

Piloting the global guidance framework for the responsible use of the life sciences in Uganda

High level stakeholders' sensitization Meeting Report

15 March 2024, Kampala



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Abbreviations

BWC Biological Weapons Convention

DUR Dual Use Research

DURC Dual Use Research of Concern

STI Science Technology and Innovation

TWG Technical Working Group

WHO World Health Organization

UNCST Uganda National Council of Science and Technology

OPM Office of the Prime Minister

MDAs Ministries, Departments and Agencies

UNSCR 1540 United Nations Security Council Resolution 1540

IHR International Health Regulations

Executive Summary

Uganda has embarked on a pioneering initiative within the World Health Organization African Region (WHO AFRO) by piloting the Global guidance framework for the responsible use of life sciences, aimed at mitigating biorisks and governing dual-use research. Coordinated by the Uganda Office of the Prime Minister in collaboration with the World Health Organization this project signifies Uganda's commitment to enhancing national and regional biosecurity.

Since October 2023, Uganda has undertaken significant actions to pilot the framework, including national stakeholder engagement workshops. Notably, a situation analysis was conducted to document the current status at the time in biosafety, biosecurity and dual-use research governance in October 2023. A national stakeholders' workshop was then held from 21 to 23 November 2023 gathering over 80 stakeholders from diverse sectors. The stakeholders were sensitized on the framework, they appreciated the need to adopt the framework and collaboratively developed a draft roadmap for domesticating and operationalizing the framework in the country. Subsequently, during a technical stakeholders' workshop held from 6 to 7 March 2024, the draft roadmap was further refined for effective operationalization.

The high-level stakeholders' sensitization meeting held on 15 March 2024 marked a milestone in Uganda's dedication to the framework. Led by Monica Musenero, Minister of Science, Technology, and Innovation, and attended by over 50 high-level stakeholders, the meeting aimed to advocate for national buy-in and support for the framework's implementation.

The meeting started with several presentations to provide context to the meeting, including an overview of Uganda's biosafety, biosecurity, and dual-use research governance capacity, the rationale for adopting the framework, and an introduction to the pilot project and an overview of the framework. The roadmap from the previous stakeholder engagements was also presented at this meeting. Vibrant discussions followed each presentation, leading to concrete ways forward.

As a meeting outcome, the Minister of Science, Technology and Innovation made a very strong commitment by taking the overall lead to advance the domestication and operationalization of the framework in Uganda and assigned the government chief scientist in collaboration with Uganda National Council of Science and Technology (UNCST) to ensure the technical lead in the process of domesticating and operationalizing the framework in Uganda under the general coordination of the office of the Prime Minister.

Key next steps agreed upon at the meeting included; sensitizing relevant ministries to adopt the ministerial statement and commitment, and start discussing the mobilization of domestic funding, a harmonizing meeting on project implementation with UNCST, specifying roles and responsibilities in the final roadmap, continued engagement with other stakeholders, and documentation of Uganda's experience.

In summary, Uganda is proactively advancing responsible life sciences use, effective governance of dual-use research, and global health advancement through concrete actions outlined by the Minister of Science, Technology, and Innovation. This initiative reflects Uganda's commitment to biosecurity and sustainable development.

1. Introduction

Life sciences research and its associated technologies stand as cornerstones in the pursuit of global health equity, aligning with the United Nations Sustainable Development Goals (SDGs), particularly SDG 3 (good health and well-being). These advancements offer promises of healthier populations and improved well-being worldwide. However, amidst these promises lie inherent safety and security risks, exacerbated by the swift pace of developments, the proliferation of actors and sectors involved, and the gaps in governance. Recognizing this complex landscape, the World Health Organization (WHO) published the Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dualuse research (the framework). This framework, published in 2022, aims to equip Member States and stakeholders with the principles, tools, and mechanisms necessary to navigate these risks while harnessing the transformative potential of life sciences for global health.

Uganda, acknowledging both the opportunities and challenges posed by advancements in life sciences, embraced a unique opportunity to pilot the implementation of this framework within the AFRO region. Under the coordination of the Office of the Prime Minister, Uganda embarked on a journey to pilot the framework in August 2023. This journey began with a series of strategic engagements, including a national stakeholders' sensitization workshop held at Speke Resort Munyonyo, Kampala, Uganda, from 21 to 23 November 2023. At this workshop, over 80 stakeholders representing diverse sectors such as human health, animal health, environment, security and defense, academia, and industry, converged to deepen their understanding and awareness of the principles of responsible life sciences use and dual-use research governance. In this workshop, the represented stakeholder groups acknowledged the framework was relevant and would key in contributing to the establishment of country specific mechanisms to mitigate biorisks and govern dual-use research. Together, the stakeholders collaboratively crafted a draft roadmap for the framework's implementation in Uganda.

Building upon this foundation, a technical stakeholders' workshop convened at the WHO country office in Kampala on 6 to 7 March 2024. Here, about 30 technical experts across various domains furthered their knowledge and deliberated on the operationalization of the framework. Through meticulous deliberation, they identified key stakeholders in the operationalization of the framework and defined the roles of each stakeholder group, reviewed the draft roadmap from the national sensitization workshop that included the strategies and practical actions essential for effective implementation.

This momentum culminated in the convening of a high-level stakeholders' sensitization meeting on 15 March 2024, where Uganda's commitment to the framework was reaffirmed, and progress on the pilot project was shared. This meeting, attended by esteemed figures such as Musenero Monica, the Minister for Science, Technology and Innovation for Uganda, Daniel Kyabayinze, the Director of Public Health of the Ministry of Health for Uganda, Emmanuel Turyatunga, representative of the Office of the Prime Minister (OPM), and many other distinguished delegates representing key Ministries, Departments and Agencies. This served as a testament to Uganda's dedication to responsible scientific advancement.

2. Objectives of the meeting

1) To raise awareness among high-level stakeholders about the global guidance frameworks for responsible use of life sciences and introduce the pilot project.

- 2) To secure ownership of the operationalization process of the framework in Uganda.
- 3) To gain commitment and support from high-level stakeholders for the implementation of the roadmap and effective operationalization of the framework in Uganda.

3. Summary of the discussions

The convened over 50 high level stakeholders including the Minister of Science, Technology and Innovation, Representative of the Minister of Health, Director General Uganda National Health Research Organization, Executive Secretary of Uganda National Council of Science and Technology, Executive Director – Joint Clinical Research Center. Heads of various institutions and their technical officers spanning various sectors, encompassing human health, nonhuman animal health, plants and agriculture, environment, security, internal affairs, foreign affairs, academia were present and various other development and implementing partners. Also in attendance were representatives from the WHO Country Office for Uganda and WHO headquarters. The meeting sessions were moderated by Sandra Matinyi, Consultant – Public Health from WHO Country Office for Uganda.

3.1 Meeting opening and objectives of the meeting.

The meeting was opened by Monica Musenero, Minister of Science, Technology and Innovation of Uganda. The Minister commenced the meeting with a warm welcome, emphasizing the transformative journey ahead as Uganda pilots the global guidance framework on responsible use of life sciences. Highlighting Uganda's rich biodiversity and innovative research landscape, the Minister stressed the importance of establishing robust mechanisms for biosafety, biosecurity, and dual-use research governance. Acknowledging the dual-use potential of research projects, the Minister underscored the urgency of adopting the framework to mitigate risks and promote responsible scientific conduct. She indicated that the decision to pilot the framework reflects Uganda's commitment to international obligations and aspirations for sustainable economic development and global health security. Emphasizing the far-reaching consequences of irresponsible research practices, the Minister called for collective commitment to ethical governance and international cooperation. The Minister expressed gratitude for the support of stakeholders, urging collaboration towards a future defined by responsibility, innovation, and collaboration.

Other distinguished guests who gave opening remarks included Daniel Kyabayinze, Director Public Health, Ministry of Health of Uganda who represented the Minister of Health. He underscored Uganda's commitment to piloting the operationalization of the global guidance framework for responsible life sciences use. Highlighting Uganda's resilience in health challenges, he emphasized the significance of aligning with the framework to foster an innovative yet ethically grounded research environment. He emphasized the importance of leveraging responsible research to safeguard public health. He commended the collaborative nature of the meeting recognizing it as a pivotal step towards shaping the narrative of responsible life sciences use both nationally and regionally.

These were followed with remarks by Emmanuel Turyatunga, Commissioner from the Office of the Prime Minister on behalf of the OPM. He affirmed Uganda's commitment to integrating responsible scientific practices and fostering an ethically sound research environment amidst

prevailing challenges such as gaps in biosafety and biosecurity legislation. He brought to light some of Uganda's vulnerabilities including emerging and reemerging infectious diseases with an example of a recent anthrax outbreak that pause high biosafety and biosecurity risks and call for collective efforts to address. He also highlighted the role of the OPM as a coordinator of efforts to address these threats and the coordination of the project to piloting the framework in Uganda.

The other remarks were given by Andrew Niwagaba Bakainaga, Country Advisor – Health systems strengthening from the WHO country office for Uganda who represented the WHO country representative for Uganda. He emphasized the critical importance of the meeting in sensitizing key stakeholders about the global guidance framework for responsible use of life sciences and its piloting in Uganda. He highlighted the dynamic nature of scientific research and the need for responsible and ethical practices. He reechoed the vulnerabilities that gaps in biosafety, biosecurity and dual use research governance create in the country that require action. He hailed the framework as a transformative step towards enhancing health research governance and fostering a culture of ethics and integrity. In conclusion, he expressed hopes for productive discussions and emphasized the shared commitment to advancing responsible life sciences use in Uganda and beyond.

3.2 Setting the scene for the meeting

This session included presentations that provided context to the meeting. The first presentation was delivered by Joseph Nkodyo, the National Coordinator, Biosafety and Biosecurity program for the Uganda Ministry of Health. He provided a comprehensive overview of Uganda's national biosafety, biosecurity and dual-use research governance landscape, emphasizing an integrated approach to biorisk management. He highlighted the concept of dual-use research, acknowledging its potential benefits while underscoring the importance of vigilance against intentional misuse. From his presentation, it was evident that Uganda has made strides in building national capacity for biosafety and biosecurity through various initiatives such as biosafety and biosecurity training, adopting a One Health approach, and establishing the UNCST for research oversight including dual-use research. Additionally, regular audits and the developed national biorisk management toolkits contribute to bolstering capacity. It was noted that dual-use research governance was not adequately covered in some of the existing national efforts. Some of the challenges he highlighted include the absence of distinct laws on biosafety and biosecurity and dual-use research governance, siloed funding, infrastructure gaps, and insufficient collaboration among stakeholders. To address these challenges, key priority areas for action were outlined, including enacting legislation, integrating biosafety and biosecurity into training curricula and both pre-service and in service levels, and enhancing infrastructure development. At the moment, Uganda's biosafety, biosecurity and dual-use research governance efforts are supported by some national guidelines, including acts such as the National Disease Act and guidelines such as the National Laboratory Biosafety Manuals. Institutional frameworks such as biorisk management policies and manuals further guide biosafety practices.

In summary, Joseph Nkodyo's presentation highlighted Uganda's ongoing efforts to strengthen biosafety and biosecurity measures, acknowledging challenges while emphasizing the importance of collaborative action and legislative support to safeguard public health and promote responsible research practices. And he reechoed the significance of the framework in the establishment of national mechanisms for dual-use research governance.

The second presentation aimed at providing rationale for piloting the framework in Uganda as well as the overview of the pilot project. This was provided by Emmanuel Turyatunga, Commissioner from the Office of the Prime Minister. He emphasized the Global Guidance Framework for the Responsible Use of Life Sciences, published by WHO in 2022 is a pivotal resource that provides comprehensive guidance, values, and principles to mitigate bio risks and govern dual-use research (DUR) globally. In an era characterized by rapid technological advancements and innovations, the framework addresses the pressing need to navigate the potential benefits and risks associated with life sciences research, including the convergence of technologies and gaps in governance. As rationale for domestication and operationalization of the framework in Uganda, he stated that Uganda, like many nations, the implementation of this framework is not only a strategic imperative but also a legal and ethical obligation rooted in international instruments such as the Biological Weapons Convention (BWC) and United Nations Security Council Resolution 1540 (UNSCR 1540). Uganda's commitment to these instruments underscores its responsibility to prevent the proliferation of biological weapons and ensure biosecurity. By aligning with these international obligations, the framework serves as a proactive measure to mitigate biosecurity risks, strengthen capacities for global health security, and elevate Uganda's biosafety and biosecurity standards. Furthermore, integration of the framework into national policies and regulations not only enhances compliance with International Health Regulations (IHR) but also reinforces the nation's resilience against potential security threats. He concluded by emphasizing that, the adoption of the Global Guidance Framework represents a strategic step towards achieving a more secure, resilient, and ethically sound foundation for the responsible use of life sciences in Uganda.

Subsequently, he provided a presentation on the piloting of the framework in Uganda highlighting the pivotal role played by the country as experiences and lessons learned from the pilot would guide implementation of the framework in the AFRO region. Beginning with Uganda's agreeing to be a pilot country in January 2023, he presented the subsequent milestones that included a national situation analysis that was conducted in October 2023, followed by a critical national stakeholders' sensitization workshop held in November 2023. In this workshop, stakeholders from relevant ministries, departments and agencies (MDAs) were sensitized on the framework, they evaluated the relevance of the framework in addressing their needs and collaboratively developed a roadmap to guide effective implementation of the framework in Uganda. This was followed by a technical stakeholder's workshop in March 2024. All these initiatives served to engage key actors and solidify commitment towards the initiative, setting the stage for the forthcoming national domestication and operationalization phase in 2024.

The third presentation on the overview of the framework was delivered by Sandra Matinyi. She introduced the global guidance framework for the responsible use of life sciences to provide insights into what it covers and how stakeholders at different levels can utilize it. She highlighted that the global framework was established in September 2022 to guide nations in the establishment of governance structures for dual-use research that aligns with the country's context by providing tools and mechanisms to evaluate and categories research. She highlighted the key elements in the framework including sources of risks and the consequences of dual use research. In her presentation, the challenges and gaps in governance of biorisks based on global context and tools and mechanisms for the governance of biorisk management were also elucidated. She also emphasized on the need for collaboration and engagement among different stakeholders to address the evolving challenges and major gaps in the governance of biorisks.

She presented the summary of the practical tools and mechanisms, including an overview of the six-step approach.

3.3 Presentation of the road map

The roadmap that had been developed at the national stakeholders' sensitization workshop in November 2023 and later reviewed during the technical stakeholders' workshop in March 2024 was presented by Lawrence Byamugisha, Professor from Makerere University.

He presented the key strategies that had been earmarked to facilitate effective operationalization of the framework in Uganda. These included establishment of a select a dual use research governance in life science steering committee to integrate the dual use research within the existing One Health strategic plan to guide the implementation and operationalization of the framework, advocacy for increased budget allocation and funding opportunities for research to include dual-use research governance and advocacy for inclusion of the dual-use research governance Key Performance Indicators (KPIs) into the National monitoring and evaluation framework to enhance timely reporting on dual-use research.

Other strategies presented include the need to strengthen multisectoral engagement to ensure widespread ownership and collaboration across various sectors, enhancing international collaboration and information-sharing systems and platforms, building capacity through training and mentorship programs aligned with the framework's elements, enhancing communication awareness on the framework's implementation through promotion, collaboration, and partnerships. Strengthening research oversight to include dual-use research governance was identified as essential, emphasizing the need for comprehensive oversight mechanisms.

He also presented various requests to the Minister on behalf of other stakeholders that including;

- Request to the Minister to take leadership of the process of domestication and national operationalization of the framework and have it incorporated into her ministry.
- Engage with other Minister from relevant ministries to sensitize them on the framework and call upon for their active support in the domestication of the framework at the various levels such as inclusion of dual-use research governance in the respective MDAs plans.

3.4 Comments and discussions by the high-level stakeholders

During the meeting, the high-level stakeholders provided comments and engaged in extensive discussions regarding the presentations made. They emphasized the critical need for comprehensive support for dual-use research alongside existing biosafety and biosecurity initiatives, leveraging the capacity already built in the latter domain.

The Minister for science, Technology and Innovation, Monica Musenero highlighted the intricacies involved in synthesizing a comprehensive biosafety and biosecurity law, emphasizing the ongoing efforts within her Ministry to refine legislation while navigating its complexities.

The stakeholders identified several gaps during the meeting, including a deficiency in human resources and capacity building within the realm life sciences. Additionally, they highlighted that there is a pronounced need for enhanced technology transfer mechanisms across institutions and heightened training efforts focused on life sciences research to bridge existing gaps. Moreover, a call for greater openness and information sharing in research was also underscored, highlighting the importance of collaborative efforts and transparent communication channels. Furthermore, it was noted that the Uganda National Council of Science and Technology needs to engage with diverse stakeholders to facilitate effective inventory taking of existing research including dual-use research and capacity building initiatives, emphasizing the necessity for comprehensive collaboration and strategic partnerships to address these critical gaps comprehensively.

Other strategies aimed at enhancing awareness on concepts of biosafety, biosecurity and dualuse research governance and the framework were discussed. The notion of collaborative endeavours between government entities and non-governmental organizations in research, especially within the realm of life sciences, emerged as a proactive measure to ensure alignment with national research priorities and maximize impact. Convening of a harmonization meeting among stakeholders prior to national program implementation of the framework was identified with the aim to facilitate cohesion and streamline efforts.

The imperative of regulatory frameworks within the private sector to fortify biosafety and biosecurity and dual-use research governance measures garnered attention, highlighted by the Executive Director of UNCST. The Minister for Science, Technology and Innovation further elucidated concerns surrounding the insufficient focus on crop science, advocating for bolstering the plant sector to proactively mitigate potential risks and enhance agricultural sustainability. She reiterated the paramount importance of the Uganda National Council of Science and Technology's active involvement in overseeing research endeavours and championing the domestication of framework through WHO courses based on the framework to augment capacity building initiatives and increasing awareness on biorisk management and dual-use research governance. These comprehensive discussions underscored the multifaceted nature of biosafety and biosecurity governance, emphasizing the imperative of collaborative, multidisciplinary approaches to effectively address emerging challenges and ensure sustainable progress in safeguarding public health and environmental integrity.

4. Meeting Outcomes

As the meeting outcome, the Minister of Science, Technology and Innovation pronounced her very strong commitment to advancing the operationalization of the framework in Uganda. The honourable Minister guided as follows;

- UNCST as the technical authority would take lead in the domestication and operationalizing of the framework in Uganda. This will happen under the general coordination of the OPM.
- The minister will oversee the establishment of a task force to comprehensively review the framework and identify KPIs for monitoring as the country domesticates the framework.

- The Ministry of Science, Technology and Innovation will take the responsibility to continue to communicate the framework clearly to other key stakeholders. Some of the initiatives earmarked to improve on awareness raising on biosafety and biosecurity and dual-use research included; Inclusion of the WHO trainings on dual-use research governance and responsible use of life sciences as a prerequisite for research protocol approvals, nomination to Research Ethics Committees or Institutional Research Committees etc. Inclusion of the training on biosafety, biosecurity and dual-use research governance into the training curriculum

The Minister committed to convene and table the framework before other Ministers and present a communique (commitment statement) for their review before signing as a commitment to a number of actions that would contribute to effective operationalization of the framework in Uganda. Areas of commitment included commitment to;

- putting in place robust national mechanisms for intersectoral coordination and partnerships to facilitate the implementation of framework and its integration into existing related programme.
- advocate for expansion of the budgetary allocations towards research to cater for arising needs including dual use research governance.
- introduction of the concept of biosafety, biosecurity and dual-use research governance to different levels of education including pre-service and in-service levels.
- put in place a mechanism for visibility and documentation and incentivize the sharing of experiences, success stories and best practices to feed into to regular national monitoring and evaluation in order to measure progress and lessons learnt.

5. Next steps: Immediate action items and follow-up activities

As next steps from the meeting, the following actions were agreed upon;

- 1. Government cabinet meeting to sensitize relevant Ministries involved on the framework to adopt the Ministerial statement and commitment, and start discussing the mobilization of domestic funding.
- 2. Meeting with UNCST to harmonize the project implementation.
- 3. Specification of roles and responsibilities and timeframe in the final roadmap for the domestication and operationalization of the framework in Uganda to keep accountability and measure collective successes.
- 4. Continued bilateral meetings with other key stakeholders' groups to secure their engagement and commitment as well as other awareness raising initiatives.
- 5. Documentation and dissemination of Uganda's experience and lessons learned on piloting the global guidance framework for responsible use of life sciences.

In conclusion, the high-level stakeholders' meeting showcased Uganda's dedication to piloting the global guidance framework for responsible life sciences use. The Minister of Science,

Technology, and Innovation outlined concrete actions to advance the framework's implementation, emphasizing inter-ministerial collaboration and stakeholder commitment. Moving forward, efforts will focus on sensitization, harmonization, roadmap finalization and implementation, and documentation of Uganda's experience. These initiatives reflect Uganda's proactive stance towards responsible life sciences use and global health advancement.

References

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- 2. Regional workshop to operationalize the global guidance framework for the responsible use of the life sciences in the WHO African Region.

Annex 1

List of participants from the high-level stakeholders' sensitization meeting on piloting the global guidance framework for the responsible use of life sciences in Uganda on 15 March 2024.

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