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

Mitigating biorisks and governing dual-use research in Uganda

August 2023 – July 2024, Kampala, Uganda

World Health Organization

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Contents

Tables

Figures

Foreword

The field of life sciences is evolving rapidly, driven by remarkable innovations in biotechnology, artificial intelligence, and health research. These advancements are instrumental in addressing some of the world's most pressing challenges—from combating infectious diseases to developing life-saving therapies and diagnostics. However, the increasing sophistication of life sciences also brings unprecedented risks, particularly in the realm of dual-use research (DUR) and dual-use research of concern (DURC). Such research, while essential for scientific progress, carries the potential for misuse, either intentionally or accidentally, threatening global health, security, and the environment.

It is in response to these emerging risks that the World Health Organization (WHO) issued in 2022 the global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research.
This framework offers a vital road map for countries seeking to balance the benefits of life sciences research with the imperative to prevent its potential misuse. Uganda's decision to pilot this framework reflects the nation's strong commitment to safeguarding public health and promoting responsible science, not only for the benefit of its own citizens but also as a model for the global community.

The pilot initiative, coordinated by the Office of the Prime Minister and supported by WHO, represents a groundbreaking effort to assess and strengthen Uganda's biosafety and biosecurity capabilities. This work is particularly significant given the growing complexity of dual-use research and the need for comprehensive frameworks to mitigate biorisks. The lessons learned from Uganda's pilot will have far-reaching implications, informing similar efforts in other WHO Member States and contributing to the global discourse on responsible science governance.

The collaboration between Ugandan institutions, ministries, researchers, and stakeholders during the pilot phase has been exemplary. It underscores the importance of a multisectoral approach, bringing together the scientific, healthcare, and regulatory communities to ensure that life sciences research is conducted in a safe, secure, and ethically responsible manner. The pilot's success highlights the critical role of awareness-raising, capacity building, and stakeholder engagement in advancing biosafety and biosecurity.

This report is the culmination of Uganda's pilot of the WHO global guidance framework for the responsible use of life sciences and serves as a key resource for nations worldwide. It outlines Uganda's achievements, the challenges encountered, and the strategic recommendations necessary for fully implementing the framework. Importantly, it provides a road map for continued collaboration between WHO, national governments, and research communities to ensure that life sciences research is a force for good, protecting health while minimizing the risks of misuse.

I commend Uganda for its leadership in piloting this important framework and thank all the institutions and stakeholders who contributed to its success. The insights gained from this initiative will undoubtedly advance global efforts to strengthen biosafety and biosecurity, ensuring that scientific progress continues to benefit humanity without compromising our collective safety.

Hon. Dr. Monica Musenero Masanza
Minister of Science, Technology and Innovation - Office of the President

Signature

Preface

The convergence of life sciences, biotechnology, and artificial intelligence presents a unique and powerful opportunity to address many of the world's pressing health challenges. With rapid advancements in these fields, new possibilities emerge for disease prevention, diagnosis, and treatment—offering immense potential to improve global health outcomes. However, alongside these benefits comes a growing recognition of the inherent risks associated with dual-use research, where scientific innovations designed for good can also be misused for malicious purposes or inadvertently result in harmful biological events.

Like many nations, Uganda faces the dual challenge of promoting scientific progress while ensuring that advances in life sciences are governed responsibly. The need for effective regulation and oversight of dual-use research (DUR) and dual-use research of concern (DURC) has become a critical issue for governments, research institutions, and the broader scientific community. It is against this backdrop that Uganda embraced the opportunity to pilot the framework.

The pilot phase of this project reflects Uganda's commitment to enhancing biosafety and biosecurity within its life sciences sector. By engaging a wide range of stakeholders—including policymakers, technocrats, research institutions, healthcare providers, and civil society—the project sought to create a strong foundation for the responsible governance of dual-use research. The pilot activities, coordinated by the Office of the Prime Minister and supported by the WHO Country Office, involved baseline assessments, workshops, and high-level stakeholder engagements, each designed to raise awareness, identify gaps, and lay the groundwork for the adoption and implementation of the framework in Uganda.

This report captures the outcomes of that pilot phase, documenting the lessons learned and the challenges encountered. It also outlines a set of actionable recommendations to guide the next steps in domesticating the framework within Uganda's existing legal and regulatory environment. The pilot revealed a clear need for improved awareness, capacity building, and the development of clear policies and mechanisms to regulate dual-use research and dual-use research of concern. It underscored the importance of fostering collaboration between government agencies, academic institutions, and international partners in the effective governance of life sciences research.

The journey to responsible governance of life sciences in Uganda is ongoing. This pilot project represents a critical first step, but much remains to be done. As we move forward, it is imperative that all stakeholders remain engaged and committed to the process, ensuring that the framework is fully operationalized and integrated into Uganda's biosecurity landscape.

On a global scale, Uganda's experience with this pilot project can serve as a model for other countries seeking to adopt the framework. The insights and recommendations presented in this report will contribute to the growing body of knowledge on how to responsibly govern dual-use research and mitigate biorisks. By sharing our experience, we aim to support international efforts to promote responsible life sciences research, enhance global health security, and prevent the misuse of scientific advancements.

We are grateful to colleagues from the World Health Organization, the Office of the Prime Minister, the Ministry of Science, Technology, and Innovation, and all stakeholders who contributed to the success of this pilot project. Their collective efforts have been invaluable in ensuring that Uganda remains at the forefront of biosecurity and biosafety governance.

As we continue this vital work, we must keep in mind that the responsible use of life sciences is not only a national priority but also a global responsibility. Together, we can ensure that scientific progress is matched by the safeguards necessary to protect humanity from the risks posed by dual-use research.

Dr. Charles Kuria Njuguna
Country Representative WHO Uganda

Signature

Acknowledgement

This report results from a collaborative process involving various stakeholders from Government Ministries, Departments, Agencies (MDAs), Research Institutions, Civil Society and Academia, coordinated by the Office of the Prime Minister with support from the WHO Country Office.

The team that invested their valuable time, effort and expertise to write this report comprised technical and subject matter experts, synthesized information from stakeholder engagements and workshops leading to the final report. The names and institutional affiliations whose collaborative efforts contributed to the completion of this report are listed below;

Andrew Bakainaga, Country Advisor World Health Organization, Kampala, Uganda.

Bencliff Wenga, Laboratory Technologist, Bududa District Local Government, Bududa, Uganda.

Emmanuel Kato Sebunya, Laboratory Technologist, Nuo Bioscience, Kampala, Uganda.

Emmanuel Turyatunga, Assistant Commissioner, Office of the Prime Minister of Uganda, Kampala, Uganda.

Joseph Nkodyo, National Biosafety and Biosecurity Coordinator, National Health Laboratory and Diagnostics Services, Kampala, Uganda.

Lawrence Mugisha, Associate Professor, Makerere University, Kampala, Uganda.

Maxwell Otim Onapa, Associate Professor, Busitema University, Mbale, Uganda.

Michael Roggers Eilu, Laboratory Technical Advisor, Infectious Diseases Institute, Kampala, Uganda.

Musa Kwehangana, Biosafety Officer, Uganda National Council of Science and Technology, Kampala, Uganda.

Sandra Matinyi, Public Health Consultant, World Health Organization, Kampala, Uganda.

Susan Kerfua, Senior Research Scientist, National Agricultural Research Organisation, Kampala, Uganda.

Coordination and Technical Support

Anna Laura Ross, Unit Head, Emerging Technologies, Research Prioritisation and Support, Research for Health, Science Division, Geneva, Switzerland.

Emmanuelle Tuerlings, Technical Officer, Emerging Technologies, Research Prioritisation and Support, Research for Health, Science Division, Geneva, Switzerland.

John Reeder, Director of the Research for Health department, Science Division, Geneva, Switzerland.

Soatiana Cathycia Rajatonirina, Technical Officer, Emerging Technologies, Research Prioritisation and Support, Research for Health, Science Division, World Health Organization, Geneva, Switzerland.

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Special thanks to the individuals, organizations and government MDAs who participated in the Stakeholder Mapping field activity. The insights shared in the online survey greatly contributed to development of this report and the operationalization of the framework.

Abbreviations

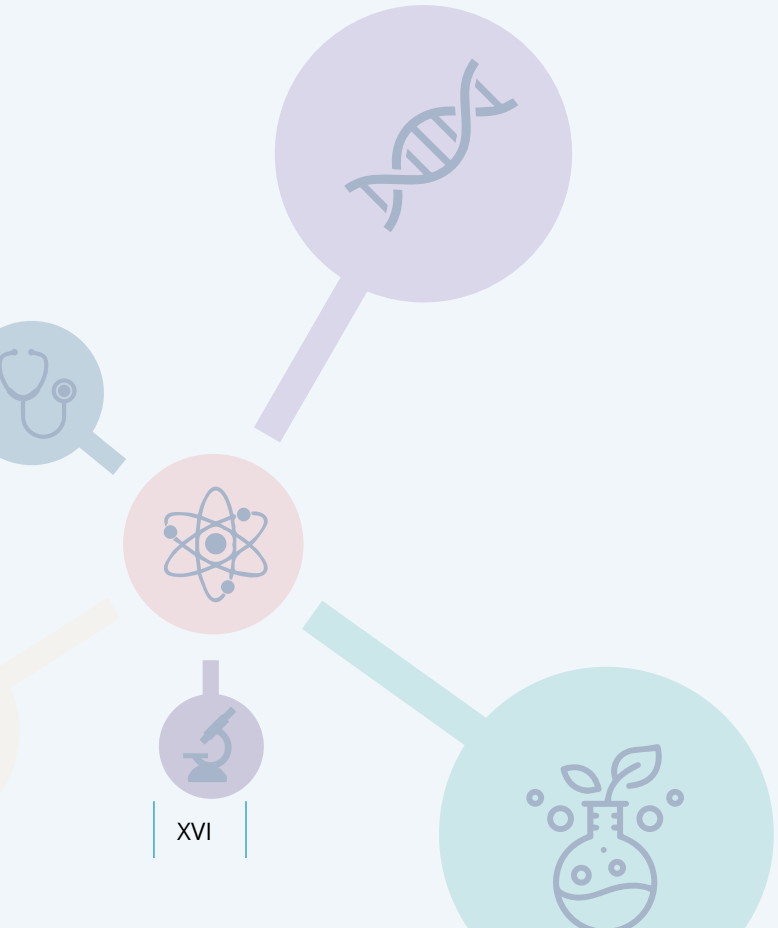
Africa CDC	Africa Centres for Disease Control and Prevention
CBD	Convention on Biological Diversity
CDC- U.S.	Centers for Disease Control and Prevention
DUR	Dual-Use Research
DURC	Dual-Use Research of Concern
FAO	Food and Agricultural Organization of the United Nations
GHSA	Global Health Security Agenda
JCRC	Joint Clinical Research Centre
IHR	International Health Regulations
JEE	Joint External Evaluation
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
NARO	National Agricultural Research Organization
OPM	Office of the Prime Minister
STI	Science, Technology and Innovation
TAG-RULS DUR	Technical Advisory Group on Responsible Use of Life Sciences and Dual-Use Research
TWG	Technical Working Group
UNCST	Uganda National Council of Science and Technology
UNHRO	Uganda National Health Research Organisation
UNSCR 1540	United Nations Security Council Resolution 1540
WHO	World Health Organization
WHO AFRO	World Health Organization Regional Office for Africa
WOAH	World Organisation for Animal Health

Glossary

Awareness raising:	Provision of information for the scientific community and the broader global community of the importance of biorisks as an essential part of responsible working practices in basic and applied life sciences.
Biological agent:	A microorganism, virus, biological toxin, particle, or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity, or otherwise create a hazard to humans, nonhuman animals, or plants.
Biological diversity (biodiversity):	The variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.
Biorisk:	The probability or chance that an event caused by accidents, inadvertent or deliberate misuse of the life sciences can adversely affect the health of humans, nonhuman animals, plants and agriculture, and the environment.
Biorisk management:	An integrated, overarching approach to address the risks associated with the life sciences research enterprise, from accidents and inadvertent actions to deliberate misuse. Biorisk management relies on three core pillars: biosafety, laboratory biosecurity and the oversight of dual-use research. Biorisk management involves the quantitative or qualitative forecasting and evaluation of the probability of harm occurring and subsequent consequences (risk assessment), together with the identification and implementation of technologies, measures or practices to avoid or minimize their likelihood or impact (risk mitigation).
Biosafety:	Containment principles, technologies, measures and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.
Biosecurity:	Policies, principles, technologies and practices implemented for the protection and control of and accountability for biological material, technology and information or the equipment, methods, skills and data related to their handling. Biosecurity aims to prevent intentional or accidental unauthorized access to, and loss, theft, misuse, diversion or release or even weaponization of such commodities.

Dual-use:	Knowledge, information, methods, products or technologies generated by peaceful and legitimate research that may be appropriated for non-peaceful or harmful purposes.
Dual-use research:	Research conducted for peaceful and beneficial purposes that has the potential to produce knowledge, information, methods, products or technologies that could also be intentionally misused to endanger the health of humans, nonhuman animals, plants and agriculture, and the environment. In the context of this framework, it refers to work in the life sciences, but the principles are also applicable to other scientific fields.
Dual-use research of concern:	Dual-use research of concern (DURC) describes research that is conducted for peaceful and beneficial purposes, but could easily be misapplied to do harm with no, or only minor, modification. This term has generally been used for research in the life sciences. DURC encompasses everything from information to specific products that have the potential to create negative consequences for health of humans, nonhuman animals, plants and agriculture, and the environment.
Governance:	The norms, values and rules of the processes through which public affairs are managed so as to ensure transparency, participation, inclusivity and responsiveness. Governance also represents the structures and processes that are designed to ensure accountability, transparency, responsiveness, adherence to the rule of law, stability, equity and inclusiveness, empowerment, and broad-based participation.
Life sciences:	All sciences that deal with living organisms, including humans, nonhuman animals, plants and agriculture, and the environment, or products of living organisms or that incorporate components derived directly or synthetically from living organisms; the life sciences include but are not limited to biology, biotechnology, genomics, proteomics, bioinformatics, pharmaceutical and biomedical research and technologies.
Pathogen:	A biological agent capable of causing disease in humans, nonhuman animals or plants.

Policies:	Include laws, regulations, standards, guidelines, best practices, codes of ethics, research review processes, training and education.
Risk:	A combination of the probability of harm occurring and the severity (consequences) of that harm if it were to occur.
Risk assessment:	A systematic process – quantitative or qualitative – of gathering information and evaluating the nature, probability and magnitude of potential harms and determining the appropriate control measures to minimize or otherwise mitigate the risks.
Stakeholders:	Persons or groups that have an interest in a policy or activity. They include scientists, the scientific community, ethics committee members, institutional and repository managers, biosafety officers, funding bodies, publishers, editors, security, regulators, authorities, civil society networks, the private sector, other relevant organizations and the public.



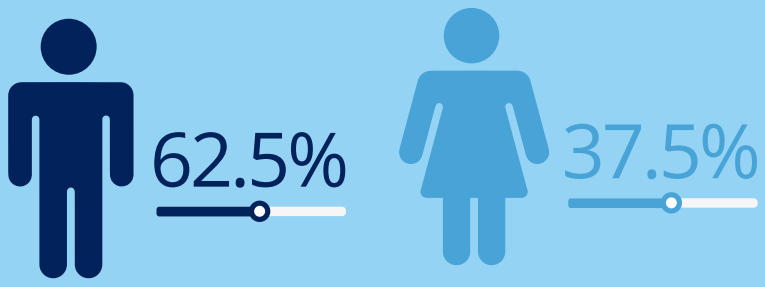
Executive summary

Globally, there is strong recognition and appreciation in the advancement of life sciences research, biotechnology, and artificial intelligence tools. These advancements facilitate rapid development of medicines, therapeutics, vaccines and diagnostics needed to address ever-increasing challenges in medical provisions and public health interventions. However, these advancements in life sciences research also present unprecedented biorisks to humans, animals, plants and the broader environment as they can cause detrimental accidental biological events or be easily misused by wrong elements for malicious purposes. Hence, it has become apparent that there is a need to regulate the dual-use research (DUR) and dual-research of concern (DURC) in life sciences.

A multidisciplinary and multisectoral regional workshop organized by the WHO Science Division in collaboration with WHO Regional Office for Africa (WHO AFRO) and the Africa Centre for Disease Control and Prevention (Africa CDC) was held in Nairobi, Kenya, 24–25 January 2023.

As such, Uganda embraced and accepted to pilot the framework published by World Health Organization (WHO) in 2022. The purpose of the pilot was to create awareness about the framework among policy makers, technocrats across Government Ministries, Departments and Agencies (MDAs) in Uganda, map key stakeholders, review current state of biosafety and biosecurity in relation to life sciences research, perform gap analysis and establish the roadmap for adoption and implementation of the framework.

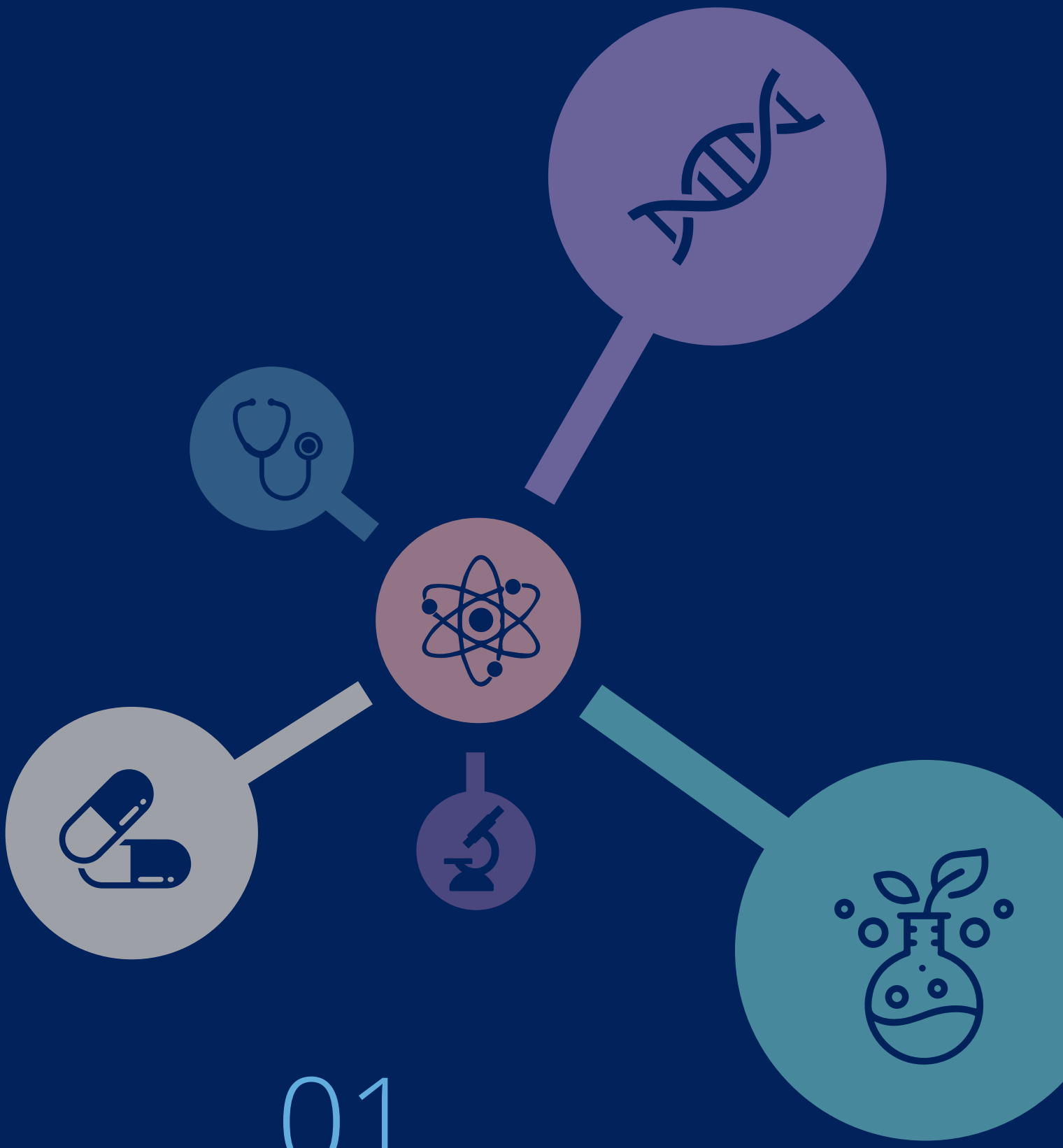
The pilot was coordinated by the Office of the Prime Minister (OPM) Uganda with support from the WHO Country Office for Uganda that facilitated the development of a concept note to be implemented between October 2023 and March 2024. A field-based survey was conducted in October 2023 revealed that 80% of the assessed institutions were unfamiliar with the framework. 36 institutions representing ministries, departments and agencies (MDAs), research institutions, universities, healthcare providers, pharmaceutical companies and NGOs, community groups, were assessed for biosafety, biosecurity implementation and awareness in life sciences research. The assessment was subsequently followed by three workshops targeting different stakeholders. The workshops were held at different times within the pilot phase with the first one from 21 to 23 November 2023 and the second one from 6 to7 March 2024. These were followed by a high-level stakeholders engagement workshop on 15 March 2024.



The three workshops were attended by a total of 160 participants, of which 60 were females and 100 males.

The participants who represented different MDAs attended at least one of the workshops and were sensitized about the framework and guided on how to use it during the adoption and implementation. From the three workshops, it emerged strongly that there is a need to regulate life sciences research especially the dual-use research (DUR). It was observed that Uganda lacked the necessary laws, regulations and policies for monitoring DUR. It was envisaged that adoption and implementation of the framework would accelerate the existing efforts to establish the legal framework for biosafety and biosecurity. Furthermore, the limited awareness and the lack of agreed mechanism for adoption and implementation observed from the baseline survey of the framework across many stakeholders required a road map to establish clear guidelines and successful adoption and application of the framework (DUR principles).

Throughout the pilot phase, Uganda has been able to document the lessons learnt, success factors and a range of recommendations to guide adoption and implementation of the framework that can be utilized by other WHO Member States. Key among the recommendations is the need to foster collaboration between the World Health Organization (WHO) and the MDAs to align the framework with existing efforts; engage stakeholders; and provide the required capacity building across a broad range of stakeholders at the start of implementing the framework. In view of this, there was a recommendation for early identification of a lead agency to coordinate the MDAs. In Uganda, the pilot phase was coordinated by the Office of the Prime Minister. It was recommended that the Ministry of Science, Technology, and Innovation, under the Office of the President, lead the domestication and implementation of the framework. The Ministry will develop an implementation plan for the framework through a multi stakeholder approach. In addition, dedicated efforts are needed to make the framework available both in hard and electronic copies to all relevant stakeholders. The Ministry will also conduct Training of Trainers (TOTs), establish compliance committees, and decentralize information dissemination to ensure effective implementation.



01

Introduction

1.1 Background

The World Health Organization published the global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research in 2022. The framework calls on Member States and relevant stakeholders to mitigate biorisks and safely govern dual-use research (DUR) while harnessing the power of life sciences for global health. The framework represents a significant milestone in the international efforts to promote responsible conduct in scientific research. It is a comprehensive global guidance document and the first global technical and normative framework that intends to set foundations to inform the development of national frameworks and approaches for mitigating biorisks and governing dual-use research in the One Health context. Whereas the framework is a comprehensive global guidance document, it needs to be tailored to different countries and stakeholders' needs and contexts with the recognition that mitigating biorisks and governing dual-use research is a global issue that requires a shared responsibility, without a one-size-fits-all approach.

1.2 Rationale

The WHO held the Africa regional workshop to operationalize the global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research in Nairobi, Kenya, from 24 to 25 January 2023. The workshop was intended to consolidate, build on knowledge and practice, and stimulate increased engagement from Member States and regional champions in the area of responsible use of the life sciences. The participants made several recommendations which are available here. One of the expected outcomes of the workshop was to initiate discussion with each country and seek for interest to pilot the global guidance framework for the responsible use of life sciences.

1.3 Purpose of the pilot project

The overall objective of the pilot was to study and determine the feasibility, appropriateness, relevance and applicability of the framework in guiding the responsible use of the life sciences: mitigating biorisks and governing dual-use research. With the framework being the first comprehensive global guidance document of its kind: the set of values and principles to guide decision making; examples of tools and mechanisms for Member States and key stakeholders; approach for implementation; checklists for various stakeholders; scenarios and case studies on the governance of biorisks and dual-use research had not been validated or tested for many countries.

Uganda expressed interest and was subsequently selected to pilot the introduction of the WHO framework. The choice was informed by among other things the fact that Uganda has a critical need to address vulnerabilities to emerging and reemerging infections, alongside meeting international obligations and enhancing biosecurity measures. Moreover, Uganda's geographic location and climate make it particularly

susceptible to outbreaks of infectious diseases such as Ebola, Marburg virus, and other zoonotic infections. These vulnerabilities highlight the urgent need for implementation of a comprehensive framework to manage biorisks effectively.

Furthermore, the WHO's recent Joint External Evaluation (JEE) in 2023 revealed significant gaps in Uganda's biosafety and biosecurity preparedness, particularly the absence of a comprehensive legal framework. By piloting this framework, Uganda aims to fill these gaps and bolster its capacity to prevent, detect, and respond to biological threats. The framework aligns with Uganda's commitments under international instruments such as the Biological Weapons Convention (BWC), UN Security Council Resolution 1540 (UNSCR 1540), the Global Health Security Agenda (GHSA), and the International Health Regulations (IHR).

Additionally, Uganda's ratification of the Convention on Biological Diversity (CBD) in 1993 and the Cartagena Protocol on Biosafety in 2001 underscores its commitment to ensuring the safe use of biotechnology and protecting biodiversity. These international obligations necessitate the establishment of a robust biosafety and biosecurity framework. Integrating the global guidance framework into national policies and regulations is a strategic step toward enhancing Uganda's resilience against public health emergencies and potential security threats arising from life sciences research, ultimately ensuring the well-being and safety of its population.

This report details the implementation of the piloting of the framework in Uganda, documenting the experience, lessons learnt and best practices to guide the introduction of the framework in other WHO Member States with similar settings and beyond.

The findings of this pilot provide insights into the applicability of the framework at national level and create awareness among multiple key stakeholders, including high-level authorities, researchers (human, veterinary, environmental health), civil society, law enforcement, and legislators.

02

Project overview

The pilot of the framework in Uganda was a six-month project with implementation of the first project activity in October 2023. The overall objective of the pilot was to study and determine the feasibility, appropriateness, relevance and applicability of the framework in guiding the responsible use of the life sciences in mitigating biorisks and governing dual-use research in the context of Uganda.

Recommendations made during the regional workshop to operationalize the framework in the WHO African region held in Nairobi, Kenya from 24 to 25 January 2023, contributed to the development of a six- month action plan by Uganda which incorporated input from a variety of national stakeholders to support the implementation of the pilot project.

2.1 Action plan

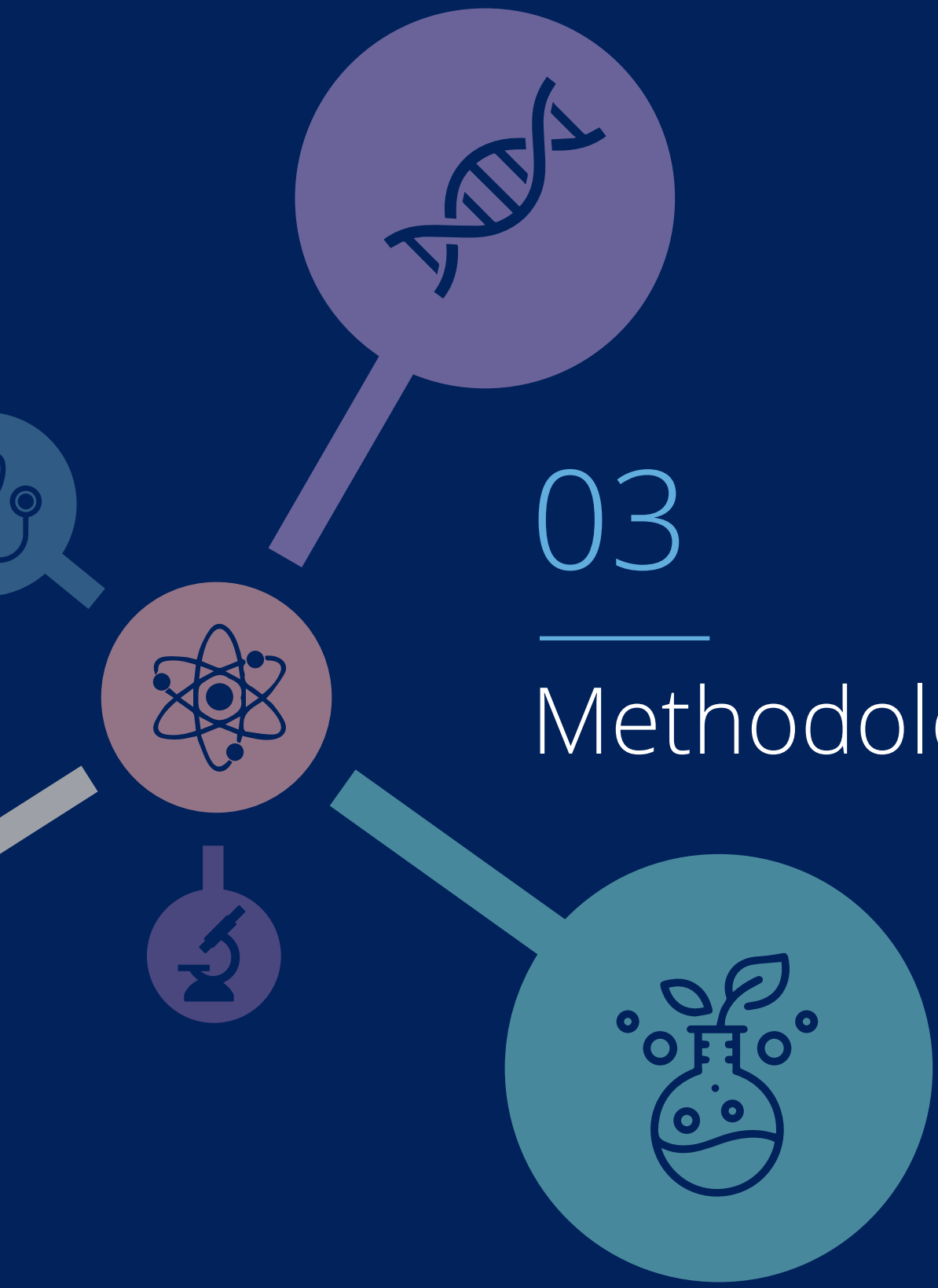
The action plan comprised six strategic actions that reflected the key messages from the Nairobi regional workshop. These activities were:

- Undertake a mapping of the existing elements and gaps to start implementing the framework at the country level.
- Conduct a situation analysis to determine the level of awareness on biosafety, biosecurity and dual-use research at the national level.
- Organize a sensitization of key stakeholders on the framework.
- Conduct country sensitization and awareness-raising on the framework.
- Ensure continuous engagement with participants through the setting-up of a virtual quarterly meeting.
- Initiate coordination on monitoring and evaluation.

2.2 Implementation

The piloting was coordinated by the Office of the Prime Minister with support from the WHO Country Office for Uganda, WHO AFRO, and WHO Headquarters. Implementation began in October 2023 with a field survey aimed at assessing the country's level of awareness and existing capacities in biosafety, biosecurity, and dual-use research governance. The activities were carried out according to the timelines outlined below:

Figure 1: Key phases of the pilot project implementation



03

Methodology

Having volunteered to pilot the introduction, Uganda developed a concept paper to guide a six months pilot phase (October 2023-March 2024) which was coordinated by the Office of the Prime Minister (OPM) and supported by WHO Country Office and Headquarters with the purpose of identifying priority activities to undertake for the introduction and implementation of the framework.

Being one of Africa's 194 WHO Member States, Uganda abides to the membership obligations and several international instruments for health, safety and biosecurity such as the Biological Weapons Convention (BWC), United Nations Security Council Resolution 1540 (UNCSR 1540), the Global Health Security Agenda (GHSA), and the International Health Regulations 2005 (IHR), Cartagena protocol on Biosafety. It is also worth noting that Uganda is prone to several emerging and re-emerging high consequence pathogens. As part of a response measure, Uganda has developed robust surveillance programs leading to acquisition and storage of pathogens used for both diagnostic and research purposes. Substantial efforts are being invested in research to develop diagnostics, therapeutics and vaccines using these pathogens. In the absence of proper containment facilities, regulation of the few existing facilities and monitoring of archives and access to high consequence pathogens, these initiatives present potential biorisks to humans, animals, plants and the environment.

For effective implementation of the project, a steering team composed of members from Office of the Prime Minister, WHO Office for Uganda, WHO Regional Office for Africa was constituted. The team conducted weekly coordination meetings through which activities were planned, implemented, reported and project process tracked.

2023

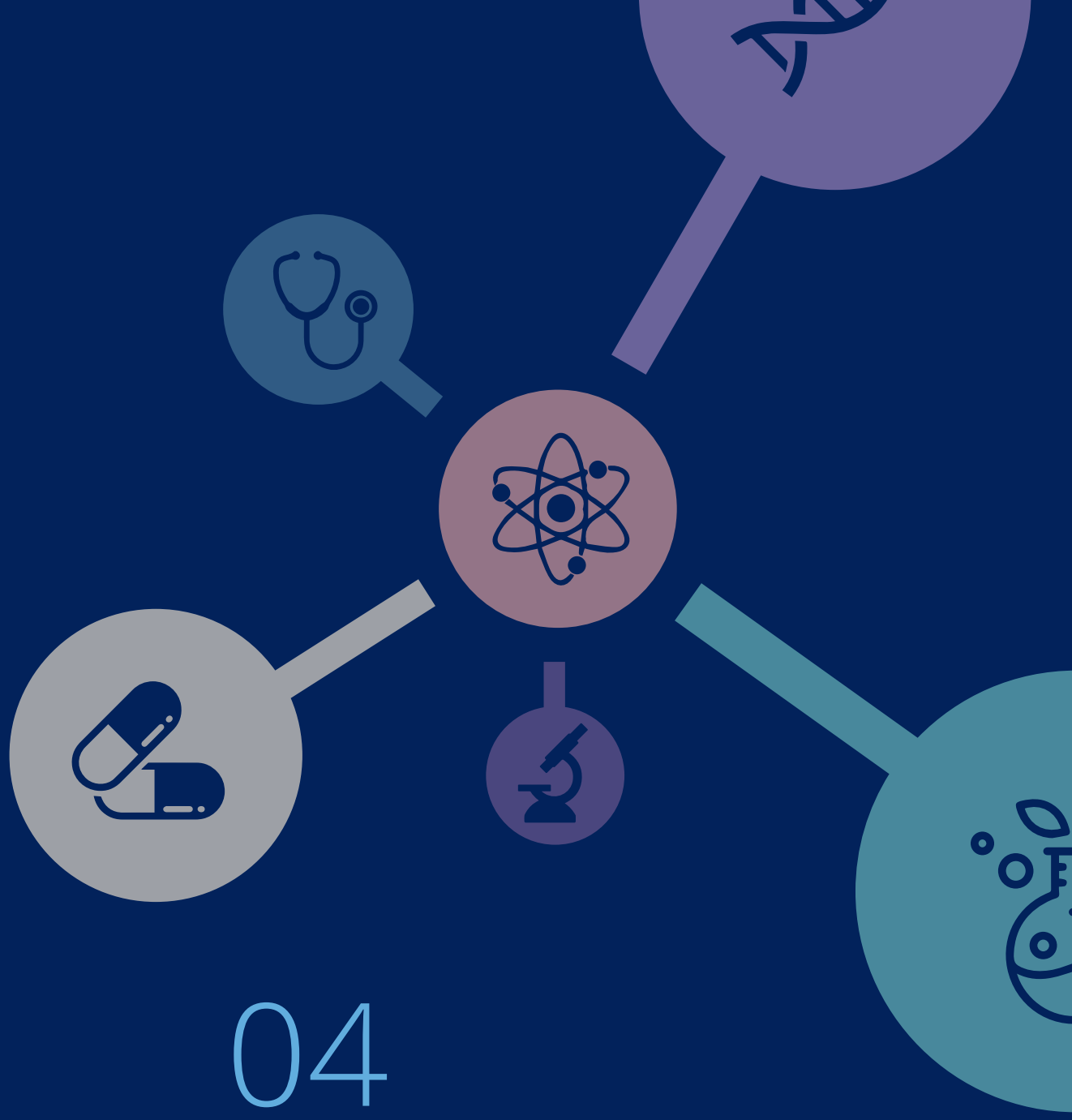
October 2023; Based on the concept paper, a baseline field survey was conducted in October 2023 where 36 national organizations were purposefully selected for the survey covering four geographical regions in Uganda. The data collection tool (Annex 1) was developed and uploaded to an Open Data Kit (ODK), an open-source software on the enabled smart tablets. The tool was used to collect data on pre-identified organizations/ institutions that included government agencies, research institutions, universities, healthcare providers, pharmaceutical companies, NGOs, community groups, and international organizations. The findings from the stakeholder survey informed the development of the follow-up stakeholder sensitization workshops.

November 2023; The first National Stakeholder sensitization workshop was held from 21 to 23 November 2023 at Munyonyo Resort Hotel, Kampala, Uganda. The workshop aimed at presenting an overview of the framework, the pilot project and to explore the current situation of the nation's biosafety, biosecurity, and dual-use research governance establishments as well as to identify the concrete applications of the framework in the Ugandan context. Eighty (80) stakeholders (representing diverse sectors such as human and nonhuman animal health, agriculture, environment, defense, security, and various partner organizations) participated in a three-day workshop that was facilitated by both WHO technical persons and Uganda subject matter experts. The workshop deployed structured presentations, informative panel discussions, interactive working group sessions, and comprehensive plenary discussions to assess the national biosafety and biosecurity frameworks and a road map was developed for the operationalization of the framework in Uganda.

March 2024; A second follow-up workshop that was attended by 30 technical stakeholders from across different sectors was held from 6 to 7 March 2024 at WHO Country Office in Uganda. The workshop aimed at further disseminating the framework and reviewing the proposed roadmap for implementation of the framework developed during the 1st workshop. The 3rd workshop held on 15 March 2024 at Uganda WHO Country Office followed after and 50 participants including policy makers from relevant Ministries, Departments and Agencies (MDAs) were invited. Further engagements in terms of physical and virtual meetings were held to share the progress and seek more input into the piloting process.

Further, a meeting was held with the management of Uganda National Council for Science and Technology (UNCST) as a follow-up of the recommendation made during the 3rd workshop where the Science, Technology and Innovation Secretariat – Office of the President agreed to be the custodian for the adoption and implementation of the framework.

April 2024; Following the workshop held in March 2024, Uganda's experience was shared at a few international events including; the meeting of the WHO Technical Advisory Group on the Responsible Use of Life Sciences and Dual-Use Research (TAG-RULS DUR) in Geneva, Switzerland from 16 to 18 April 2024 as part of dissemination and sharing of Uganda's experience. Also, the International Working Group on Strengthening the Culture of Biosafety, Biosecurity and Responsible Conduct in the Life Sciences was held on 21 June 2024 and hosted by U.S Department of Health and Human Services and the U.S Department of Agriculture.



04

Pilot findings

4.1 Collecting data and developing strategies for effective implementation of the framework

A stakeholder mapping exercise was identified as one of the strategic objectives of the pilot project. Core activities of the stakeholder mapping objective included; identification of stakeholders, assessment of levels of national awareness regarding biosafety, biosecurity, and dual-use research, including dual-use research of concern. Additionally, the project aimed to identify challenges faced by stakeholders in promoting the responsible use of life sciences and gather suggestions for effective introduction and implementation of the WHO global guidance framework for the responsible use of life sciences in Uganda. Data collection was carried out through a field survey involving 36 organizations across the country.

Outcome: Results from the survey revealed that over 90% of the facilities were engaged in life sciences research, with 80% focusing on healthcare, 13% on agriculture and environment, and 7% on general biotechnology and genetic engineering. It was revealed that facilities conducted research and surveillance in the areas of Human Immunodeficiency Virus (HIV), antimicrobial resistance, tuberculosis drug resistance, wildlife diseases, livestock health, nutrition and production studies and clinical vaccine trials on COVID-19 and malaria. The results further indicated that the concept of dual-use research and dual-use research of concern was relatively new to most respondents, with over 50% reporting a lower level of understanding on dual use research and dual-use research of concern, despite 67% of the organizations having had over 10 years of research experience (Figure1). Notably, 83% of respondents believed their organizations were working on projects that qualified as dual-use research, despite lacking prior knowledge of the concept. The survey also showed that 80% of the organizations reported unfamiliarity with the WHO global guidance framework for the responsible use of life sciences (Figure 3). Two organizations reported to have been trained on the framework in 2022 and 2023.

90%
Facilities were engaged in life sciences research

80%
Focusing on healthcare

13%
Focusing on agriculture and environment

7%
Focusing on general biotech-nology and genetic engineering.

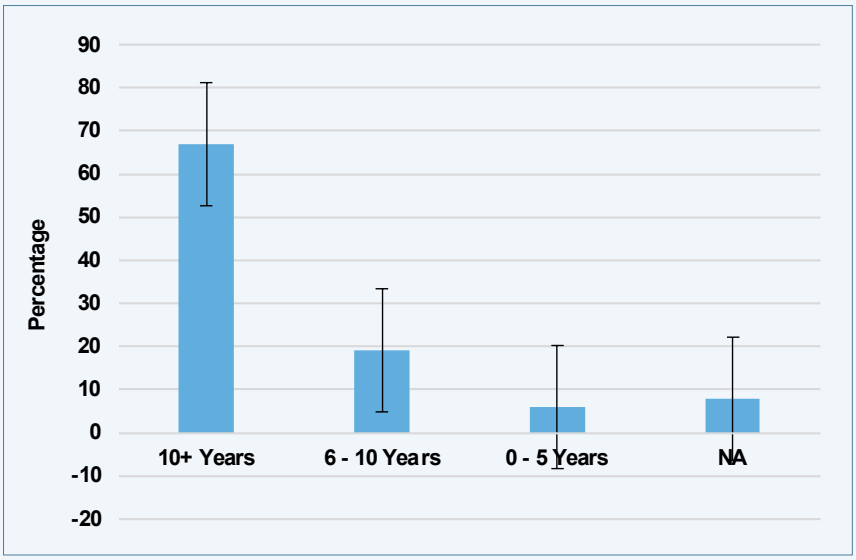


Figure 2: Years of conducting research in life sciences by various organizations

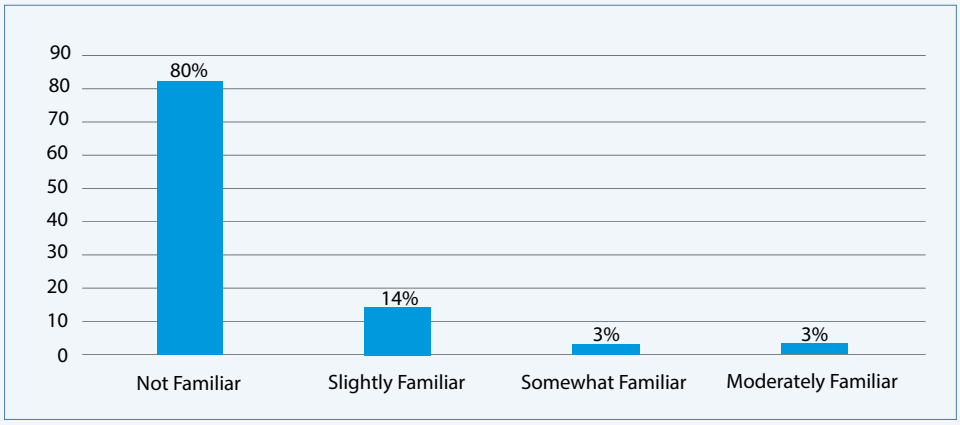


Figure 3: Familiarity with and access to the WHO global guidance framework for the responsible use of life sciences.

Overall, the respondents from the organizations demonstrated a generally greater level of understanding of the principles of biosafety and biosecurity principles. They also indicated that their facilities had designated Biosafety Officers and various biorisk management measures in place. The most commonly implemented measures included containment protocols, physical access control, restricted access to biological materials, personnel training, and environmental safety practices. Despite most of the organizations having received training on biorisk management, there were significant gaps in the coverage of dual-use research and dual-use research of concern.

During the survey, respondents raised the following foreseen challenges in promoting responsible use of life sciences:

- Knowledge gaps in the concept of dual-use and dual-use research of concern.
- Inadequacy in the regulatory frameworks, especially in wildlife research, was highlighted. The complexities surrounding the laws governing specific studies add another layer of difficulty.
- Training deficiencies at organizational level.
- Funding constraints impact various aspects, including knowledge dissemination, access to information, and overall resource availability.

During the survey, respondents suggested strategies for effective implementation of the WHO global guidance framework for responsible use of life sciences in Uganda. These included:

- Fostering collaboration between the World Health Organization (WHO) and the government Ministries, Departments and Agencies to align the framework with existing efforts, engage stakeholders, and provide required capacity building strategies.
- Stakeholder involvement through sensitization, consultations, and awareness programs for advocacy and support.
- The government should develop a strategy for domestication of the framework.
- Conduct essential sensitization sessions for researchers using a phased approach and advocate for legislative inclusion of the framework.
- Engage various stakeholders through meetings, consultations, and appointing national focal persons to facilitate implementation.
- Introduce the framework at a regional level, engage non-government organizations, and raise awareness through conferences and events.
- Develop a phased implementation plan from the national to facility level, addressing specific needs, gaps, and customization requirements.
- Make the framework available, conduct Training of Trainers (TOTs), establish compliance committees, and decentralize information dissemination to ensure effective implementation.

In conclusion, the survey showed that there was:

1. A significant lack of awareness and training on dual-use research and dual-use research of concern.
2. Most research activities are perceived as falling under dual-use research.
3. Many organizations in Uganda have a low understanding and limited exposure to concepts related to dual-use research and dual-use research of concern.
4. Several organizations engage in life sciences research in Uganda but the majority of them engage in research on pathogens.

4.2 Sensitizing key stakeholders about the framework and creating a road map for implementation

As part of an initial strategic action plan for piloting the framework, Uganda convened a series of workshops to sensitize stakeholders about the framework. The first engagement was a three-day national stakeholder workshop, which was held in Kampala from 21 to 23 November 2023. The workshop was coordinated by the Office of the Prime Minister and supported by the WHO Country Office in Uganda, WHO Regional Office for Africa, and the WHO headquarters. The workshop, which was attended by over 80 stakeholders, drew participants from diverse sectors including human and animal health, agriculture, environment, defense and security, academia, and industry. Various partner organizations also attended the workshop.

The major objective of the workshop was to sensitize key stakeholders on the operationalization of the framework in the context of Uganda.

The workshop specifically aimed to:

1. Provide an overview of the framework, and other regional and national related existing initiatives, and to introduce the pilot project in Uganda and its expected outcomes.
2. Discuss and understand the current situation of biosafety and biosecurity in Uganda.
3. Discuss and determine concrete applications of the framework to the context of Uganda.
4. Agree on actions/strategies to translate the insights of the discussion towards a national action plan to enable effective domestication, adoption and implementation.

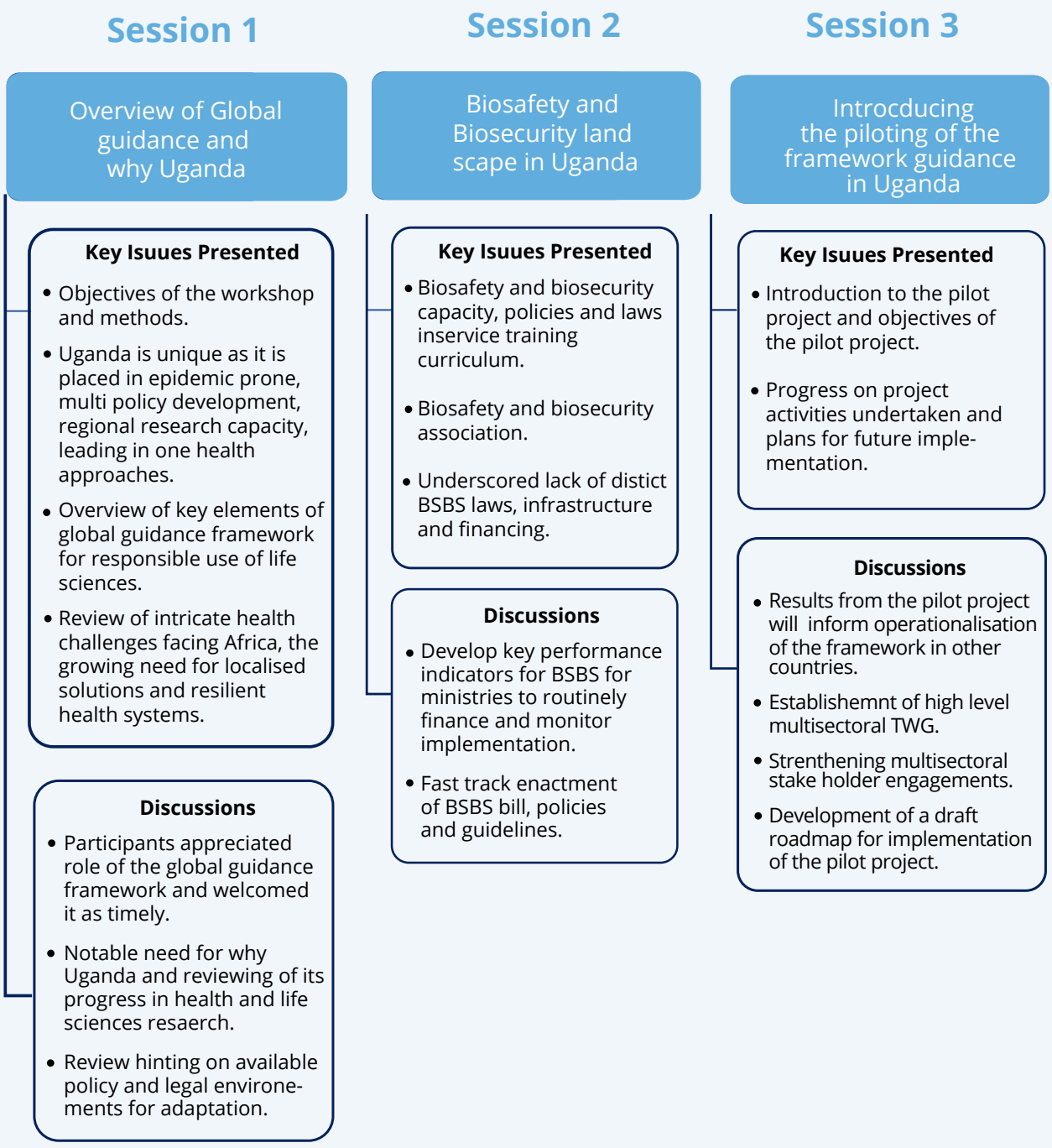


Figure 4: Key sessions of the national stakeholder engagement workshop

Road map for implementation of the framework

During the workshop, participants developed a road map that emphasized an integrated, efficient, and cost-effective approach and articulated key steps underpinned by the creation of a governance system to implement the framework in Uganda.

Key Strategies identified for implementation of the above road map included:

- Establishment of functional committees including a functional high-level multisectoral national steering committee and a Technical Working Group (TWG).
- Strengthening multisectoral stakeholder 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 among key stakeholders to ensure a well-informed and engaged community.
- Strengthening research oversight to include dual-use research governance emphasizing the need for comprehensive oversight mechanisms.
- Advocating for resources and funding opportunities, specifically towards dual-use research governance to sustain and advance implementation efforts.
- Strengthening monitoring and evaluation systems in alignment with WHO or national reporting structures was identified to ensure ongoing assessment and improvement of the framework's implementation. This strategy involves drafting a monitoring and evaluation plan and tools with defined key performance indicators (KPIs).

4.3 Identifying roles of technical stakeholders and refining implementation road map of the framework

- A technical stakeholders' workshop was convened as a follow-up activity of the national stakeholders meeting from 6 to 7 March 2024 at WHO Country Office in Kampala.

The objectives of the workshop were to:

- Continue with sensitization of key stakeholders on the global guidance for the responsible use of life sciences and the pilot project.
- Review and refine the road map and the implementation strategies that were developed at the national workshop to operationalize the framework.
- The meeting was attended by 30 technical stakeholders from across different sectors including human health, animal health, environment, security and defense, academia, and industry. The participants were sensitized on different areas through presentations by key experts as shown in the table below;

Figure 5: Key focus areas for sensitization of technical stakeholders

Figure 6: Photo of the participants during the technical sensitization workshop, 6 March 2024

Scoping of stakeholders' roles

During the technical stakeholders sensitization workshop, participants were subdivided into two groups to conduct brainstorming and an in-depth desk review of key stakeholders who are relevant to biosafety, biosecurity and dual-use research governance.

Key participants focused on stakeholders who make policies, regulations, conduct research in life sciences, academia that produce the human resources, funders, development partners directly involved in life sciences research, communities and public.

Table 1:List of national stakeholders and their roles.

Stakeholder	Role
National Level	
Office of the Prime Minister	Provide coordination and policy formulation for operationalization of the framework. Supervision, monitoring and evaluation during the operationalisation.
Science, Technology and Innovation Secretariat – Office of the President.	Provide technical leadership in the operationalization of the framework.
Ministry of Defense and Veteran Affairs.	Foster a partnership with the international community on dual-use research.
Ministry of Security	Link health security with public health.
Ministry of Education and Sports.	Incorporate the curriculum in different institutions and support training of technical staff.
Ministry of Finance, Planning and Economic Development .	Provide the necessary resources to fund activities on dual-use research.

Ministry of Health-Department of Health laboratories and Diagnostics services.	Responsible for providing human approach technical support. Customize the framework to their mandate and provide oversight over dual-use research.
Ministry of Water and Environment	Customize the framework to their mandate and capacity building of the staff on dual-use research. Identify biorisks within water and the environment.
Ministry of Agriculture, Animal Industry and Fisheries	Customize the framework to their mandate and capacity building of the staff on dual-use research. Creating awareness in the sector. Identify the biorisks associated with the animal, plant and fisheries units through the different sectors.
Ministry of Tourism, Wildlife and Antiquities	Customize the framework to their mandate and capacity building of the staff on dual-use research. Provide training in biorisk management within animal systems. Create awareness on dual-use research.
Ministry of Trade Industries and Cooperatives	Regulate export control.
Ministry of Justice and Constitutional Affairs	Regulate the laws and regulations.
Academia	
Universities and other Tertiary Institutions	Develop, review, deliver and promote appropriate curriculum in dual-use research, biosafety, and biosecurity in life sciences. (Either develop a stand-alone curriculum or incorporate courses within the curriculum).
National Council for Higher Education	Develop and review appropriate curriculum in dual- use research, biosafety, and biosecurity in life sciences. (Either develop a stand-alone curriculum or incorporate common courses within curriculums across sectors).
Agencies	
Uganda National Council of Science and Technology	Oversee research and ensure that the aspect of dual-use research is incorporated in Research Ethics Committees (RECs) and Institutional Biosafety Committees (IBCs). Ensure that institutions form IBCs. Develop guidelines on responsible conduct of research.
National Curriculum Development Center	Develop content on life sciences customized for pre-university institutions.
National Environment Management Authority	Capacity building of technical staff on environment bio risks and dual-use research.
National Agricultural Research Organization	Capacity building in safety and dual-use research on their mandate.
National Drug Authority	Regulate chemical agents used as drugs for treatment of humans and animals.
Uganda National Bureau of Standards	Regulate and test all products that come into the country.

Uganda Revenue Authority	Regulate equipment and reagents importation that could ensure biosafety and biosecurity.
Financial Intelligence Authority.	Monitor and control transactions.
Civil Aviation Authority	Monitor the transfer of potential bioterrorism materials.
National Water and Sewerage Corporation	Research on water systems, water pollution, proper waste management.
Uganda Parliament	Focus on regulatory governance.
Uganda Atomic Energy Council	Regulate the use of nuclear and radiation technologies.
Implementing Partners- Infectious Diseases Institute, Nuo Bioscience	Provide technical support for implementation of framework.
Development Partners WHO, FAO, CDC, WOAH	Provide oversight, funding, and technical support.
Regional and District Stakeholders ▪Ministry of Local Government	Ensure advocacy and implementation of government programs.

Refining of implementation road map for domestication and operationalization of the framework

During the road map review, key strategic objectives for operationalization of the framework in Uganda were determined as;

- To foster coordination among stakeholders.
- To strengthen collaboration among stakeholders and partners.
- To enhance awareness, education, and capacity-building on biorisk management and dual-use research governance.
- To provide guidance, values, and principles for mitigating and governing biorisks and dual-use research.
- To monitor and evaluate the implementation of the WHO global guidance framework for the responsible use of life sciences in Uganda.

The refined road map draft that includes key strategic actions and activities is attached in Annex 2

- To facilitate effective operationalization of the framework, the technical stakeholders made the following recommendations;
- The need for human resource capacity building in different sectors.
- The need for a comprehensive legislative mapping to identify how the existing laws align with the framework to subsequently facilitate its customization.
- The need to conduct an assessment to identify and establish mechanisms to regulate unchecked research by herbalists and various Do-It-Yourself (DIY) research communities.
- Continued sensitization of all regulators and key stakeholders to simplify their understanding of the framework, cultivate ownership and commitment to operationalize the framework.

General outcomes from the technical stakeholders workshop

- Undertake an in-depth desk review of stakeholders involved in dual-use research in life sciences.
- Conduct a review of the road map for the implementation of the activities.
- Fast-track the enactment of the biosafety, biosecurity bill and guidelines, and the associated regulations.
- Undertake licensing of professionals and institutions that handle life sciences at national level.
- Carry out comprehensive training, research and partnerships.
- Foster a One Health approach for consolidated effort from all sectors for effective dual-use research governance.

4.4 Advocating for national buy-in and support for the framework's implementation from high level stakeholders

The high-level stakeholders sensitization was opened on 15 March 2024 by Hon. Dr. Monica Musenero, Minister of Science, Technology, and Innovation, and was attended by over 50 high-level stakeholders. The meeting aimed to advocate for national buy-in and support for the framework's implementation.

Key stakeholders were drawn from diverse government MDAs, development and implementing partners, who are directly involved in dual-use of research and life sciences.

Table 2: The stakeholders who attended the high-level stakeholders sensitization meeting.

SN	Category of stakeholder	Name of institution	Number of delegates
1	OPM	Office of the Prime Minister	01
2	Ministry	Health	02
		Secretariat of Science, Technology and Innovation	03
		Water and Environment	01
3	Departments and agencies	National Health, Laboratory and Diagnostic Services	02
		Uganda National Council of Science and Technology	03
		Uganda National Health Research Organization	01
		National Agricultural Research Organization	02
		Atomic Energy Council	01
		National Drug Authority	01
		Joint Clinical Research Centre	01
		Regional Referral Hospitals	04

SN	Category of stakeholder	Name of institution	Number of delegates
4	Academia/ Universities	Makerere University	02
		Nkumba University	01
		Kampala International University	01
		Uganda Martyrs University	01
5	Partners	WHO Country Office	03
		WHO Headquarters	01
		Infectious Diseases Institute	02

Figure 7: Photo of the participants of the high-level stakeholders meeting, 15 March 2024.

The Minister of Science, Technology and Innovation (STI)-Office of the President, Hon. Dr. Monica Musenero opened the meeting by welcoming the participants. 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, and urged collaboration towards a future defined by responsibility, innovation, and collaboration.

Several presentations then followed 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, an introduction to the pilot project and an overview of the framework. The road map from the previous stakeholder engagements was also presented at the meeting. Each presentation was followed by vibrant discussions leading to concrete ways forward.

Figure 8: Key issues raised during the high-level stakeholders meeting.

General outcomes from the high-level stakeholders sensitization meeting

The Science, Technology and Innovation Minister's role to lead the domestication and operationalization of the framework will involve:

- Overseeing the establishment of a task force to comprehensively review the framework and identify KPIs for monitoring as the country domesticates the framework.
- Assign UNCST the role of technical authority to implement the framework in Uganda.

- Take on the responsibility to continue communicating the framework clearly to other key stakeholders. Some of the initiatives earmarked to raise awareness on biosafety and biosecurity and dual-use research included;
- Inclusion of the WHO training on dual-use research governance and responsible use of life sciences as a prerequisite for research protocol approvals, nomination to Research Ethics Committees (RECs) or Institutional Research Committees (IRCs) etc.
- Inclusion of the training on biosafety, biosecurity and dual-use research governance into the training curriculum.

4.5. Information dissemination

As a way of disseminating information on the pilot project, sharing Uganda's experiences, lessons learned, and successes attained at both local and international meetings, presentations on the progress on pilot project were made at the WHO TAG-RULS DUR meeting on 16 April 2024 in Geneva, Switzerland and also at the meeting of the international working group on strengthening the culture of biosafety and biosecurity and responsible conduct in the life sciences held on 21 June 2024.

Some of the aspects highlighted during these dissemination sessions included;

- Adequacy in the representation of stakeholders during the survey including involvement of students.
- The audience sought to understand the effect of cultural differences on the introduction of the framework.
- The piloting of the framework in other regions or countries.
- An elaborate understanding of the next steps.
- Uganda's consideration of the implementation of ISO 5441:2024 competence requirements for biorisk management advisors .
- And how Uganda leveraged the existing strengths in the introduction of the framework.

05

Key results / outcomes

The following are some of the key outcomes from the piloting the framework

5.1 Creation of an information paper

The information paper was prepared by the Office of the Prime Minister and published targeting researchers, policymakers, government and its partners (e.g., WHO), institutions, and the public. It helped to create awareness of the WHO global guidance framework for the responsible use of life sciences throughout the report, the potential consequences of dual-use research risks, Uganda's current biosafety/biosecurity landscape and physical infrastructure, preparedness on biosafety/biosecurity (WHO JEE held in October 2023), and the understanding and implementation of biosafety/biosecurity measures among different organizations in Uganda. The details of the information paper can be accessed at https://opm.go.ug/uganda-leads-who-guidance-frameworkmework/

5.2 Increased stakeholder engagement:

The implementation fostered greater engagement among researchers, policymakers, and regulatory bodies. This collaboration improved communication and coordination in addressing DUR and DURC issues, creating a more integrated approach to biosecurity.

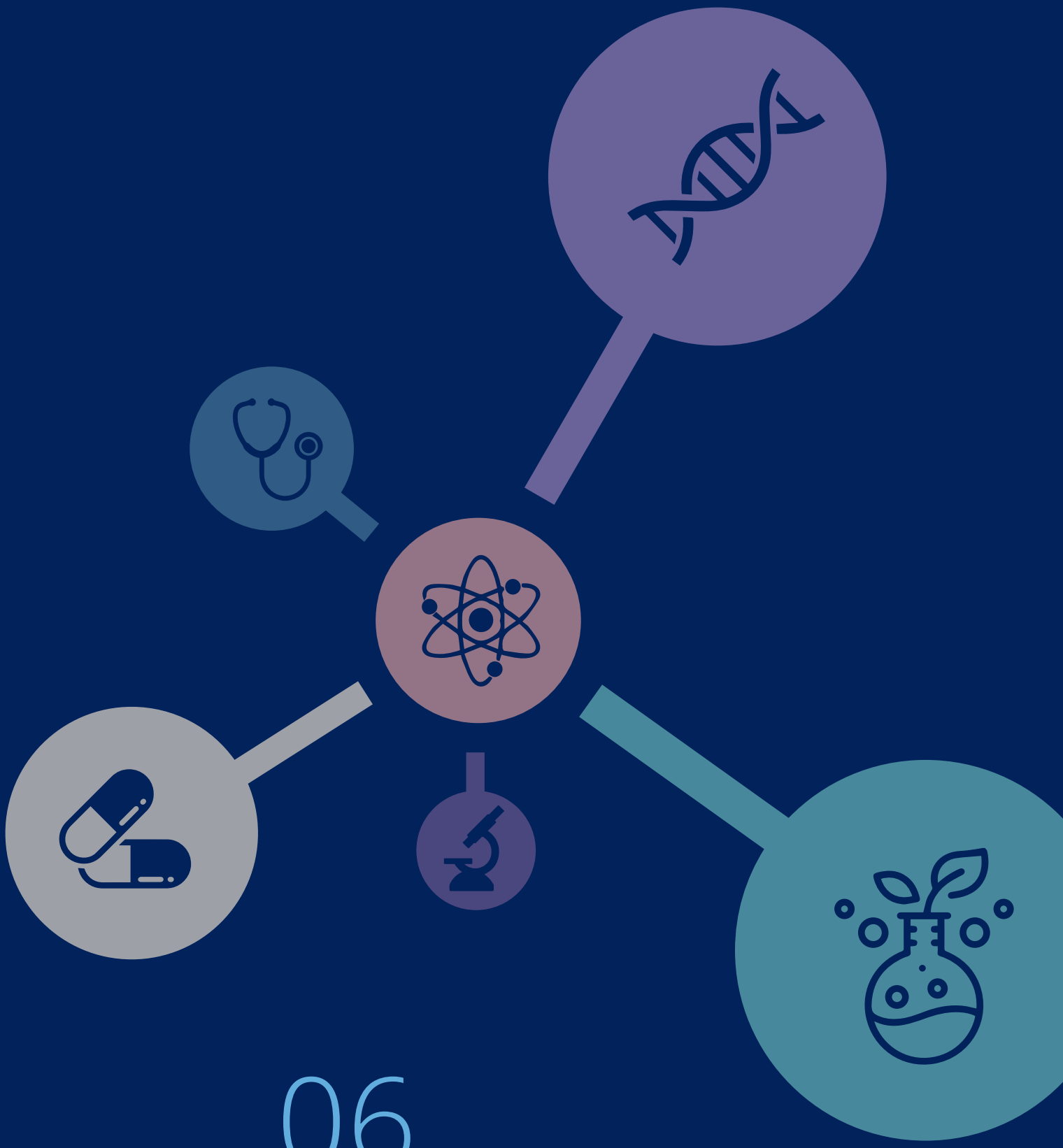
5.3 Risk awareness and mitigation:

Awareness of the risks associated with DUR and DURC was significantly heightened among stakeholders. This led to more proactive measures in identifying and mitigating potential biosecurity threats, enhancing the overall safety of research practices.

5.4 Sustainability and long-term planning:

The implementation laid a foundation for sustainable DUR and DURC governance by establishing ongoing support mechanisms, such as networks of trained professionals and partnerships with international bodies. This has ensured continued attention to DUR and DURC issues as well as readiness for future challenges.

These outcomes represent significant progress in enhancing DUR and DURC awareness, governance, and safety in Uganda.



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Lessons learned

6.1 Key takeaways

In the course of piloting the framework, these are the main points of what Uganda has learnt presented at both local and international meetings;

- Identifying an agency with authority to convene key policy stakeholders is very important in the initial stages. In the case of Uganda, the Office of the Prime Minister played a critical role in this.
- National stakeholder engagement of different stakeholders' MDAs is relevant to the implementation of life sciences.
- Obtaining commitment and buy-in of decision makers from different MDAs to authorize the participation of key stakeholders is important.
- Careful appreciation of the leadership hierarchy and mandates of the MDAs is key in implementing this pilot.
- Availability of funds to support the process of domestication and operationalization of the framework by respective states is a necessity.
- Leveraging existing structures and frameworks to anchor the domestication process is imperative.
- Developing a clear road map and strategic plan for the domestication of the framework is essential.
- Exploring the existing legal framework, policy and guidelines that can facilitate the domestication and operationalization of the framework is also important.
- Working with development partners to support the process of domestication is essential for success.

6.2 Success factors

- Development partner support (WHO) that funded the process.
- Mobilization of relevant stakeholders for the initial process.
- Identify key subject matter experts in the country to support the process.
- Documentation of reports and lessons from each engagement.
- Following the global scene on innovations and opportunities to disseminate the findings.
- Enabling environment by the Government of Uganda.

6.3 Challenges and limitations

Difficulty in achieving comprehensive representation: Ensuring adequate representation of all relevant stakeholders, including diverse research institutions, government agencies, NGOs, and students, can be challenging. Differences in interests and priorities may hinder effective engagement and cooperation.

Aligning with national policies: Integrating the new framework with existing national biosafety and biosecurity policies and practices may face resistance or require significant modifications to existing systems, causing delays or conflicts.

Securing funding and other resources: Adequate funding and resources are crucial for the successful implementation of the framework. Securing these resources amid competing priorities and budget constraints is a significant challenge.

Limited resources for effective training programs: Ensuring that all stakeholders, including researchers and students, are adequately trained and understand the framework's principles may require substantial effort and resources. Developing and delivering effective training programs can be logistically and financially demanding.

Lack of effective monitoring and evaluation systems: Designing and implementing effective monitoring and evaluation systems to track the framework's impact and effectiveness can be complex.

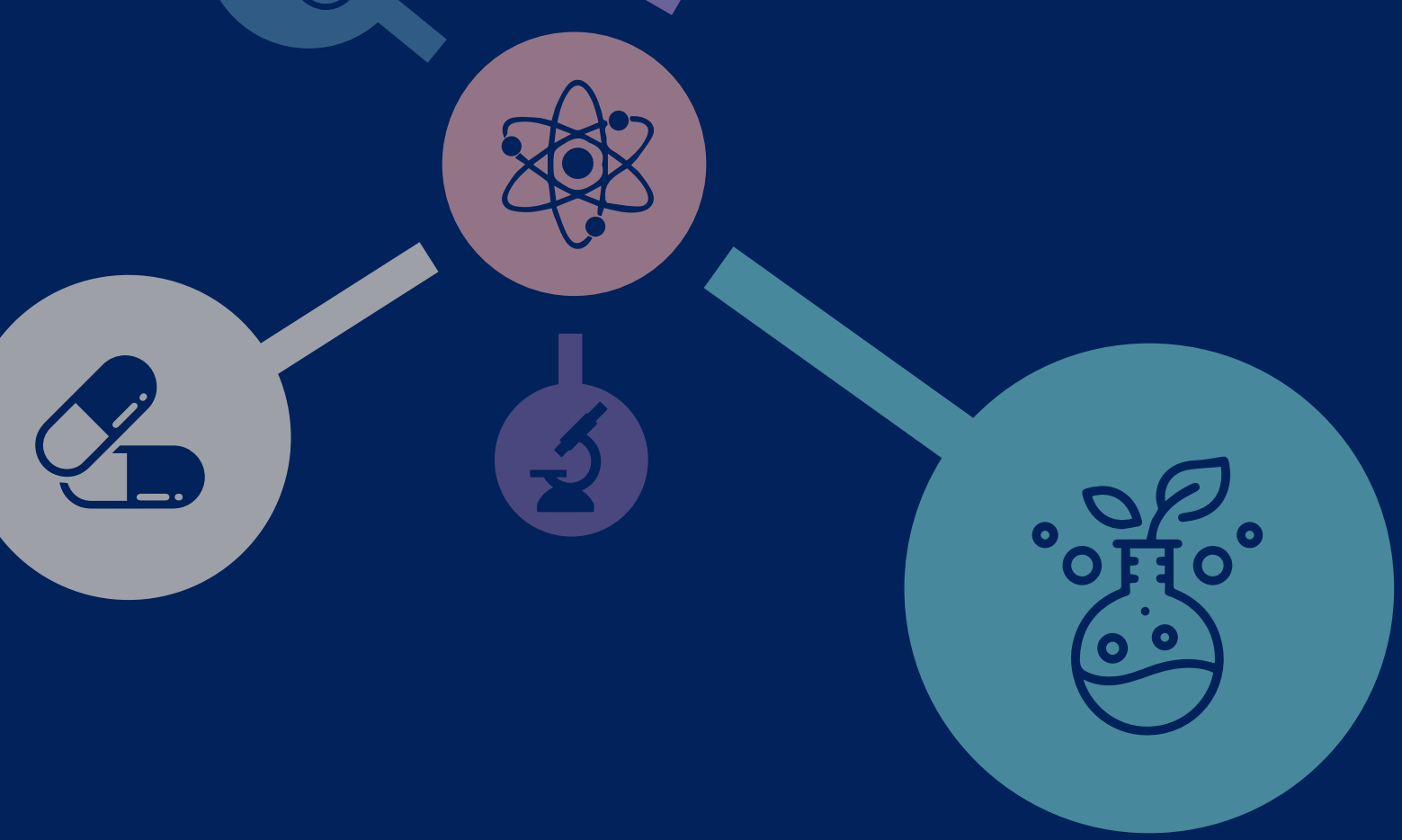
Limited knowledge and awareness: Because of a significant lack of understanding and awareness about dual-use research and DURC concepts among stakeholders, the rate of acceptance of the framework is affected and its relevance is questioned.

Lack of regulatory oversight: The absence of a comprehensive legal and regulatory framework for biosafety, biosecurity, and DURC governance can make it difficult to enforce standards and practices, especially in areas with limited oversight, such as wildlife research.

Integration with existing systems: The existing infrastructure and protocols in place can limit how easily the new framework is to be integrated. The lack of infrastructure may hinder the smooth adoption and implementation of new guidelines.

Limitations

Limited funding restricted the scope and scale of the pilot project. Because of budget constraints, only the introduction and awareness raising of the framework were covered and the ability to extend the pilot to domestication and operationalization of the framework in the country was affected.



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Recommendations for future implementation

Establish relevant partnerships: The partnership between the World Health Organization (WHO) and relevant government Ministries, Departments, and Agencies (MDAs) is crucial. Such partnerships help to align the framework with national biosafety and biosecurity initiatives, allowing for coordinated resource allocation, capacity-building strategies, and stakeholder engagement. This kind of partnership will be instrumental in driving the comprehensive adoption and implementation of the framework across the country.

Develop a national strategy for the domestication of the framework: The government should create a strategic plan that includes a phased approach to legislative inclusion, aligning the framework with national priorities, and crafting localized guidelines. This strategy will provide a clear road map for integrating the framework into the country's existing regulatory landscape and ensure that it addresses the specific needs and challenges faced at different levels of governance.

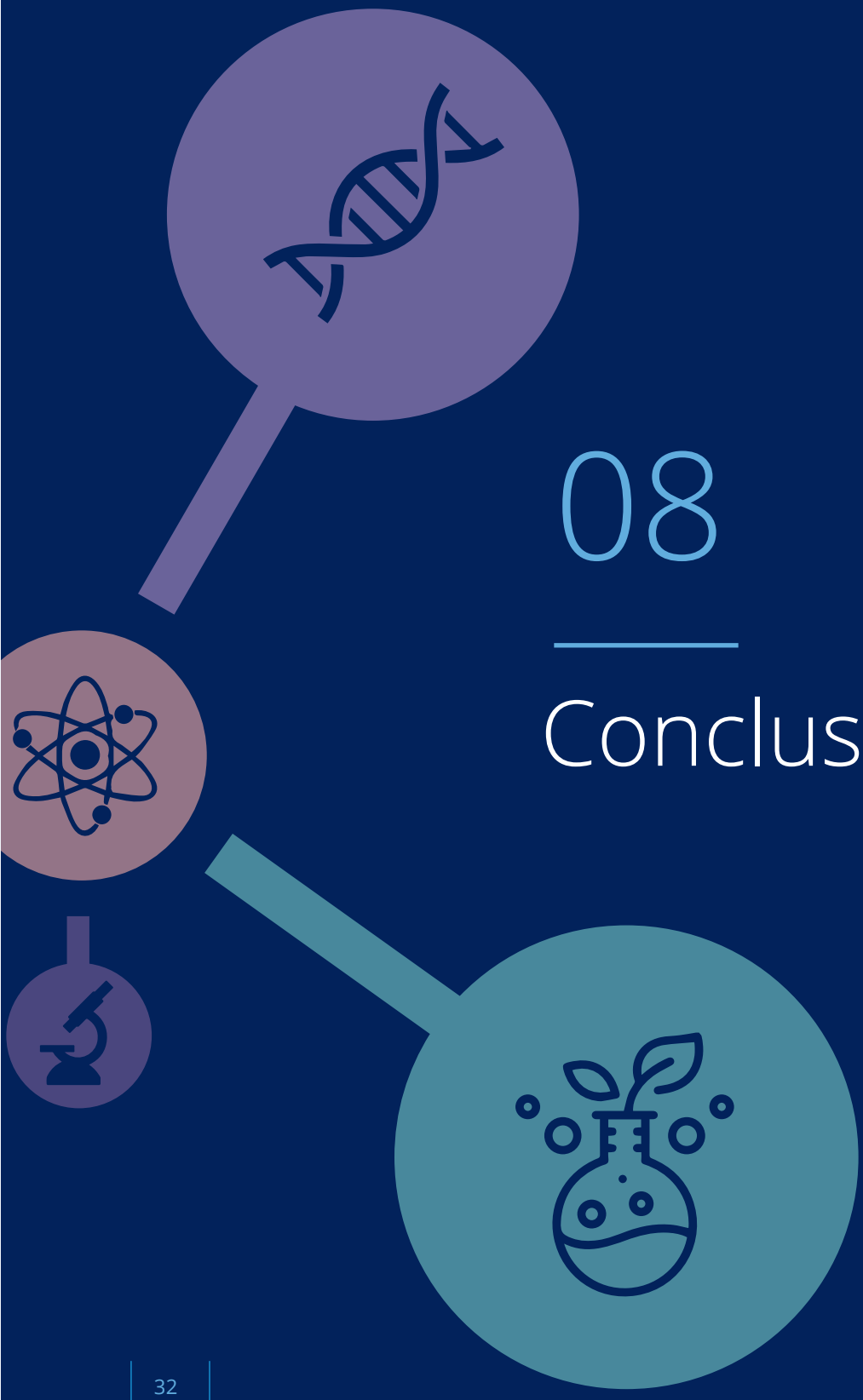
Map and sensitize stakeholders: Implementing phased sensitization sessions for researchers, policymakers, and other stakeholders will help raise awareness of the framework, clarify its relevance to their work, and encourage active participation in its implementation. This approach is critical for building the necessary understanding and commitment among key players involved in the framework's adoption and use.

Develop a comprehensive and phased implementation plan: This plan should address specific gaps and needs identified at each level, allowing for the customization of the framework to local contexts. A structured and context-specific rollout will ensure that the framework is effectively adopted and implemented across all relevant sectors and institutions.

Establish a monitoring and evaluation mechanism: A robust system for supervision, monitoring, and evaluation will track the progress of the framework's implementation, ensure accountability, and allow for data-driven adjustments as needed. This will help maintain momentum and address any emerging challenges or gaps throughout the implementation process.

Promote regional and non-governmental organization (NGO) collaboration: Introducing the framework at a regional level through partnerships with NGOs and regional bodies will foster wider stakeholder awareness, facilitate cross-border collaboration, and ensure that the framework's principles are aligned across the region. This approach will help create a more cohesive and supportive environment for the framework's implementation.

Integrate the framework into professional education and training programs: The framework can be incorporated into the curricula of medical, veterinary, and life sciences institutions to ensure that future professionals are well-versed in its principles. Additionally, refresher training for existing professionals will help maintain the framework's relevance and application in their practices. By embedding the framework into educational systems, the country can ensure that its principles are upheld across generations of professionals in the life sciences.



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Conclusions

8.1 Summary of key insights

The pilot project of the WHO global guidance framework for the responsible use of life sciences in Uganda has provided critical insights into the feasibility, relevance, and applicability of the framework. The project successfully raised awareness and engaged key stakeholders across various sectors, laying the groundwork for enhanced biosafety, biosecurity, and dual-use research governance. The findings underscore the urgent need for increased training and awareness on dual-use research and the associated risks. Despite initial gaps in understanding, the project fostered a collaborative approach, leveraging existing structures and fostering partnerships. The lessons learned from Uganda's experience offer valuable guidance for other countries seeking to implement similar frameworks, highlighting the importance of stakeholder engagement, regulatory oversight, and sustained capacity building.

8.2 Next steps

The next steps of the pilot project involve the domestication and operationalization of the WHO global guidance framework for the responsible use of life sciences in Uganda. The Uganda National Council of Science and Technology (UNCST) will lead the technical adaptation of the framework, ensuring it aligns with Uganda's specific national context, needs, and regulatory environment. The Office of the Prime Minister (OPM) will oversee the overall coordination of this process, guaranteeing that the implementation is consistent and comprehensive across the country.

To facilitate the implementation, a multidisciplinary technical working group is planned to be established. This group will include representatives from key ministries, departments, and agencies, providing oversight and promoting inter-agency collaboration. Stakeholder engagement will also be a priority, involving government bodies, academia, industry, and civil society to build awareness and secure broad support for the framework. Training and capacity building programs will be conducted to ensure that all relevant parties are well equipped to contribute to the framework's successful implementation. Monitoring and evaluation will be integral to the process, with a robust framework developed to track progress and assess the effectiveness of the framework's application.

Additionally, Uganda's experience highlighting challenges, successes, and best practices will continue to be shared with other countries and stakeholders, providing guidance for similar initiatives regionally and globally.

Through these efforts, Uganda will not only strengthen her biosafety and biosecurity landscape but also contribute valuable insights and lessons to the global community, helping to ensure responsible and secure use of the life sciences research worldwide.

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Annex I: Checklist developed and used for the field activity

Stakeholder mapping field activity on piloting the operationalisation of the global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research in Uganda.

Background to the stakeholders' survey

The responsible use of life sciences, particularly in the context of dual-use research, presents a unique set of challenges and opportunities. The life sciences sector plays a crucial role in addressing healthcare challenges, promoting scientific research, and driving economic growth in Uganda. Effective stakeholder engagement is essential for the sustainable development of this sector. WHO has recently published the global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research. Uganda has been chosen as the pilot country for the operationalization of the framework. This survey seeks to identify key stakeholders and their interests in regard to conduct of dual-use research (DUR) and dual-use research of concern (DURC) and the baseline information on knowledge, access and utilization of the framework. Thank you for participating in the survey and your insights are crucial to shaping the operationalisation of the framework.

Instructions: For each of the sections, provide the information by typing in the provided section and for multiple choice questions, select the most applicable option(s).

By responding to this checklist, you confirm your understanding of the information and consent to participate voluntarily.

A. Introduction

A. Introduction

1. **General Information**
   a. Name of the organization/Individual
   b. Position/role within the organization
   c. Contact information (Email, Phone)

2. **Understanding of life sciences and dual-use research**

   a. How would you define "dual-use research" in the context of life sciences?
   a) Research with both beneficial and harmful applications.

   b) Studies that lead to advancements in both healthcare and bioterrorism prevention.
   c) A type of research that combines biology and chemistry for dual purposes.
   d) I'm not sure or don't have a definition.

3. **Experience in the life sciences sector**

   a. Is your organization directly involved in the conduct of research in the life sciences?

a) Yes
b) No

b. If yes, how long has your organization been involved in the life sciences sector?
a) Less than 1 year
b) 1-5 years
c) 5-10 years
d) More than 10 years

c. In what capacity has your organization been involved in life sciences research and related initiatives? Choose all that apply.
a) Research and development
b) Education and training
c) Policy and regulation
d) Other (please specify: _____

4. DURC projects at your organization

a. Does your organization currently have any projects related to dual-use research of concern (DURC)?
a) Yes
b) No

b. If yes, what is the primary type of DURC project(s) is being carried out by your organization.
a) Medical and healthcare research
b) Biotechnology and genetic engineering
c) Agricultural and environmental research
d) Security and defense applications
e) Other (please specify: _____

5. Biosecurity measures

a. What biosecurity measures does your organization currently have in place to mitigate potential risks associated with life sciences research? (select all that apply)
a) Secure access control
b) Laboratory containment protocols
c) Personnel training and certification
d) Regular risk assessments
e) Controlled access to biological materials
f) Waste management protocols
g) Incident reporting and response plans
h) Environmental safety measures
i) Other (please specify): _____
j) No specific biosecurity measures in place

b. How frequently are biosecurity measures reviewed and updated within your organization?
   a) Annually
   b) Every 2-3 years
   c) Less frequently
   d) Not sure

B. Knowledge of global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research

6. Awareness and understanding

a. Are you familiar with the WHO global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research?
   a) Not familiar at all
   b) Slightly familiar
   c) Somewhat familiar
   d) Moderately familiar
   e) Very familiar

7. Access and utilization

a. Have you accessed the WHO global guidance framework document?
   a) Yes
   b) No

b. If yes, how did you access it?
   a) Online
   b) Through an organization or institution
   c) Other (please specify): _____

8. Training and awareness

a. Has your organization conducted training or awareness programs to educate staff about the WHO global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research?
   a) Yes
   b) No

b. If no, have your staff participated in any other training or awareness programs on DURC?
   a) Yes
   b) No
   c. If yes, provide details of the program. (Open-ended response)

9. **Impact on decision making**

    a. Have you observed any changes in decision-making processes within your organization since becoming aware of the WHO global guidance framework?
        a) Yes
        b) No
    b. If yes, can you provide an example of how the framework influenced a specific decision? (open-ended response)

C. Knowledge of national and international legal frameworks

10. **Knowledge of Legal Frameworks**

    a. Are you aware of any existing national or international legal frameworks and regulations related to life sciences and dual-use research in Uganda?
        a) Yes
        b) No
    b. If yes, please provide details if known (open-ended response).
    c. Are you aware of any national soft laws (manuals, guidelines, policies) related to life sciences and dual use research in Uganda?
        a) Yes
        b) No
    d. If yes, please provide details if known. (open-ended response)

11. **Experience with legal frameworks**

    a. Have you or your organization previously interacted with or used any legal frameworks or regulations related to life sciences and dual-use research?
        a) Yes
        b) No
    b. If yes, please provide details about your experience and how these frameworks were utilized (open-ended response).

12. **Integration of legal requirements**

    a. How are national and international legal requirements integrated into the policies and practices of your organization? (open-ended response).
    b. Are there specific departments or individuals responsible for ensuring compliance with legal frameworks? If yes, provide details (open-ended response).

D. Stakeholder mapping and engagement

13. **Identification of key stakeholders**
    a. In your opinion, who are the other key stakeholders in the life sciences sector in Uganda concerning dual-use research and biosecurity? (open-ended response)

14. Stakeholder Interests and Challenges

a. As a stakeholder in the life sciences sector, what are your primary interests concerning dual-use research and biosecurity? (select all that apply)
   a) Promoting ethical research
   b) Ensuring public safety
   c) Collaborative research
   d) Compliance with regulations
   e) Enhancing biosecurity measures
   f) Knowledge sharing
   g) Innovation
   h) Other (please specify): _____

b. What major challenges do you encounter in promoting responsible use of life sciences and mitigating bio risks? (select all that apply).
   a) Regulatory compliance
   b) Funding constraints
   c) Lack of awareness
   d) Ethical concerns
   e) Access to resources
   f) Collaboration barriers
   g) Legal complexity
   h) Other (please specify): _____

15. Stakeholder engagement

a. How does your organization currently engage with other stakeholders in the life sciences sector to address dual-use research and biosecurity concerns? (select all that apply)
   a) Collaborative projects
   b) Information pharing
   c) Policy advocacy
   d) Workshops and conferences
   e) Joint Research initiatives
   f) Regulatory compliance efforts
   g) Other (please specify): _____

b. What strategies does your organization employ to enhance collaboration and information sharing with other stakeholders? (open-ended response)

E. Specific objectives of the pilot

16. Feasibility and appropriateness

a. Do you believe the WHO global guidance framework is appropriate and relevant to the unique context of stakeholders in Uganda?
   a) Strongly disagree
   b) Disagree
   c) Neutral
   d) Agree
   e) Strongly agree

b. Please provide your rationale for your answer to the previous question (16a). (select the most relevant option)
   a) The framework aligns with our organization's existing practices.
   b) The framework enhances biosecurity efforts and ethical standards.
   c) The framework offers practical solutions for our specific context.
   d) The framework requires adjustments to better suit our needs.
   e) The framework does not align with our organization's goals and practices.
   f) Other (please specify): _____
   g) I'm not sure.

17. Relevance to stakeholders

a. How relevant do you think the WHO global guidance framework is to the diverse stakeholders in the life sciences sector in Uganda?
   a) Not relevant
   b) Somewhat relevant
   c) Neutral
   d) Relevant
   e) Highly relevant

18. Strategies for improvement

a. Can you propose specific strategies to improve the introduction and implementation of the framework in Uganda? (open-ended response)

F. Closing

19. Expectations from the pilot

a. What are your organization's expectations from participating in the pilot of the WHO global guidance framework in Uganda? (open-ended response)

Annex 2: Roadmap for domestication and implementation of the global guidance framework for the responsible use of life sciences in Uganda.

Objective: 1.0	**To foster coordination among stakeholders**			
	Proposed Strategy	Prioritized Activities	Timelines	Responsible Office/ Ministry
1.1	Establishment of a functional High Level multisectoral Steering Committee	1.1.1 Institute a one health select a dual-use research governance steering committee to guide the domestication and implementation of the framework 1.1.2 Establish terms of reference for the Steering Committee members	Short term	Office of Prime Minister (OPM)
1.2	Establishment of a functional National Technical Working Group (TWG) to guide implementation	1.2.1. Select technical personnel from relevant ministries, departments, and agencies (MDAs) to constitute the National TWG. Appoint and activate focal persons and sector specific secretariats 1.2.2. Specify terms and references for the National TWG 1.2.3. Develop and rollout the operational plan for the framework implementation leveraging on country priorities, policies and opportunities to anchor the framework and its implementation - Biosafety and biosecurity bill - 2nd JEE and development of National Action Plan for Health security (NAPHS) - Development of 4th National Development Plan (NDP).	Short term	Multisectoral Steering Committee
Objective 2.0	**To strengthen collaboration among stakeholders and partners**			
2.1	Strengthen multisectoral stakeholder engagement for ownership	2.1.1 Map out the relevant multisectoral stakeholders and define their respective roles and responsibilities.as well as partners working in this area by utilizing WHO 4W Matrix. Each stakeholder to have clear roles and map out shared roles within different stakeholders 2.1.2 Map out existing guidelines, protocols, standard operating procedures and projects to identify areas of synergy. 2.1.3 Establish a collaboration mechanism for regular engagement, development of joint strategies and work plans, and joint advocacy to achieve a common goal for area-specific requirements. 2.1.4 Conduct a harmonization workshop to identify areas of synergy 2.1.5 Development of joint implementation strategies and work plans 2.1.6 Foster annual multi-sectoral performance review meetings 2.1.7 Joint advocacy to achieve a common goal for area specific requirements.		

2.2	Strengthen International collaboration and information sharing systems and platforms	2.2.1 Promote the adoption of the framework at regional level through information sharing about lessons learnt during implementation and scale-up. 2.2.2 Foster implementation of the ratified international conventions and treaties such as the Biological Weapons Convention (BWC). 2.2.3 Identify and engage potential collaborators	Long term	
Objective 3.0	**To enhance awareness, education, and capacity-building on biorisk management and dual use research governance**			
	Identification and Prioritization of activities			
3.1	Building capacity through training and mentorship programs aligned to framework	3.1.1 Conduct capacity building needs assessment including national human resources, certification of personnel and institutions, fellowships, and exchange programs. 3.1.2 Develop or review DUR or other relevant national reference training materials, manuals, SOPs, and job aids. 3.1.3 Create a national training strategy and rollout plan 3.1.4 Train the research ethics committees (RECs)/ institutional review boards (IRBs) members on policies on dual-use research governance.	Long term	Line ministries, departments and agencies (MDAs)
3.2	Enhance communication awareness on the framework implementation through promotion, collaboration and partnerships among key stakeholders.	3.2.1 Draft or revise the multi-sectoral communication strategy regarding the framework. 3.2.2 Support regular awareness raising on biosafety and biosecurity and governance of dual-use research advocacy information, education, and communication (IEC) materials development. 3.2.3 Establish mechanism (s) for information sharing among key stakeholders at national level and externally. Engage the communication staff within different sectors to foster accurate and clear information on dual-use research including the utilization of the national media centre.	Midterm	Uganda National Council of Science and Technology Line MDAs
Objective 4.0	**To provide guidance, values, and principles for mitigating and governing biorisks and dual-use research**			
4.1	Strengthen research oversight for the dual-use research governance	4.1.1 Revise or develop research policies and regulations for dual research in life sciences. 4.1.2 Review the scope of research governance requirements at the coordination unit for inclusion of dual-use research. 4.1.3 Advocate for expanding on the current scope of research coordination unit to include dual-use research governance. 4.1.4 Update the national research inventory (institutions and approved RECs/IRBs across all ministries. 4.1.5 Sensitize and train the RECs on dual-use research governance. 4.1.6 Conduct regular monitoring visits (site initiation, interim and close-out) for research adherence. 4.1.7 Establish a mechanism to monitor the DIY research	Midterm	Uganda National Council of Science and Technology

4.2	Advocate for increased budget allocation and funding opportunities for research to include dual-use research governance	4.2.1 Review the resource mobilization strategy or model to determine the funding needs required for sustainable implementation. 4.2.2 Develop a costed prioritization matrix for resource mobilization 4.2.3 Advocate for inclusion of the costed plans into plans of respective MDAs for securing government support 4.2.4 Advocate for an increase in budget allocation for research and domestication of the framework. Justify more resources towards the governance of dual-use research	Midterm	
Objective 5.0	**To monitor and evaluate the implementation of the WHO global guidance framework for responsible use of life sciences in Uganda.**			
5.1	Strengthen monitoring and evaluation systems in alignment to the WHO or National reporting structures	5.1.1 Design the M& E framework that stipulates key performance indicators (KPIs) to enhance timely reporting 5.1.2 Incorporate the dual-use research governance key performance indicators (KPIs) into the National M&E framework to enhance timely reporting on dual-use research. 5.1.3 Develop, refine, or review monitoring and evaluation tools for the defined key performance indicators (KPIs) for national reporting. 5.1.4 Conduct annual performance review meetings/workshops to support Data quality assurance (DQA) and analysis. 5.1.5 Compile and submit regular M&E reports to relevant authorities. 5.1.6 Perform audits to monitor the implementation of the policies on DUR research	Long term	Office of the Prime Minister Line MDAs


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