken (2020); Regalado (2020).

\(^{45}\) Kuiken (2020).

\(^{46}\) ABSA International (n.d.).
Cloud Labs
Advances in artificial intelligence and robotics have enabled the creation of robotic experimental biology platforms or laboratories that allow experiments to be conducted remotely over the Internet. Although a nascent field, such ‘cloud labs’ have tremendous potential to make scientific experiments faster, more cost-effective, accurate, and scalable. Transcriptic, established in 2012 and now known as Strateos, was one of the first robotic cloud labs; its stated mission is to transform “biology into information technology driven by data, computations, and high-throughput robotics.”

Cloud labs have enabled on-demand life sciences research. Once scientists sign up to a cloud lab service, they can access it through a web interface. In that manner, scientists can access complex automated life sciences equipment to remotely conduct advanced experiments that traditionally would be conducted in person manually. In doing so, cloud-based solutions are increasing testing capacity, reducing costs of experimentation, and accelerating the design–build–test cycle in scientific discovery. Their value addition is that they facilitate collaboration among scientists and facilities. Scientists can initiate experiments and more easily reproduce results from their homes and work with colleagues across the globe. Regarding collaboration among facilities, cloud labs enable the development and standardization of repeatable and reproducible experimental protocols that can be accessed anywhere in the world.

While a democratized research and development landscape where a range of actors can remotely access and conduct advanced experiments with ease and at reduced costs serves as an innovation catalyst, a lowered barrier to entry for life sciences research also presents risks of possible misuse. As opposed to traditional research laboratories that require scientists to provide information regarding the experiments they want to conduct, cloud labs offer scientists privacy. Once access to a cloud lab is secured, the service provider may not

47 Strateos (n.d.).
48 Lentzos and Invernizzi (2019).
necessarily know what experiments are being run. This adds another layer of complexity to mitigating the possible risks of misuse.49 In addition, since cloud labs operate over the Internet, they could be vulnerable to cyberattacks.

It would be prudent to understand and address the potential security implications of cloud labs at this early stage of their emergence. **Bottom-up self-governance initiatives may be a natural fit for cloud labs.** Given their decentralized character that allows users to access a lab from disparate regions that may not be bound by common rules and regulations, a top-down governance framework may not be feasible. Some proposed self-governance tools include robust customer screening and controlled access to dangerous materials. As the cloud lab industry is currently quite small, companies are able to manually screen users and the experiments they want to conduct to ensure that their platform is used by validated commercial entities. However, as the industry grows, and more actors have access to these advanced tools, screening of users and experiments will become increasingly challenging. This may engender community driven efforts to develop best practices and encourage the development of more effective experimental protocol screening methods to prevent restricted or prohibited activities.

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**SUMMARY**

The research and development landscape in the life sciences is constantly evolving with the growing DIYbio community and the emerging cloud lab industry, which are in turn democratizing and accelerating the design–build–test cycle in biology and lowering the barriers to advanced biological research.

**DIYbio**
- The DIYbio community is a movement of biologists that encourages open and inclusive exploration of biology outside of traditional laboratory settings.
- DIYbio is opening doorways to new innovation pipelines as individuals who previously might not have had access to biotechnology tools are now able to collaboratively participate in the world of biotechnology.
- However, its open-source nature transcends international boundaries and governance mechanisms and could potentially be exploited for the production of biological weapons.
- As top-down governance frameworks are unable to match the pace of this dynamic community, bottom-up governance initiatives that can instill biosafety and biosecurity norms, ethics, and philosophy in the community may need to be supported and strengthened.

**Cloud Labs**
- Advances in artificial intelligence and robotics have enabled the creation of experimental biology platforms or laboratories that allow experiments to be conducted remotely over the Internet. These facilities are known as cloud labs.
- The advent of cloud labs has the potential to drive innovation in the life sciences by making advanced scientific experiments faster, more cost-effective, accurate, and scalable.
- However, this low cost and accessibility also makes it easier for malicious actors to exploit biology for malevolent purposes.
- **Bottom-up self-governance initiatives may be a natural fit for cloud labs, especially due to their decentralized character that allow users to access the interface from geographic locations that may not be bound by common rules and regulations.**

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49 Lentzos and Invernizzi (2019).
Nanotechnology refers to a broad range of tools that allow us to build and engineer organic and inorganic materials and devices at the nanoscale – one-billionth of a meter. Engineered at a molecular scale, nanomaterials are highly accurate. At this scale, nanomaterials exhibit different features and characteristics and have different effects than they would at the macroscale including increased permeability, strength, chemical resistance, and conductivity. While the idea of manipulating materials at the smallest scale emerged in 1959, the recent convergence of advances in the use of nanomaterials combined with artificial intelligence and increased computing capacity have expedited the development of new nanomaterials, specifically by enabling advance modelling capabilities. Nanotechnology has many powerful applications for advancing economic development and human well-being in the fields of agriculture, environment, energy, medicine, mechanical engineering, information technology, etc. However, its use also poses known and unknown risks. Ongoing research has shown that certain engineered nanomaterials may have harmful effects on the human body and possibly the environment, some of which may be long term.

The intersection of nanotechnology and biology is known as nanobiotechnology. Specifically, this term refers to the application of nanotechnology tools to build materials and devices to explore biology at the nanoscale where biological processes happen. It has many powerful applications, particularly in health care, agriculture, and the pharmaceutical sector, from therapeutics and diagnostics to preventative medical applications. The knowledge of

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50 Leins (2020) illustrates the concept of nanoscale in the following way: “a nano-sized object is to an apple what an apple-sized object is to the Earth. Or to give another example, one nanometre particle could fit approximately 80,000 times across the width of a human hair”.
51 AZoNano (2005); Leins (2020).
52 Leins (2020).
53 Ibid.
54 European Commission (n.d.).
55 Warmbrod et al. (2020).
nanomaterials is currently being applied to the creation of coronavirus vaccines, improved protective masks, stronger disinfectants, and better diagnostic methods.\textsuperscript{56} One of the most prominent applications of nanobiotechnology is the use of nanomaterials or nanorobots\textsuperscript{57} for targeted drug delivery to cells and tissues. As nanoparticles are taken up by cells more efficiently than larger micromolecules, they are transforming drug delivery systems and improving vaccines.\textsuperscript{58} Many anti-cancer drugs today have been formulated using nanomaterials.\textsuperscript{59}

Engineered \textbf{nanomaterials have a range of defensive and offensive applications} in the military domain. As an enabling technology, nanobiotechnology does not introduce new weapons as such, but allows a wide range of enhancements to existing weaponry, security, and defence technologies, particularly in relation to modifications to, and intervention in, the human body. With respect to offensive capabilities, nanorobots enable new and creative methods to target and deliver protein-based biological and chemical warfare agents to the human body, particularly within the cell. They can also act as micro-explosives, micro-weapons or inhalable micro-particles.\textsuperscript{60} In terms of its defensive applications, nanobiotechnology could potentially enhance sensors and sensing capabilities to better detect chemical, biological, and potentially nuclear weapons. Nanobiotechnology may also have many enabling capabilities for external and internal human enhancement that can augment the soldier’s capabilities and resistance in the battlefield. Due to the range of defensive and offensive capabilities it offers, many States have been investing heavily in the military applications of nanobiotechnology.\textsuperscript{61}

Nanobiotechnology is thus a dual-use technology, the use of which will have to be regulated to ensure that its benefits are fully harnessed and its risks to international security and arms control are mitigated. However, \textbf{the miniscule size and resultant non-detectability of nanomaterials may present considerable challenges to its governance by existing arms control arrangements and export control regimes.}

In addition, many unknowns remain about the long-term effects and safety risks of the use of nanomaterials on human health and the environment. Different uses of nanomaterials may present different issues and risks and may need to be considered by different governance instruments. The BTWC and the Chemical Weapons Convention (CWC) prohibits the use of some nano-based, nano-enabled, and nano-containing agents.\textsuperscript{62} However, regulatory gaps remain. For example, substances that are not toxic at the macroscopic scale may become toxic at the nanoscale. A dedicated regulatory instrument may not be necessary as existing instruments could be adapted and strengthened to specifically address risks presented by nanobiotechnology. For example, the CWC could develop a list of materials prohibited at the nanoscale.\textsuperscript{63} Given the breadth and interdisciplinary nature of nanotechnological advances, both the BTWC and CWC will need to closely monitor advances in nanobiotechnology to ensure that provisions of both conventions are effectively and adequately addressed.

\textsuperscript{56} UnderstandingNano.com (n.d.).  
\textsuperscript{57} Gutierrez et al. (2017).  
\textsuperscript{58} Suri et al. (2007).  
\textsuperscript{59} Ibid.  
\textsuperscript{60} AcumenIST (2020, 5).  
\textsuperscript{61} Ibid., p. 4.  
\textsuperscript{62} Ilchmann et al. (n.d.); Leins (2020).  
\textsuperscript{63} Leins (2020).
This panel focused on the challenges in governance of innovation, science, and technology in the life sciences. Panellists examined what new governance instruments, if any, are needed and how existing instruments could be adapted to address governance gaps. Given the emergence of new actors such as cloud labs and DIYbio labs in the research and development landscape, panellists also explored the feasibility and desirability of a multi-stakeholder approach to governance, and how new stakeholders could be brought into governance frameworks.

What new governance instruments, if any, are needed to address dual-use technologies?

Any technological advancement will push the boundaries of how existing regulations can be interpreted and applied. As science and technology in and beyond the life sciences is rapidly advancing, along with the biological risks associated with this work, it is not feasible to formulate new top-down multilateral regulations with every new technological innovation. Unlike some areas of new and emerging technologies, which are not covered by any existing governance instruments, the life sciences are governed by legal and normative regulatory instruments including the BTWC and the Australia Group. These existing biosecurity and biosafety regulatory frameworks allow for a degree of flexibility and can be adapted, improved, and strengthened to fill the governance gaps created by dual-use technological innovations.
How can existing governance instruments be adapted and improved to fill the governance gaps?

Rapid technological advancement and increased investment and entrepreneurship in the life sciences and biotechnology have resulted in a **research, development, and innovation landscape that is outpacing existing national, regional, and multilateral dual-use regulatory instruments and governance frameworks**. While life sciences and biotechnology are creating novel biosecurity threats, there are many States, particularly in the Global South, that are yet to develop comprehensive biosecurity governance structures that integrate dual-use considerations in their thinking about governance. This suggests that traditional and non-traditional actors driving innovation—academic and research institutions, industry, community laboratories, investors, etc.—should work closely with the biosafety and biosecurity communities and position themselves at the forefront of safeguarding biological research and innovation. However, currently the technology and innovation communities and the biosecurity and biosafety communities tend to operate in silos, with limited communication and engagement on dual-use issues and concerns. A **combination of bottom-up and top-down national, regional, and international capacity-building, awareness-raising and standard-setting initiatives are needed** to complement and strengthen the BTWC’s norms for responsible and peaceful uses of biology.

A **voluntary code of conduct** that establishes ethical guidelines and principles for dual-use research in the life sciences could be a complementary multilateral governance tool to enhance and support the implementation of the BTWC. Such a code of conduct could be modelled on the CWC’s Hague Ethical Guidelines, which were developed by an international group of chemical practitioners in collaboration with the Organisation for the Prohibition of Chemical Weapons to guide the responsible practice of chemistry. In addition, **like the CWC, the BTWC could also benefit from establishing an effective verification and on-site inspection regime** to address and mitigate dual-use risks. Furthermore, regional leadership could facilitate the development of harmonized standards and guidelines for governance of innovations in the life sciences. Strong regional leadership from the African Union has encouraged the development of ethics guidelines and regulation for gene drive technologies.

As actors from outside traditional academic and laboratory settings become increasingly active in the research, development, and innovation landscape, **cultivating a culture of responsibility at the national and regional levels is requisite for effective dual-use risk management**. Inculcating a culture of responsibility goes beyond developing guidelines and applying principles. It involves education, awareness-raising, and training initiatives that teach innovators to recognize problematic applications of life sciences innovations and sensitize them to their possible ethical, safety, and security implications. Moreover, providing training and education to innovators at an early stage would allow for the integration of the consideration of biosafety and biosecurity into design thinking. The iGEM competition may serve as a valuable case study for how education and training initiatives can instil a culture of responsibility among university and high school students, young entrepreneurs, and community laboratories.

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65  OPCW (n.d.).
66  Glover et al. (2018). To learn more about gene drive technologies, see Warmbrod et al. (2020).
Furthermore, **education and training activities need to be locally contextualized**. Unless young citizen scientists and innovators appreciate dual-use concerns, they will not see the value in regulations that seek to address those concerns. In the southeast Asian context, one successful strategy has involved identifying key players including national academies that have the access to a network of innovators and policymakers to educate and train young scientists, community labs and other small-scale innovators. To take another example, the evolving African continental free-trade agreement that is currently under discussion can be leveraged for capacity-building on dual-use issues. A trade agreement that considers dual-use issues will not only strengthen the research, development, and innovation landscape but also ensure that it is more responsive to biosafety and biosecurity concerns.

**Is a multi-stakeholder approach to governance desirable and feasible? How can non-State stakeholders be brought into governance frameworks?**

As the range of stakeholders in the research, development, and innovation landscape in the life sciences is expanding, a multi-stakeholder approach is not just desirable but a requirement for encouraging peaceful innovation while effectively mitigating dual-use risks. There are two aspects to multi-stakeholder engagement in governance. The first is to involve a broad range of stakeholders in the development of governance and regulatory frameworks. The second is to involve stakeholders in their implementation and include them in making decisions about technology. Therefore, multi-stakeholder engagement should address not only challenges and risks of innovations, but also the desirability of certain technological or scientific developments. This requires both top-down alignment and bottom-up engagement.

Some proposals for multi-stakeholder cooperation in the life sciences have been made. A team from Harvard University has proposed setting up a global genome editing observatory of stakeholders, including members of the DIYbio community, that can meet regularly to discuss
technological advancements, their desirability, and possible ethical and security implications.\textsuperscript{67} In addition, there have been various proposals for sector-specific national, regional or possibly global multi-stakeholder review boards to make decisions or provide guidance on new and emerging technological applications.

However, there are many important obstacles to engaging a wide range of stakeholders in the development of regulations. In many countries there is no tradition of public engagement in policymaking due to a hierarchical culture where engagement is not necessarily part of how regulations are developed. Furthermore, there is scant evidence for how to effectively engage multiple actors in policy building. It is as yet unclear what exactly it means to be representative, who should be engaged and how to account for inherent power differences. In many countries, there is no public provision for multi-stakeholder engagement in the research and innovation fields. There is a lack of knowledge and understanding of what organizations or individuals are operating in the innovation landscape and who they are interacting with. A quantitative and qualitative assessment of the actors populating the research, development, and innovation landscape needs to be conducted before the policy community can start strategizing on how to engage such stakeholders. Finally, there is a lack of communication and a resultant lack of trust between the innovation community and the biosecurity community. This is particularly true for the emerging DIYbio community, which is commonly perceived as a high-risk innovation environment.

Limiting inherent biases and establishing clear channels of communication are pre-requisites for bringing multiple stakeholders into governance frameworks.

\textsuperscript{67} Saha, Krishanu et al. (2018).
REFERENCE LIST


All conference materials including video recordings and speaker presentations are available on UNIDIR’s website here.

Related UNIDIR Publications:
Warmbrod, Kelsey Lane, James Revill & Nancy Connell. 2020. Advances in Science and Technology in the Life Sciences and their Implications for Biosecurity and Arms Control. UNIDIR. https://doi.org/10.37559/SecTec/20/01.

# 20 AUGUST 2020

## WELCOMING

**OPENING REMARKS**

Giacomo Persi Paoli - UNIDIR

**13:30**

## KEYNOTE ADDRESS

**Mitigating Risks, Harnessing Benefits and Demystifying Myths of Innovation in the Life Sciences**

Andrew Hessel - Humane Genomics Inc.

**13:45**

## CREATION: GENE EDITING / CRISPR

**MODERATOR**

Eleonore Pauwels - Global Center on Cooperative Security

**PANELISTS**

Pawan K. Dhar - Jawaharlal Nehru University

Pierson Millett - iGEM Foundation / University of Oxford

**14:30**

## PRODUCTION: DIYBIO & CLOUD LABS

**MODERATOR**

Jaime Yassif - Nuclear Threat Initiative

**PANELISTS**

Todd Kuiken - North Carolina State University

Peter Lee - Strateos

**15:45**

## CLOSING

**CLOSING REMARKS**

Giacomo Persi Paoli - UNIDIR

**16:45**
## 21 AUGUST 2020

### WELCOMING

**WELCOMING & HOUSEKEEPING**  
**GIACOMO PERSI PAOLI**  
**UNIDIR**  

### DELIVERY: NANOBIO TECHNOLOGY APPLICATIONS FOR DELIVERY

**MODERATOR**  
**KOBI LEINS**  
*University of Melbourne*  
**PANELISTS**  
**XIAN-EN ZHANG**  
*Chinese Academy of Sciences*  
**STEFFI FRIEDRICH**  
*AcumenIST*

### INNOVATIONS DEBRIEF: INSIGHTS & OPEN QUESTIONS FOR DISARMAMENT AND ARMS CONTROL

**PANELISTS**  
**DANIEL FEAKES**  
*UNODA*  
**FILIPPA LENTZOS**  
*King’s College London*

### MULTILATERAL GOVERNANCE OF INNOVATION, SCIENCE & TECH IN THE LIFE SCIENCES

**MODERATOR**  
**DANIEL FEAKES**  
*UNODA*  
**PANELISTS**  
**NISREEN ALHMOUD**  
*Jordan Royal Scientific Society*  
**CHENG TANG**  
*OPCW Scientific Advisory Board*  
**ABHI VEERAKUMARASIVAM**  
*Sunway University*  
**LOUISE BEZUIDENHOUT**  
*University of Oxford*  
**JANTINA DE VRIES**  
*University of Cape Town*

### MULTILATERAL GOVERNANCE IN ACTION: CHANNELING REFLECTIONS INTO MULTILATERAL AGENDAS

**MODERATOR**  
**RENA B WAIKOI**  
**AMARITA SOWTONG**  
**PANELISTS**  
**IZUMI NAKAMITSU**  
*High Representative for Disarmament Affairs*  
**AMB. CLEOPA KILONZO MAILU**  
*Permanent Representative to UNOG, Kenya*  
**AMB. MARIA TERESA T. ALMOJUELA**  
*Deputy Permanent Representative to UNOG, Phillipines*

### CLOSING

**CLOSING REMARKS**  
**RENA B WAIKOI**  
**AMARITA SOWTONG**
the 2020 innovations dialogue.

20-21 AUGUST 2020
LIFE SCIENCES, INTERNATIONAL SECURITY AND DISARMAMENT
CONFERENCE REPORT