

**WHO Consultative Meeting on a Global Guidance Framework  
to Harness the Responsible use of Life Sciences:**

**Meeting report, 11 March 2021**



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ISBN 978-92-4-002787-9 (electronic version)

ISBN 978-92-4-002788-6 (print version)

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**Suggested citation.** WHO consultative meeting on a global guidance framework to harness the responsible use of life sciences: meeting report, 11 March 2021. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

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## **Executive Summary**

The WHO Science Division organized a Consultative Meeting on a Global Guidance Framework to Harness the Responsible Use of the Life Sciences, on 11 March 2021, bringing a broad range of stakeholders that included academia, scientists and researchers, publishers and editors, security actors, public health officers, policy makers, research donors, and representatives from regional and UN entities.

The objectives of the meeting were to consult on the scope of the Global Guidance Framework and on the critical elements this framework should address. The outcomes of this consultation will contribute to inform the development of the Global Guidance Framework. The meeting consisted of presentations and plenary discussions guided by a series of key questions. Overall, participants recommended to set up, at international level, a common terminology covering safe, secure and responsible research. Two major themes emerged during the discussions: the need for an overall risk management and a unified approach as well as the importance of awareness, education and training across the different stakeholder groups.

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## **1. Background**

Advances in the life sciences and the advent of new technologies hold great promise for new and improved ways to address global health and support healthier populations worldwide. Science and technology (S&T) have an undisputed role in working towards WHO's 13th General Programme of Work to achieve the triple billion targets. Yet progress in the life sciences and associated technologies are not without risk. The risks under consideration in this report are those posed by accidents and the misuse of life sciences research, knowledge and technologies to cause harm.

The landscape of innovation in the life sciences is a global endeavour that is moving at a fast pace. The diffusion of knowledge, technologies and data, the diversity of actors involved in the life sciences and the convergence of the life sciences with other disciplines such as chemistry, engineering, artificial intelligence, machine and deep learning, computer science, and the physical sciences constitute major trends and developments that could benefit society and global health but could also pose new risks or increase existing risks. The applications of research, knowledge and technologies may generate risks caused by accidents, by inadvertent applications and by deliberate misapplications with the intention to cause harm. These risks need to be identified, mitigated and managed. Related to this, there is a need for a greater awareness among scientists, students, policy makers, the security communities and private sector on the potential risks of accidents and misuse associated with the life sciences, and a need for continued training and education for the responsible use of the life sciences.

In 2020, the WHO Research for Health Department organized three Dialogues on Dual Use Research of Concern<sup>1</sup> with the scientific communities, science editors and publishers and research donors to discuss and learn about current activities and challenges in addressing these risks. In the beginning of 2021, WHO initiated the development of a Global Guidance Framework to address these risks within the context of promoting the global health benefits of the life sciences. As part of this work, WHO organized this consultative meeting with a broad range of actors involving scientists, academies and science councils, publishers and editors, scholars, regulators, regional and international organizations to discuss and get input on the scope and the critical elements that this framework should address.

## **2. Meeting key points**

On 11 March 2021, 32 participants attended virtually the WHO Consultative Meeting on a Global Guidance Framework to Harness the Responsible use of Life Sciences (Annex 1). Soumya Swaminathan, the WHO Chief Scientist, welcomed the participants and briefed the meeting on the role of the Science division established in 2019. The Science division aims at anticipating and leveraging S&T advances for public health and clinical medicine, at putting centralized processes to develop timely standards and norms and adopting and scaling-up innovation and digital health.

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<sup>1</sup> <https://www.who.int/activities/ensuring-responsible-use-of-life-sciences-research>, accessed 13 April 2021.

The current pandemic has highlighted the risks posed by biological agents. Biological risks, whether natural or man-made, by accident or by design, can pose unprecedented challenges for public health. The Global Guidance Framework for the Responsible Use of Life Sciences will be aimed at providing Member States and other stakeholders with options to promote the responsible use of the life sciences and to protect against the potential risks caused by accidents and misuse. The development of this Global Guidance Framework coincides with the initiative launched by the United Nations Secretary General that established a UN Biorisk Working Group to strengthen the response of the international community to biohazards and to improve prevention and preparedness for the deliberate use of biological pathogens.

Participants were subsequently briefed by Anna Laura Ross, from the Emerging Technologies, Research Prioritization and Support unit, on the activities undertaken by the Research for Health Department, which contribute to risk prevention and mitigation. WHO approaches biorisk from a multifaceted perspective, from identification, prevention, mitigation to management and addresses this issue from a public health perspective. The unit comprises a Foresight function and activities related to governance and oversight mechanisms, which include the Global Guidance Framework. Raising awareness, engaging a wide range of stakeholders with a broad geographical scope and the ethical considerations associated with this topic constitute important elements of the efforts of the WHO in this area.

The Global Guidance Framework will build upon previous work and existing initiatives on dual use research and responsible life science research. Pre-existing work by WHO in this area include the Guidance on Responsible Life Sciences for Global Health Security (WHO, 2010)<sup>2</sup>, which developed a biorisk management framework for responsible life sciences research. This guidance needs to be revised in light of the advances in the life sciences and associated fields and their impact on risks and governance.

In the second session, participants discussed the different terminologies used for describing the risks caused by accidents and the misuse of the life sciences and briefly considered how S&T developments impact risks and governance. Emmanuelle Tuerlings briefly presented the origins and scope of different terminologies used by different communities, in particular dual use, dual use research and dual use research of concern, biosecurity and biorisk. Prior to the meeting, an online discussion forum had been set up for participants to share their thoughts on several questions, including on the existence of different terminologies. There was no consensus on a term that would best define dual use research and participants recognized the diversity of terminologies. At the meeting, participants were invited to answer the question “Is the diversity and plurality of terminologies a problem for governance?”, with over three quarter of the participants (79%) responding affirmatively.

In the plenary discussion, several participants noted that different terminologies create confusion and misunderstandings, especially when terms are interpreted differently by stakeholders and are translated into different languages. For some, the term dual use research of concern lacks a clear definition and suggests a false aspect of duality of being half good and half malicious. For others, the term also refers to categories of research that raise concerns about potential misuse. Furthermore, for some participants, the major obstacle for developing a governance framework was not due to a confusion around terminology. Rather, governance itself was deemed difficult. Changing established terms which are embedded in policies and different languages would be difficult. At the international level, participants heard that it would be helpful to agree on a common terminology that takes into account national variations and understandings. The importance of having public friendly terminologies was underlined along with the need to clearly define the risks under consideration and the mechanisms to address them. The importance of having a working definition in the context of the Global Guidance Framework was also stressed.

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<sup>2</sup> [Responsible Life Sciences Research for Global Health Security. A guidance document. Geneva: World Health Organization, 2010 \(WHO/HSE/GAR/BDP/2010.2\)](#), accessed 13 April 2021.

Participants agreed on the importance of moving towards a more unified and integrated biorisk management approach which includes laboratory biosafety, biosecurity and research. This term would act as an umbrella capturing the different risks and would create a broad, flexible and enduring framework. Some participants however noted that the terminology biorisk management could itself be compartmentalizing because it might not allow for the cross disciplinary dialogues that are required by the increasing convergence of disciplines. Scientists, regardless of their disciplines, need to have the capacity to analyze both the benefits and risks of their work. Research raising concerns does not only involve experiments with pathogens. Fields such as gene therapy, genome editing, synthetic biology, the neurosciences and immunology are increasingly being viewed as areas where risks of accidents and of misuse could emerge. In addition, data management, misinformation and disinformation were pointed out as areas for consideration. This broader range of disciplines need to be brought into a global management framework, and this is going to be a key challenge in developing this Global Guidance Framework. In addition, this management approach should not be seen as an endpoint but an iterative process that regularly reevaluates new ways in which life sciences create risks. For cases where risks and benefits are unknown or uncertain, it was highlighted that risk benefit assessments will not be the most appropriate tool, thus requiring additional means for evaluating and governing risks, challenges and uncertainties posed by new technologies.

The Global Guidance Framework should avoid creating lists of research of concern, of specific agents, technologies, research and outcomes as they lack flexibility and adaptability in an environment where S&T advances are rapidly unfolding and are potentially detrimental to legitimate research purposes. Instead, key principles for governance, tools, process and training should be developed to enable scientists and their institutions to identify and assess the potential risks and benefits of the life sciences, to look at options for risk mitigation and to communicate in a responsible manner. An all-risk management approach would promote a multi-sectoral approach and underscore the need for collaboration at different levels. Member States will need to implement this guidance in collaboration with other sectors and actors, including with the scientific communities, funding bodies, publishers and editors, security actors and the private sector. The scientific communities, which are in the best position to understand the new ways in which their research could create both benefits and risks, should be provided with adequate resources, information and training to undertake the risk assessments of their research. Additional perspectives and information from other stakeholder groups should be part of these assessments. The development of this Global Guidance Framework should therefore be accompanied by renewed robust stakeholder engagement to raise awareness and help to identify potential risks of their research.

In the third session, participants discussed the key elements of the Global Guidance Framework and provided inputs on the implementation and sustainability of the framework. Matthew Lim, from the Biosecurity and Health Security Interface (BSI), presented their activities on the risks posed by high threat pathogens. Their work will explore the impact of advances in S&T in the past 10 years on the risks posed by high threat pathogens and how these have changed since the publication of the WHO Guidance on Responsible life science research for global health security (2010). Their analysis will complement the work undertaken by Global Guidance Framework.

Katherine Littler, from the Global Health Ethics & Governance Unit, briefed the meeting on the ethical considerations that are a key part of any governance framework and presented the work of the WHO Expert Advisory Committee on Human Genome Editing. Some key learnings from the work of this Committee included: the necessity to articulate the values and principles underpinning a global governance framework; the importance of considering governance as an ecosystem which includes several parties and stakeholders with different responsibilities; the growing role of society in governance and decision making; the adaptability of a governance framework that should be a living document regularly updated; the capacity elements of the governments and stakeholders to be able to engage and implement the guidance; the importance of the interconnectivity between a particular technology and the broader context of emerging technologies; the importance of addressing systemic

issues for having a governance framework that works; and the role of scenarios to apply the key elements of the framework in a concrete manner.

In the plenary discussion, several participants commented on the importance of mapping existing mechanisms, building on pre-existing work, exploring collaborative efforts and identifying lessons learned where possible. For instance, the strengthening of existing structures such as ethics committee was emphasized, as was the importance of engaging a variety of stakeholders and of the role of engagement and communication.

On engaging with the industry, it was emphasized that one way to incentivize this sector could be through the use of standard setting organizations and positive role models. Another way could be the identification of good practices and corporate social responsibility. Industry is becoming increasingly aware of the need to demonstrate responsibility, safety and security in their work. In addition, industry could play a role in supporting universities and higher educational establishments to bring issues of responsibility into the professional development. Participants further stressed the increasing role of the private sector in funding research. Oversight mechanisms should cover both private and publicly funded research.

On engaging with the scientific communities, participants heard that scientists develop innovative approaches for thinking about the risks and benefits of their research. Articulating the ways in which the scientific communities can work with their institutions, policymakers and the global community to address these problems would be very important, including by engaging it in a consultative and deliberative process for policy making. The scientific communities also have a responsibility when it comes to communicating with public health agencies, other authorities and the public, mitigating the harms of misinformation and disinformation about their research. Infodemic, misinformation and disinformation amplify false narratives providing wrong information about health outcomes. These impact people's behaviors and lead to tangible effects that can cost lives, resulting in the same effects of harmful events under consideration by the Global Guidance Framework. Finally, engagement activities and communication should further include the security communities.

Engaging all relevant stakeholders will also be important for having a common language across sectors and given the increasing number of players in this area, the Global Guidance Framework needs to develop a common set of principles for governance that should guide policies and practices. It was pointed out that debates on the governance of these risks assume that there is interdependence between different stakeholders, all working towards to the same common goal. However, the presence of inequities between and among countries affect governance, including when inequities may lead to higher risk situations. This should be factored into the Global Guidance Framework.

### 3. Key takeaways and next steps

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