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Graduate Institute of International and Development Studies

In partnership with the World Health Organization (WHO)

STRENGTHENING HEALTH RESEARCH AND DEVELOPMENT CAPACITY IN LOW-INCOME AND LOWER-MIDDLE-INCOME COUNTRIES

Policy recommendations for sub-Saharan Africa

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Applied Research Project

In partnership with the World Health Organization (WHO)

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- Dr. Philip A. Adeniyi, Founder of African Young Scientists (AYS);
- Ms. Odireleng Keipopele, Patent Examiner, The African Regional Intellectual Property Organization (ARIPO);
- Dr. Suerie Moon, Director, Global Health Center, Geneva Graduate Institute (IHEID);
- Dr. John Arne Røttingen, Ambassador for Global Health, Norwegian Ministry of Foreign Affairs, and founding Chief Executive Officer of Coalition for Epidemic Preparedness Innovations (CEPI);
- Dr. Rhoda Wanyenze, Dean, Makerere University School of Public Health in Uganda;
- Dr. Alexandra Graham, Former CEO of LaGray Chemicals and Founder of LaGray Financing
- Dr. Nanthalile Mugala, Director of the Africa Division, Program for Appropriate Technology in Health (PATH);
- Mr. Philippe Guinot, Chief Technical Officer, IntraHealth.

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List of Acronyms and Abbreviations

AHS	Africa Health Strategy
AMRH	African Medicine Regulatory Harmonization
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Organization
AU	African Union
AUDA	African Union Development Agency
AVAREF	African Vaccine Regulatory Forum
AYS	African Young Scientists
CEPI	Coalition for Epidemic Preparedness Innovations
CDC	Center for Disease Control and Prevention
COE	Centers of excellence
COHRED	Commission on Health Research for Development
CTC	Clinical Trials Community
EDCTP	European and Developing Countries Clinical Trials Partnership
EMRO	WHO Regional Office for the Eastern Mediterranean
FTAs	Free-Trade Agreements
GDP	Gross Domestic Product
HICs	High-Income Countries
HR	Health Research
IP	Intellectual Property
ISO	International Standards Organization
LMICs	Low-Income and Lower-Middle-Income Countries
NMRAs	National Medicines Regulatory Associations
NEPAD	New Partnership for Africa’s Development
OAPI	L'Organisation Africaine de la Propriété intellectuelle
PANTHER	PANdemic preparedness platform for Health and Emerging Infections Response
PATH	Program for Appropriate Technology in Health
PPPs	Public-Private Partnerships
R&D	Research and Development
REC	Regional Economic Communities
SSA	sub-Saharan Africa
SWOT	Strengths-Weaknesses-Opportunities-Threats
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHA	World Health Assembly
WHO	World Health Organization

Executive Summary

The global discussion surrounding the importance of improving and strengthening health research and development (R&D) across the world started in earnest 30 years ago. Even so, the issue of insufficient and fragmented health R&D capacity persists, particularly in low-income and lower-middle-income countries (LMICs). Nevertheless, the COVID-19 pandemic gave a new wind to this discussion and sparked interest in localizing both manufacturing and R&D of medicine, vaccine, and diagnostic tools. In this context, the World Health Organization (WHO) is now exploring the creation of a recommendation framework to empower LMICs in building and strengthening their domestic health R&D system. This research aims to provide the WHO with a starting point, by identifying good practices across LMICs and providing policy recommendations specifically tailored to the sub-Saharan African (SSA) region.

Our analysis highlights that the current regional political and economic context does not yet lend itself to the creation of a resilient health R&D system due to the difficulty to sustain sufficient funding and retain skilled researchers, as well as the lack of overall incentives to conduct health R&D. However, we also found that the region displays a true appetite for overcoming these difficulties, as shown by the increased political commitments and the wide array of new regional initiatives.

Through a hybrid methodology and thanks to a series of qualitative interviews, we structured our recommendations according to a seven-pillar framework to help SSA governments in this endeavor:

1. **Strategic agenda-setting and monitoring:** including the creation of a locally relevant, evidence-based research program, and the establishment of a dedicated public body to coordinate it and streamline ethical and regulatory frameworks.

2. **Building on and taking advantage of global and regional opportunities:** including advocating for and leveraging international support, taking advantage of regional initiatives, and creating a regional health R&D agenda.

3. **Fostering the application and management of intellectual property (IP) rights and medicine/health technologies regulation regimes that promote innovation while maximizing public health and equitable access:** through efforts to match international standards, to aim toward regional harmonization, and to conduct sustainable IP promotion.

4. **Creating sustained, sufficient, and intentional financing schemes and mechanisms:** through innovative revenue generation, transparent funding distribution systems, and incentives for the private sector or researchers to conduct health R&D.

5. **Improving, increasing, and sustaining research infrastructure as well as investing in innovative and material capacity:** by meeting basic infrastructure needs and subsidizing local infrastructures, including centers of excellence.

6. **Building, improving, retaining, and sustaining human capacity with research knowledge, skills, and experience:** through better health research education, mentorship programs, career opportunities and incentives, and empowering researchers.

7. **Fostering cooperation, synergies, and efficient management of resources and research efforts:** through network-building and information sharing across the region, sectors, and domestic stakeholders to create a supportive research environment.

Our mapping exercise of best practices at the country level shows the diversity of ways in which these recommendations can be implemented and anchors our framework within real-world evidence. We believe that through these recommendations and by learning from other LMICs, sub-Saharan countries can develop cutting-edge and locally relevant health R&D systems, contributing to the region's socio-economic development.

Introduction

Background

The global discussion surrounding the importance of improving and strengthening health research (HR) and health research and development (R&D) across the world started in the 1980s. In 1990, the Commission on Health Research for Development (COHRED) stated that strengthening research capacity in low-income and lower-middle-income countries (LMICs) is "one of the most powerful, cost-effective, and sustainable means of advancing health and development" (COHRED, 2012). Then, throughout the 1990s, the Commission published a series of reports highlighting that less than 10% of global health research funding was directed toward addressing the health needs of LMICs, which account for 85% of the world's population and 92% of the global burden of disease (World Health Organization, 2012). With health R&D knowledge being increasingly considered a global public good, the World Health Organization (WHO) and the international community deployed many efforts to foster health R&D, as a separate issue from overall HR (Matlin and al., 2013). In 2008, the World Health Assembly adopted the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property promoting the development of new medicines, vaccines, and other health technologies that are affordable and accessible to all (World Health Organization, 2011a). Shortly after, in 2011, the publication of the Financing and Coordination Report of the Consultative Expert Working Group on Research and Development (WHO commissioned) completely reframed the conversation around what the global and international response should look like (J.-A. Røttingen & Chamas, 2012). In parallel, other solutions were explored often in the form of public-private partnerships.

Yet, after 20 years of coordinated efforts, the issue of insufficient and fragmented health R&D capacity persists in LMICs and globally. Still today, health R&D remains low on the priority list of LMICs. Overall, very little of their government expenditure on health goes into R&D, forcing research institutions to rely on external funding. This situation leads both to high-income countries (HICs) and foreign private pharmaceutical firms having control over domestic health R&D agenda (Lapres, 2022), and a limited domestic pharmaceutical industry, often focusing on manufacturing generic medicine. However, the COVID-19 pandemic gave a new wind to the global and local interest in addressing inequalities in access and R&D/manufacturing capacity of vaccines, therapeutics, and diagnostic tools. We are witnessing a historic recognition of the need to take local ownership of these processes across the world (S. Moon, personal communication, May 11, 2023). In particular, building local health R&D capacity could enable the African continent to overcome its disproportionate disease burden and better prepare for and respond to future pandemics. Sustained health R&D capacity could empower sub-Saharan African (SSA) countries to build a knowledge-based economy, moving away from dependence on foreign commodities and agricultural production (Wenham and al., 2021). Although the region still displays limited government support and scarce logistical, financial, and human resources (Kuepfer & Burri, 2009), it shows an increasing interest in improving its health R&D capacity. Indeed, governments are making progress in strengthening their health research and innovation agendas by creating or joining several regional initiatives and adopting international, local, and public policies (Al-Bader, Masum, and al., 2010; Masum & Singer,

2010). We see the beginning of a systemic interaction that can be built upon to develop resilient and self-sustaining health R&D systems in the SSA region.

Purpose, Research Questions, and Structure of the Research

In this context, the WHO is now looking to create a set of recommendations and a roadmap framework for LMICs to build and strengthen national and regional effective and sustainable health R&D systems. But what policies should LMICs favor in order to create and develop a resilient and robust R&D system? Our research aims to answer this question through the mapping of good practices across LMICs and the curation of a set of policy recommendations directed at sub-Saharan African countries. In this document, we will first describe health R&D and its associated enabling system, as well as present our methodological framework and the process through which we created our recommendation set. Then, in our core findings, we will present the specific SSA challenges and opportunities, the recommendations to overcome or capitalize on them, and a series of successful or creative concrete applications across LMICs. Finally, we will present the current gaps identified, the limitations on the scope of our research, and the relevant next steps.

Methodological Framework

Definitions

Although there is no universally accepted definition of health R&D systems, for the purposes of this report we will use the following definitions:

Health R&D encompasses the basic and applied research, clinical trials, and product development of new medical products, such as vaccines, drugs, or diagnostics.

We define a **resilient national R&D system** as a set of interrelated processes and institutions that enable the development of health products and medical devices in a manner that is aligned with the goals of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (World Health Organization, 2011a). Therefore, indicators such as the number of new and improved health products receiving internationally recognized approval for use, and the number of peer-reviewed publications or clinical trials, are important but not sufficient to evaluate the performance of a national R&D system. The medicine and medical devices resulting from such a system would have to be developed ethically; available in sufficient quantities; effective, safe, and of good quality; affordable and accessible; used rationally (World Health Organization, 2011a).

Throughout this work, we remain mindful that **health R&D**, **non-health R&D**, and **health research**[1] are not terms that can be used interchangeably. However, we acknowledge and use literature regarding the three concepts, to the extent that many recommendations aimed at

[1] Research and development (R&D) refers to the systematic process of investigation, experimentation, and innovation aimed at expanding knowledge, developing new technologies or products, and improving existing ones. Health research refers to the systematic investigation that aims to generate new knowledge or understanding about health, disease, and healthcare interventions.

improving HR or non-health R&D in LMICs are relevant to creating and sustaining domestic health R&D systems, in particular when it comes to building material and human capacity, as well as questions of information sharing. However, in this research, we will refer to health R&D simply as R&D.

Methodology and Scope of the Research

The methodology of this policy-oriented research project follows three central steps:

STEP 1

First, we proceeded to a thorough review of the current global and regional initiatives and recommendations aimed at improving R&D systems in LMICs and the specific R&D landscape in SSA. Through this top-down lens, we first gathered a framework of the most relevant and recurring recommendations directly binding by LMICs governments. We bundled these recommendations into seven cohesive pillars: (1) strategy and governance (2) regional and international opportunities and initiatives (2) enabling intellectual property rights and medical regulation regimes (4) sustained, sufficient and innovative funding (5) infrastructure and capacity-building (6) training and human capacity (7) networks and synergies (see Annex 1). Through this initial step, we also undertook a deep analysis of the SSA R&D landscape, which materialized in a Strengths-Weaknesses-Opportunities-Threats analysis (SWOT, see Annex 2) and a mapping of the relevant African initiatives (see Annex 3).

STEP 2

Second, we identified more specific policies, good practices, and country-level examples across LMICs within the identified sets of recommendations. We did so through a broad literature review of case studies[2].

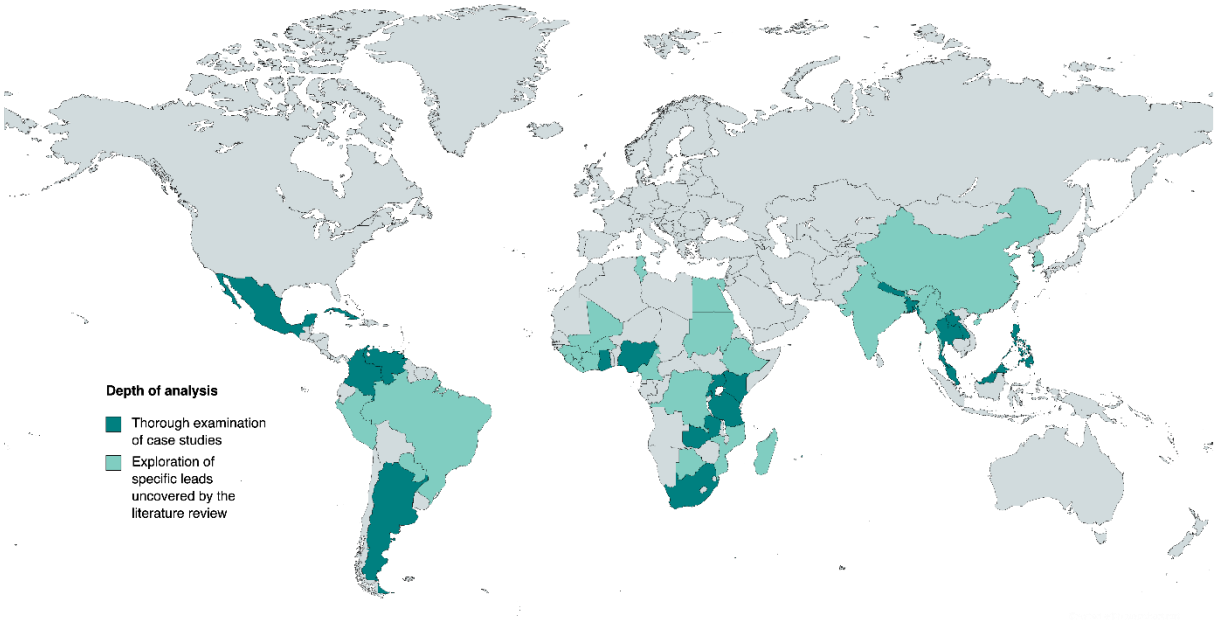

Figure 1. Scope of the best practices.

[2] Based on resource availability, we thoroughly examined case studies of Mauritius, Tanzania, Zambia, Kenya, Uganda, Nigeria, Ghana, South Africa, Rwanda, Nigeria, Cuba, Argentina, Mexico, Venezuela, Colombia, Bangladesh, Nepal, Laos, Malaysia, Singapore, Philippines, and Thailand. In addition, we also explored specific leads and examples uncovered by our literature review in the following countries (including some emerging economies): Peru, Tunisia, Egypt, Burkina Faso, Cameroon, Ivory Coast, DRC, Ethiopia, Guinea, Mali, Mozambique, Sudan, Sierra Leone, Liberia, Paraguay, Brazil, India, Myanmar, China, Madagascar, South Korea, and Botswana.

STEP 3

Finally, we probed each good practice's applicability and relevance to the SSA region through a series of qualitative interviews and using the filter of our SWOT analysis. We selected our interviewees based on three criteria: (i) expertise in health R&D and/or research in SSA, (ii) expertise in international frameworks, initiatives, and recommendations directed to LMICs, and (iii) diversity in perspective both when it comes to geography and sectoral backgrounds. In particular, we sought to have the most and foremost African voices (see interviewee list and template of interview questions in Annex 4). In other words, once the mapping exercise was done, we extrapolated more specific, concrete, and policy-oriented recommendations within our framework in a now bottom-up process, to then cross these findings with our initial top-down curated recommendation framework.

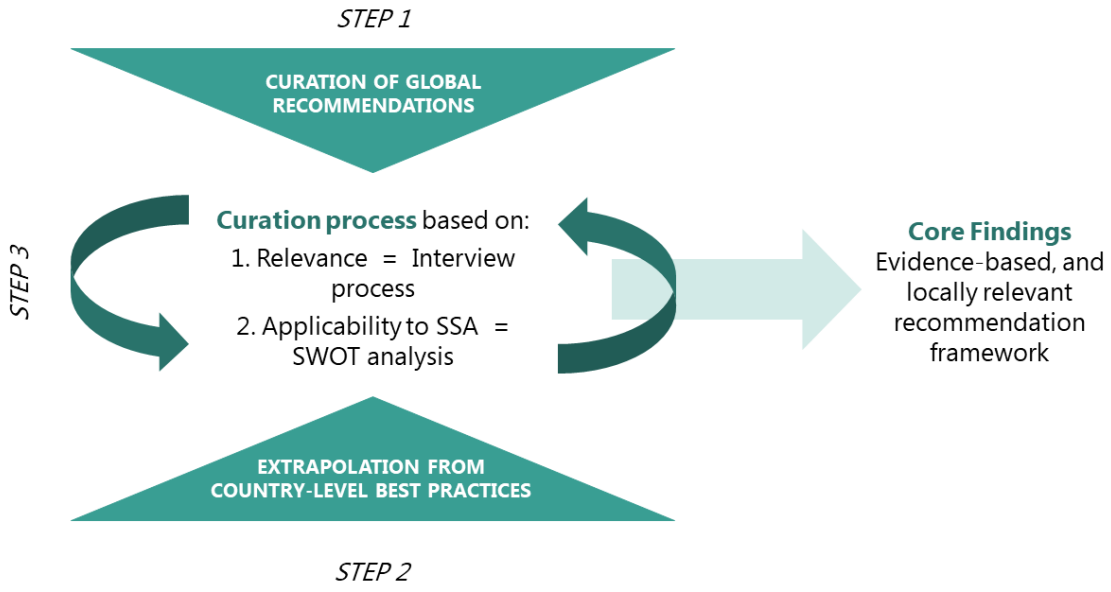

Figure 2. Methodological Framework.

Limitations

Throughout the research process, we encountered a series of hurdles. Our principal limitation was the overall lack of policy-oriented literature and national case studies directly focusing on health R&D. We mitigated this challenge by extending our research to the relevant literature regarding both health research and R&D across sectors, which allowed us to deepen and complete our analysis. However, we stress the need for further specific research on national health R&D systems in all regions.

Other challenges are more difficult to mitigate, such as accessing relevant literature due to the variety of languages of local publications across SSA and LMICs, securing interviews from African stakeholders, and the unavoidable trade-offs between systematism in the scope and selection of examples to deliver a qualitative report. However, to properly overcome these challenges and avoid trade-offs, a narrower scope of research or a longer timeframe would be needed. In all, we believe that the hybrid top-down and bottom-up methodology and the resulting recommendations are relevant and provide a strong basis for the WHO to build its guidance for LMICs to create and strengthen their health R&D systems.

Key findings: Recommendations framework and country-level applications

In this central section, we structured our findings according to our seven-pillar framework. Within each pillar, we will begin by elaborating on the specific challenges and opportunities associated with the issue at hand, whether regulatory, IP-related, financial, associated with material and human capacity, or fragmentation. Then, we will proceed to present our specific recommendations, which we curated through our bottom-up and top-down hybrid research process. For each of these recommendations, we will provide real-world examples of potential implementations. We note that this research is policy-oriented and that we will not dive into these examples – however, we aim to map them to empirically anchor our recommendations.

1 PILLAR ONE: Strategic agenda-setting and monitoring

First, we focus our lens on the political and regulatory undertakings. Indeed, the recent increase in international commitments bears witness to the interest of SSA countries in health R&D, but governments need to integrate them into local policies and institutionalize them as a priority so that they can have an impact (S. Moon, personal communication, May 11, 2023). Nevertheless, according to a recent study measuring health science research and development in 54 countries in Africa, less than half of SSA countries have "a nationwide official health research policy, a national health research strategy/policy plan, a health sciences research law or regulation, or a budget line for health sciences research within the ministry of health" (Wenham and al., 2021). Oftentimes, health R&D falls in between or at the intersection of the health and innovation strategies, which are not managed by the same ministries[3], leading to overlapping and fragmented management of the issue.

> *"R&D is a very specialized and technical issue, and it often takes decades to reap results. Contrary to access to medicine, you can't get headlines about it and therefore advocacy groups do not play a big role. When it comes to R&D, nothing can be done without strong government commitments and strategy."* (S. Moon, personal communication, May 11, 2023)

As mentioned in the previous section, due to the external funding structure and the lack of internal means and commitments, states often lack ownership over the research agenda within their borders, which leads to an R&D that does not match their burden of disease. The domestic relevant political bodies should re-take control over the agenda, establish clear priorities, and the supporting regulations. Indeed, if countries have an explicit and formal strategy, donors increasingly channel their investments in support of national priorities. This is an opportunity to work with, and not against, the existing global funding structures and institutions (P. Guinot, personal communication, May 30, 2023). Furthermore, when the priority is institutionalized and is reflected in cohesive regulatory frameworks, the government is more

[3] Health R&D regulation often falls under the authority of the Ministry of Science, Technology and Innovation.

easily involved in R&D and domestic or external opportunities are more likely to emerge. Finally, streamlining ethical review processes is central to facilitating the implementation and creation of such opportunities. In SSA, ethics committees are too often underfunded, understaffed, or do not have properly trained personnel making the approval process long and costly for research institutions. There is also an interest in harmonizing these ethical criteria to approve or register a project across the region to favor multi-countries research (P. Guinot, personal communication, May 30, 2023).

Recommendations

1. ***Create an evidence-based and locally relevant research agenda:*** the R&D priorities and objectives should be explicit within the policy framework and the national health strategy.

   1.1 Undertake a situational analysis, working with local stakeholders to identify gaps, needs, and priorities to create a national strategy. Such systematic analysis can ensure that the priorities match local needs and are implementable through existing research structures.

   *In **Mexico**, the National Council on Science and Technology coordinates evidence-based policy, following indicators derived from large-scale national surveys* (Inicio – Conahcyt, 2023; Martínez-Martínez and al., 2012).

   1.2 Ensuring the inclusion of local communities throughout the design and implementation of the national health strategy.

   *In **Zambia**, the National Health Strategic Plan lays out a strategy to establish linkages between neighborhood health committees and community research advisory boards* (Juma and al., 2021; Republic of Zambia Ministry of Health, 2022).

   1.3 Identify and capitalize on areas of comparative advantage, including traditional and phytomedicine.

   *The National Centre for Plant Medicine Research (CPMR) was established by the government of **Ghana** in 1975 to facilitate and coordinate all research work on Ghanaian medicinal plants. It is the first SSA traditional plant R&D center recognized by the WHO* (Center for Plant Medicine Research, 2022; A. Graham, personal communication, June 1, 2023).

2. ***Create or designate a coordinating and monitoring body or mechanism ensuring the implementation and assessment of the strategy***, this can be done through:

   2.1 A single statutory institution or authority, responsible for both research regulation and coordination

   *In **Zambia**, the National Health Research Authority operates as a public independent body in the health sector that is responsible for regulation, coordination, promotion of research, building research capacity, and facilitating knowledge translation* (Juma and al., 2021).

2.2 A dedicated overseeing and coordinating body or institutional mandate

*Although the **Mauritius** Research and Innovation Council conducts, coordinates, and funds R&D, it only acts as the advisor to the government, not as the regulator, leading to duplication of efforts* (Juma and al., 2021; Musango and al., 2023; Uganda National Health Research Organization, 2023).

2.3 A parastatal institution mandated to conduct health R&D: to improve sustainable access to safe, high-quality, and affordable medicines

Box 1 - To explore further

*The public sector agency Kenya Medical Research Institute (KEMRI) regulates, advocates for, coordinates, and gives advice on R&D in **Kenya*** (Juma and al., 2021).

*Established in 2011, the **Uganda** National Health Research Organization works to coordinate, promote and provide guidance for health R&D* (Jones and al., 2021).

*In **Nigeria**, the National Institute for Pharmaceutical Research and Development (NIPRD) operates under the Federal Ministry of Health, statutorily charged with the responsibility for R&D of drugs, vaccines, phytomedicines, commodities, and diagnostics* (National Institute for Pharmaceutical Research and Development, 2023).

3. Improve and streamline the regulatory and ethical framework

3.1 Implement a national legislative framework on health R&D

***Kenya** launched a Research for Health Policy Framework aligning research investment with national priorities. Among others, it streamlines the regulatory system and outlines key priorities and structures for health research agenda-setting* (PATH Organization, 2015a).

3.2 Transitioning responsibility for the governance of science, technology, and innovation (STI) to a specific health R&D institution

*In **Uganda**, National Health Research Organization and the National Council for Science and Technology are both responsible for regulation and oversight of health R&D, potentially leading to regulation overlaps* (Jones and al., 2021; Uganda National Council for Science and Technology, 2023; Uganda National Health Research Organization, 2023).

3.3 Enhance visibility and clarity of national health R&D through public interfaces and clarify the responsibilities of R&D stakeholders

***Kenya**'s Health Act establishes the links between institutions and stakeholders in the regulatory environment and streamlines the regulatory process for researchers, according to one decision-maker. It defines the key stakeholders in the public and private sectors* (Jones and al., 2021).

3.4 Establish a standardized ethical code and national Research Ethics Committee office: for centralized oversight of ethical research in the country, and/or enhance the capacity of individual ethics committees in the country (Silaigwana & Wassenaar, 2015).

Box 2 - To explore further
*The National Research Ethics Board in **Zambia** performs particularly well* (P. Guinot, personal communication, May 30, 2023; National Health Research Ethics Board, n.d.).

2 PILLAR TWO: Building on and taking, advantage of global and regional opportunities

In this section, we focus on the role of the state as an actor in the international and regional systems. At the international level, Africa has strong and deep-rooted partnerships with other regions. Yet, it relies heavily on HICs' resources and technology transfers. LMICs and African countries have many avenues for negotiation within existing international agreements and initiatives to enhance their R&D capacity, notably the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements and Free-Trade Agreements (FTAs).

Within Africa, health R&D, as well as the overall economic structure, are fragmented. There are several Regional Economic Communities (RECs) wherein an abundance of resources remains untapped, and the lack of stakeholder transparency does not allow for a better allocation regionally. Public-Private Partnerships (PPPs), memorandum of understanding (MoUs), and stakeholder consultations are some of the many available mechanisms for collaboration. However, strong leadership is necessary to continuously conduct cooperation and coordination efforts across the region.

"I think there is a lot to learn from one another. Many challenges we have across countries in Africa are similar. It is surprising to realize how much we share when we get together to talk. It is also interesting just how, within the same context and the same problems, some countries have managed to break through and advance solutions that have moved and improved health and health outcomes, while other did not." (R. Wanyenze, personal communication, May 18, 2023)

The 55 member-states of the African Union (AU) recognize, through the Africa Health Strategy and the New Partnership for Africa's Development (NEPAD), the importance of African-centered research and innovation to tackle challenges in the region (African Union Development Agency (NEPAD), 2019). It is a laudable initiative, but specific, strong, clear, and coordinated action is required to make an impact. There is a need to include all health R&D stakeholders – research institutions, higher-education institutions, and public and private sectors – within one vision and framework. Advocacy and leadership efforts of SSA local governments would welcome technology transfers and health research innovation in their countries.

1. *Leverage international support and initiatives*

1.1 Fully leverage flexibilities and development opportunities associated with ratified international agreements and initiatives

Overall, LMICs should use the opportunities and flexibilities within the agreements they ratified, such as the TRIPS. 39 out of 47 ***African Countries*** *have used TRIPS flexibilities*[4] *at least once* (Motari and al., 2021).

While the ***European and Developing Countries Clinical Trials Partnership (EDCTP)*** *is a European Union-funded initiative, SSA health challenges are its sole focus and it involves cooperation between 15 European and 25 African governments* (European & Developing Countries Clinical Trials Partnership, 2018).

1.2 Advocate for technical and physical support from the international community:

including grants, technology transfers, and training.

During the research development program in West Africa during 2009–2013, ***West African Health Organization (WAHO) Research Units*** *were highly successful in helping countries with material support, professionals participated in national meetings, and a WAHO consultant was supporting the development of policy documents and research plans* (Aidam & Sombié, 2016; Sombié and al., 2017).

Box 3 - To explore further

In ***Nigeria*** *and* ***Ghana,*** *the NIH-Funded Research Capacity Grant launched the Multiple-PI Approach in 2006, as a mechanism for collaborative health research and stimulating interdisciplinary science for selected grant applications* (Sam-Agudu and al., 2016).

2. *Support, encourage, and invest in regional cooperation*

2.1 Push toward the establishment of a regional agenda:

by the African Union or the African CDC to tackle common challenges in the SSA region.

The ***Association of Southeast Asian Nations (ASEAN)*** *has a technical working group for specific matters such as improving IP rights and harmonizing medicinal regulations, having measurable deliverables per year, and meeting regularly to review these deliverables, with the overall goal of harmonization of IP rights and regulatory frameworks in the region* (ASEAN, 2016).

2.2 Leverage, join, and support the initiatives of regional communities:

by creating a national mechanism to manage these partnerships, and create additional opportunities for regulatory collaboration.

[4] There are many forms of TRIPS flexibilities, some of them being: (1) compulsory licensing; (2) exemption from patentability based on what constitutes novelty; (3) limits on test data protection; and (4) patent term extension (Motari and al., 2021).

*In the African region, the **African Vaccine Regulatory Forum AVAREF**'s mission is to "help national regulatory authorities, ethics committees, and sponsors achieve consensus on ethical and regulatory questions surrounding the research and development of medical products in Africa"* (African Vaccine Regulatory Forum (AVAREF), 2023).

2.3 Reinforcing the promotion role of the state and advocacy diplomacy

*In **Colombia** and **Cuba**, the governments have the goal of promoting their country as a destination for health R&D in their foreign policy strategy* (BioCubaFarma, 2018; *Colombia Promotes Itself as a Destination for Clinical Research*, 2014).

3 PILLAR THREE: Fostering the application and management of intellectual property rights and health technology regulation regimes that promote innovation and maximize public health and equitable access

In this pillar, we emphasize and explore the enabling power of performing intellectual property (IP) and health technologies regulations across sub-Saharan states. Indeed, there is a need for harmonization among SSA governments in both areas. Concerning IP rights, researchers are largely unaware of the benefits of applying IP protections in the form of patents, copyright, plant breeder's rights, geographical indications, and trade secrets, on their work. They often ignore that such tools can be applied to technologies, biopharmaceuticals, and medical devices, and are equally efficient to protect plant discoveries and traditional medicines. Moreover, patents are an essential tool for R&D and cooperation with other states (O. Keipopele, personal communication, May 10, 2023; Ndomondo-Sigonda and al., 2023). Due to the little awareness and the cumbersome administration of the application process, there is low utilization of these protections by health scientists in Africa. Thus, patent applications in SSA countries come mostly from HICs, such as the United States and Europe, as well as from multinational pharmaceutical companies[5] (Motari and al., 2021; O. Keipopele, personal communication, May 10, 2023). Individuals and organizations pursuing health R&D should be able to maximize the available IP protection in Africa.

Meanwhile, when it comes to medicine regulation, there are persisting differences between SSA National Medicines Regulatory Associations (NMRAs) in terms of management and structures. For example, there is fragmented expertise and capacity in NMRAs within the region, demonstrating the need for cooperation to leverage resources (Ndomondo-Sigonda and al., 2023). A faster and more efficient harmonization of medicine regulations would be a win for all health R&D stakeholders.

"When LaGray Chemical registered a drug in Ghana but wanted to export it to Nigeria, we had to go through the registration process again. So, these manufacturing and intellectual property regulations need to be harmonized regionally in line with international standards." (A. Graham, personal communication, June 1, 2023)

[5] To elaborate, Cameroon and South Africa were the only African countries in the top 10 in terms of the number of patents in ARIPO and OAPI (Motari and al., 2021).

Several SSA countries have come together to address this regulatory issue through instituted initiatives, namely the African Regional Intellectual Property Organization (ARIPO), L'Organisation Africaine de la Propriété Intellectuelle (OAPI), and the African Medicine Regulatory Harmonization (AMRH)[6]. Each regulatory institution has its own objective, which is either IP protection (OAPI and ARIPO), or health technologies regulatory facilitation (AMRH). Although they still have limited human resources and budgets for capacity-building activities, cooperation with these initiatives should be encouraged "to share best IP practices, allow harmonization and fast-tracking registration of medicines" (Ndomondo-Sigonda and al., 2023; PATH Organization, 2015a).

Recommendations

1. *Leverage international recognition*

1.1 Amendment of regulatory policies and guidelines with international standards: develop national guidelines on establishing formal collaboration agreements between national and foreign R&D institutions and ensure that patent protection laws are recognized by the international community.

Malaysia *has amended its Patent Act to ensure that its patent protection laws are in line with international standards/agreements. The amendments incorporate Malaysia's commitments to various international treaties* (Koty, 2022).

1.2 Ensure that National Medicines Regulatory Authorities (NMRAs) are in line with international standards and ISO accreditations: to attain more leverage and international recognition in the testing of regulated products, to ensure quality and safety of health technologies, while countering substandard and counterfeit products, and boost consumer confidence.

The Food and Drugs Authority (FDA) of ***Ghana*** *has successfully achieved ISO 17025 re-accreditation by the ANSI National Accreditation Board (ANAB)* (Promoting the Quality of Medicines, 2016).

Box 4 - To explore further

In Africa, the NMRAs of ***Nigeria Tanzania, Egypt, Ghana, and South Africa*** *are elevated to WHO Maturity Level 3* (NAFDAC, n.d.; World Health Organization, 2021).

2. *Foster medicine and IP rights-related regional harmonization*

2.1 Foster mutual recognition of quality control within NMRAs in the SSA region: enhance harmonization buy-in of regulations between SSA countries. This will positively impact the cost and timeliness of medicines regulation between countries that attain international accreditation for their NMRA Quality Control laboratories (Okezue and al., 2020).

[6] AMRH was established in 2009. It is in charge of ensuring harmonization among national regulatory agencies (NMRAs), specifically coordinating, and performing regulatory reliance and other principles of smart regulation (Ndomondo-Sigonda and al., 2023).

2.2 Support and cooperate with activities initiated by ARIPO, OAPI, and AMRH: these institutions are well-functioning despite limited resources and budget. There is a need to harmonize regional countries' regulations with the organization's legislation to facilitate the registration process. Moreover, member states should take advantage of their capacity-building programs.

*Today, **ARIPO** is understaffed, but its potential for development is substantial. Moreover, ARIPO does not require member states to have patent laws in line with its own (unlike OAPI), showcasing the potential for regional harmonization* (O. Keipopele, personal communication, May 10, 2023).

***AMRH** supports national NMRAs by conducting joint assessments and inspections to allow transparency and reliability and by practicing regulatory reliance*[7] (Ndomondo-Sigonda and al., 2023).

3. Increase IP rights understanding and visibility across R&D stakeholders

1.1 Encourage publication under IP regime at the institutional and academic levels: raise researchers' awareness of the benefits of IP rights and encourage them to commercialize their work, by providing information, funding, and grants, as well as by ensuring access to information on the administrative status of health-related patents.

*In **Uganda**, Makerere's University School of Public Health, with about 250 publications per year, encourages academics to publish and commercialize their research under IP laws by holding information sessions and grants. It has created an IP office to support researchers in the patenting process* (R. Wanyenze, personal communication, May 18, 2023).

***ARIPO** and **OAPI** continuously pursue IP capacity-building and awareness through various workshops catered to both academia and private sector researchers. Some of the capacity-building activities are funded by the institution, but its budget is limited* (O. Keipopele, personal communication, May 10, 2023; l'OAPI, 2023).

[7] Reliance leverages the "output of the regulators whenever possible, so they can concentrate on carrying out regulatory activities like market surveillance and in-country pharmacovigilance" (Ndomondo-Sigonda and al., 2023).

4 PILLAR FOUR: Creating sustained, sufficient, and intentional financing schemes and mechanisms

In this section, we explore the current public financial commitments and shortcomings in the region, as well as innovative approaches to incentivize health R&D within the private sector. In sub-Saharan Africa, public financing remains very low as most governments have not met the commitment of allocating at least 1% of GDP to health and non-health R&D agreed upon by African Union Member States in 2015 (Dr Boutsika, 2018). In several countries, the international community is the primary funder of research, with the governments only in third place (Simpkin and al., 2019). As previously explained, health R&D in Africa depends on external funding, thus, governments have little say over the national research agenda (J. A. Røttingen, personal communication, May 16, 2023). They are often not engaged in this funding process, with the money flowing directly to the health research institutions (A. Graham, personal communication, June 1, 2023). Whether at the government or institutional level, investment in research is neither monitored nor well allocated, often resulting in double funding or shortfalls in certain areas of research.

> *"The external funds that Makerere University receives are not even well managed due to a lack of management or administrative capacity."* (R. Wanyenze, personal communication, May 18, 2023)

Finally, there are few or no government incentives for private companies to invest in healthcare R&D. Where they do exist, they usually place a disproportionate burden on pharmaceutical companies or fail to prioritize the local market.

> *"As a pharmaceutical company in Ghana, one requirement is that you export 70% of drugs outside the country in order to qualify to be a free zones company, and receive tax incentives."* (A. Graham, personal communication, June 1, 2023)

Fortunately, we are witnessing a commitment on the part of SSA governments to increase long-term public investment in R&D. Indeed, all members of the African Union have adopted the African Health Strategy (2016-2030), in line with the AU Agenda 2063[8] and the SDGs, recognizing the importance of investing in research and innovation (African Union Development Agency (NEPAD), 2019). This can be achieved by building a strong national research funding system, through increased government funding, and should be progressively followed by private sector investment (J. A. Røttingen, personal communication, May 16, 2023).

[8] Adopted in 2015**,** Agenda 2063 is Africa's development blueprint to achieve inclusive and sustainable socio-economic development over a 50-year period.

1. ***Find innovative revenue generation mechanisms to decrease reliance on foreign and private funding***, through the exploration of direct or indirect taxes, etc.[9]

   *In 2009, WHO identified 28 countries that allocated a proportion of tobacco-tax-related revenues for health-related purposes, including **Ghana** and **Gabon*** (World Health Organization. Regional Office for South-East Asia, 2012).

2. ***Ensure coordinated, sustained, and sufficient funding mechanisms to support health R&D across the value chain***

   2.1 Commit to devoting 1% of GDP to research and development: reach the target set by the **African Union** in 2006 and set aside a part of this funding to create a national research budget to develop health R&D (Simpkin and al., 2019).

   *The **South African** government committed to allocating at least 2% of the total R&D budget to health[10]. In 2021, the government (including scientific councils and universities' own funds) contributed 56.3% of the country's R&D funding and health sciences accounted for the majority of R&D expenditure* (PATH Organization, 2015; The Department of Science and Innovation (DSI) and al., 2022).

   2.2 Establish a national fund for R&D: gathering government budget, any levy established by law to finance R&D, and all external health R&D donations.

   Box 5 - To explore further

   *A Research Trust Fund has been set up by the National Health Research Authority in **Zambia*** (Juma and al., 2021).

   *The National Research and Innovation Fund established by the **Mauritius** Research and Innovation Council gathers external and internal investments* (Musango and al., 2023).

   *The Organic Law of Science, Technology, and Innovation (2005) required companies operating in **Venezuela** to invest a minimum percentage of their gross income in research R&D. The funds generated were collected in a national fund called the Fund for Science, Technology, and Innovation, managed by the National Council for Scientific and Technological Development. This system is similar to the Italian Medicines Agency's ad hoc fund, which requires pharmaceutical companies to contribute 5% of their annual expenditure to build researchers' capacity* (Avalos and al., 2020; World Health Organization, 2012).

[9] There is already a great number of literature, such as The World Health Report on Health Systems Financing (World Health Organization, 2010) and growing discussion on how to increase funding in the health and research sectors, which is why it will not be further discussed here. The literature lists several direct and indirect revenue generation mechanisms such as a levy on currency transactions, diaspora bonds, financial transaction tax, income tax, Value-Added Tax (VAT), consumption tax, tobacco and alcohol excise tax, etc.

[10] The South African government is meeting the 2008 Bamako Agreement, an important international commitment to direct 2% of the national health budget to health R&D.

2.3 Provide long-term funding and flexible grants to research institutions and scientists: within a stated strategic plan adapted to national priorities and ensure that the annual availability of funds is made public. Provide an easy, open, and transparent grant application process, with appropriate constructive feedback (Sam-Agudu and al., 2016).

*The **Ghanaian** government grants universities an annual allowance for research to help faculty members conduct small studies and collect preliminary data to support applications for larger grants. Yet, the fund has often suffered from delays and inconsistencies that undermine its sustainability* (Sam-Agudu and al., 2016).

Box 6 - To explore further

*In **Uganda**, the government's Research and Innovation Fund is supporting research institutions and universities to build their own R&D budget* (Jones and al., 2021).
*The **Nigerian** government has established the National Research Fund to finance research in education, funded through a 2% tax on profit of all registered companies* (Sam-Agudu and al., 2016; TetFund, 2023).

3. Create a stable, and transparent financing environment and incentivize private investment and entrepreneurship

3.1 Create a transparent and open database of all available grants, investments, and expenditures in research: to get a comprehensive picture of the up-to-date total health R&D budget (PATH Organization, 2015a).

3.2 Facilitate the creation of venture capital companies: to help R&D institutions be proactive in seeking financial support through financial incentives such as recoverable grants, below-market loans, forgone taxes, outright subsidies, preferential regulation, or through partnerships with funds overseas to grow the initial investment (Masum & Singer, 2010).

*Bioventures was the first venture capital company focused on life science in SSA, based in **South Africa**. Due to the fund's small size, it faced difficulties in making follow-on investments* (Masum & Singer, 2010).

*The Venture Capital Trust Fund (VCFT) is a semi-public fund established by the government of **Ghana** which provides investment capital to Small and medium-sized enterprises (SMEs), to date has invested little in the health sector* (Al-Bader, Masum, and al., 2010).

3.3 Incentivize R&D within the private sector and attract private sector funding in R&D: to support research in small firms, create a favorable business environment with tax incentives on equipment and raw material, lower banking rates, improved market access, and advance market commitments, etc. (Al-Bader, Masum, andd al., 2010). The government should reduce barriers to obtaining financial incentives (PATH Organization, 2015b).

*In **Mexico**, the Programa de Estímulo Fiscal a la Investigación y Desarrollo de Tecnología (2001) gives tax breaks to companies that invest in R&D. By 2007 the private sector's participation in the domestic spending on research had increased to 45.5%* (Martínez-Martínez and al., 2012).

*The **South African** government has successfully introduced a tax incentive to encourage private sector companies to invest in R&D. They can apply for a 150% tax deduction on their R&D expenditure* (PATH Organization, 2015b; World Bank Group, 2019).

5 PILLAR FIVE: Improving, increasing, and sustaining research infrastructure and investing in innovative and material capacity

This pillar focuses on the physical state and the panorama of R&D infrastructure in SSA and explores the need for better investment in infrastructure broadly, the key areas of capacity building, as well as the institutional arrangements that could streamline the existing human and material resources.

First, it is important to note that infrastructure in a broad sense is required to be able to conduct research, that is access to water, road systems, internet, etc. (R. Wanyenze, personal communication, May 18, 2023). Only then a strong lab infrastructure can be built. As of now, most researchers have to send their samples to a partner university in Europe or the United States for processing. This is partially the reason why the majority of SSA countries have established basic manufacturing systems but have few emerging R&D players. Indeed, most sub-Saharan pharmaceutical companies lack R&D units or directors to oversee innovation (Kuepfer & Burri, 2009). The size of the sector in the region varies considerably, with some countries having more than 200 registered pharmaceutical manufacturers, such as South Africa, Nigeria, Ghana, and others fewer than five, such as Cameroon, Swaziland, Lesotho, and Malawi (African Union Commission, 2012; Wenham and al., 2021). However, very few active manufacturers produce active pharmaceutical ingredients (APIs), as the continent relies mainly on imports, which appear to be more trusted by locals.

"We did a market survey in Ghana and the conclusion was that the industry is not ready to buy APIs from an African company. Even if selling our APIs for a dollar less than our Indian or Chinese competitors, domestic customers would still favor them over local producers." (A. Graham, personal communication, June 1, 2023)

When it comes to R&D, the product development phase is mostly oriented toward participation in clinical trials, which represents only about 4% of global clinical trials output (Wenham and al., 2021). Indeed, the region displays a large pool of "naive patients"[11]. The Health Ministries should focus on supporting and building the clinical trial capacity of specific institutions and then promote them as a destination for this step of the R&D process (P. Guinot, personal

[11] Naive patients are individuals that were not administered any previous treatment or medication.

communication, May 30, 2023). Furthermore, the market penetration of medicine is faster in countries that participated in the clinical trial.

Finally, in SSA, there is a broad diversity of bodies of researchers, whether public or private. Sometimes large public research groups are referred to as “research centers'', whereas that term technically refers to a body of researchers that is formally approved by a given university to operate as an independent unit within the academic structure (A. Graham, personal communication, June 1, 2023). These inconsistencies of terms across the region and institutional layers add to the confusion and fragmentation. Overcoming these difficulties and centralizing public research has been proven difficult due to resistance and competition from the private sector, as well as competition across institutions and countries (P. Guinot, personal communication, May 30, 2023).

Recommendations

1. ***Ensure an enabling environment and infrastructure for development broadly,*** including upgrading public libraries, and information technology, as well as stable power and water supplies while keeping utility costs low (World Health Organization, 2021).

2. ***Encourage and support progress towards self-sufficiency in drug production,*** while combating the import of low-quality products and counterfeit drug production.

   *In **Ghana**, LaGray Chemical aimed to set up an international-standard manufacturing facility for the production of active pharmaceutical ingredients (APIs) but had to close due to a lack of funding and government support* (A. Graham, personal communication, June 1, 2023).

3. ***Fund and develop national research institutes and centers of excellence,*** centrally located, easily accessible, well-networked, and equipped with specialized equipment, to prioritize certain diseases according to the research agenda and local needs. These centers could build competitiveness by focusing on downstream R&D, to then scale back up to upstream research once the center is well established (P. Guinot, personal communication, May 30, 2023; Nwaka, 2021; Simiyu and al., 2010; World Health Organization & Alliance for Health Policy and Systems Research, 2021). These centers would ensure a continuum of projects to maintain and sharpen researchers’ expertise, allow for better coordination with Health Ministries, and ensure the domestic accessibility and marketability of the research output (P. Guinot, personal communication, May 30, 2023).

*In **Zambia**, the Tropical Diseases Research Centre (center of excellence) leads to improvements in research infrastructure and outputs, attracts external funding, and builds capacity in the country* (Jones and al., 2021; Tropical Diseases Research Centre, n.d.).

*The **African CDC** could play a central role in the creation and coordination of these hubs. It could also be instrumental in creating and endorsing harmonized minimum standards to facilitate foreign and private investment, like quantity and quality of equipment, training, ethical practices, etc.* (P. Guinot, personal communication, May 30, 2023).

Box 7 - To explore further

***Biovac** is a successful biopharmaceutical company born from a partnership formed with the South African government in 2003 to establish a local vaccine manufacturing capability for national health management and safety* (*Biovac*, n.d.; A. Graham, personal communication, June 1, 2023).

6 PILLAR SIX: Improving, increasing, retaining, and sustaining human capacity with research knowledge, skills, and experience

One of the main challenges in sub-Saharan Africa is building research capacity, due to factors such as limited funding, inadequate curriculum, brain and talent drain, limited access to training and mentorship opportunities, and the lack of continuum between educational and professional settings (N. Mugala, personal communication, May 19, 2023).

In fact, only a few universities across the region offer higher education training in health R&D. In general, SSA governments prioritize primary and secondary education, partly due to the recommendations of the World Bank and International Monetary Fund and the old structural adjustment issues of how best to invest limited resources (P. Adeniyi, personal communication, May 22, 2023; R. Wanyenze, personal communication, May 18, 2023). There are therefore no well-established policies and support mechanisms for postdoctoral programs, inducing local talents to go abroad to continue their studies.

"*Upgrading curriculum is the most crucial step if African health R&D is to catch up with developed countries.*" (P. Adeniyi, personal communication, May 22, 2023)

Furthermore, a doctorate is expensive and time-consuming, and few people have the resources to pursue it, especially women and young scientists.

"I heard from the women researchers repeatedly, they are not doing their PhDs as quickly because they do not want to go away for three years from their children or their husband." (R. Wanyenze, personal communication, May 18, 2023)

Lack of sustainable access to funds or grants hinders participation in scientific conferences, payment of open-access publication fees, or support for the dissemination and translation of research results. Instead, the university or individual scientist must bear the financial burden (Jones and al., 2021). For these reasons, R&D training in the healthcare sector is largely

dependent on external funding, which is reflected in the priority given to subjects of major interest such as HIV research. (R. Wanyenze, personal communication, May 18, 2023).

Currently, Africa only produces 2% of the global publication output (Simpkin and al., 2019; Wenham and al., 2021), the majority being issued by South Africa and North African countries. But this number could increase, thanks to the proliferation of private sector training programs, national grants, centers of excellence, and universities offering training and education in pharmaceutical innovation and manufacturing (A. Graham, personal communication, June 1, 2023). In other words, SSA governments urgently need to strengthen the creation and maintenance of human and institutional resources for research and development.

Recommendations

1. ***Prioritize capacity building in research and medical education systems***

   1.1 Invest in building human health research capacity and prioritize doctoral and post-doc training: by including it in the national research agenda to enable the creation of funding streams for a wide variety of doctoral programs (not only program-specific), strengthen local capacities, and avoid brain drain.

   *In **Kenya,** the government is the major funder of the state corporation and graduate school, Kenya Medical Research Institute (KEMRI) that trains postgraduate students in health research. It currently ranks as one of the leading centers of excellence in health R&D* (Jones and al., 2021).

   1.2 Take advantage of nationals abroad to build local knowledge: through mentoring programs, collaboration, or co-supervision on research projects or by offering them a teaching position in educational institutions.

   Box 8 - To explore further
   *In the **Philippines**, the government, through the Balik Scientist Program, encourages national scientists to return to the country and share their expertise* (Department of Science and Technology, 2020).

   *At independence, the **Tunisian** government invited researchers from the tunisian diaspora to organize and lead the research institutions that benefited the Tunisian health system through academic training, collaboration on R&D projects, online courses, and co-supervision of theses* (Jones and al., 2021).

   1.3 Favoring mentorships and empowering young researchers

   *The **Africa Young Scientists Organization** uses peer support and a mentoring platform to obtain training in research topics not covered by traditional education programs, by bringing together experienced researchers and young scientists based on the African continent. It also actively supports mentees to find internships thanks to partnerships across the industry* (P. Adeniyi, personal communication, May 22, 2023; Africa Young Scientists, 2023).

2. ***Improve industry linkages and encourage careers in health R&D***

2.1 Increase incentives for career progression by reducing the financial burden on scientists: such as raising researchers' salaries, harmonizing evaluation with public faculty members, and covering the cost of publication and attendance at conferences.

State interventions have been implemented in ***Côte d'Ivoire*** *to incentivize health research, such as increasing payments to researchers through allowances from 100 to 120% and harmonizing evaluation and career progression* (Jones and al., 2021).

2.2 Facilitate the transition from academia to the private sector for researchers

In ***Uganda****, the Makerere's University School of Public Health has permanent training sites within 50 private organizations, where Master's students spend 2 to 3 months working in the industry, and it has launched the Makerere University Private Sector Forum (MUPSF) to create linkages between industry and the university* (R. Wanyenze, personal communication, May 18, 2023; World Bank, n.d.).

3. ***Strengthening the recognition of scientists and the empowerment of research***

3.1 Boost scientific publication: through the following incentives (Mugabo and al., 2015; Musango and al., 2023):

- Improve writing and communication skills at the academic and institutional levels;
- Provide mentorship on the publication process;
- Acknowledge publishers and negotiate with national research institutions to make publication of articles in peer journals a criterion in salary increments or career progression;
- Include the number of publications as a criterion for the annual performance of institutions and universities.

In ***Cuba****, professional researchers are categorized using a system that considers their years of experience, professional level, and achievements. This system involves annual evaluations that assess individual and institutional indicators such as involvement in scientific projects and events, publications, supervision of dissertations, receipt of scientific honors and degrees, as well as the registration of patents, copyrights, and the implementation of research outcomes* (Pérez and al., 2018).

Box 9 - To explore further

The ***Tunisian*** *government has set up networks of business incubators (technopoles) and career development centers to help research laboratory units open and encourage scientists to commercialize their research* (Jones and al., 2021).

3.2 Empower and encourage young and female researchers to undertake research or doctoral studies: by offering scholarships or tailored education programs, such as part-time and subsidized Ph.D. training for women with children (R. Wanyenze, personal communication, May 18, 2023).

7 PILLAR SEVEN: Fostering cooperation, synergies, and efficient management of resources and research efforts through network-building and information sharing

In the SSA region, the challenges are similar from one country to another, and thus require cooperation between private and public research institutions, universities, pharmaceutical companies, and governments. The lack of coordination between regional players results in fragmented domestic markets, isolated research, and misallocation of already limited resources.

"Each research institution is trying to find a solution to a disease that may already exist, and investing resources in developing a new treatment when we could be learning from each other. By working together, we can solve cross-cutting continental challenges." (R. Wanyenze, personal communication, May 18, 2023)

Due to the poor availability of information, those conducting R&D are often unaware not only of the key players involved but also of the nature of their work (Kuepfer & Burri, 2009). As a result, national or regional partnerships and networks aimed at strengthening R&D capabilities are still rare and far behind. Moreover, inadequate data collection systems hamper access to data to guide decision-making, knowledge transfer, and measure performance (Coulibaly, 2011). Although conferences can help strengthen the governance of research, they still present a challenge of providing equitable access to researchers.

Encouragingly, SSA countries are making progress in strengthening their health research and innovation agenda by creating local and regional partnerships (Al-Bader, Masum, and al., 2010; Kuepfer & Burri, 2009; Masum & Singer, 2010). Indeed, governments have a strong desire to create links between actors, enable research institutions to reach regional markets, and build research capacities.

Recommendations

1. ***Facilitate regional collaboration, enhance transparency, and reduce fragmentation***

    1.1 **Engage with regional initiatives to provide and disseminate R&D strategies and opportunities:** facilitate regional standardization, collaborative agreements, protocols, and information sharing, and transfer innovations to enable long-term viability and lessons learning across SSA countries. Collaboration can be facilitated by consulting information centers and regional databases (Sam-Agudu and al., 2016).

The West and Central African Research and Education Network (WACREN) *is a non-for-profit that provides digital infrastructure and services to the West and Central African research and education community to improve regional collaboration* (Sam-Agudu and al., 2016; WACREN, 2023).

The ***Clinical Trials Community (CTC)*** *is an online platform to identify African clinical trial sites by providing easy access to feasibility data and regulatory and ethical information* (CTC Platform, n.d.).

2. Break silos across sectors nationally

2.1 Explore domestic public-private partnerships (PPPs): to pool financial, material, or knowledge resources.

Colombia *has established public and private innovation accelerators to bridge the funding gap between basic research and prototype development, clinical trials, and production. These accelerators select projects based on their potential and development stage, providing funding under the pre-invested amount by the technology owners* (Andes, 2023).

2.2 Encourage partnerships between regional academia and private institutions: to build high-level capacity for health research skills by enhancing knowledge exchange, networking, and pooling financial and material resources.

In ***Tunisia****, the government has set up a call for proposals mechanism, under which research institutes must establish a partnership between the academic and private sectors in order to qualify for government funding* (Jones and al., 2021).

3. Streamline and facilitate research sector collaboration in the policy-making process

3.1 Ease policy-research dialogues at the national level and involve researchers in policy-making: by organizing regular meetings between stakeholders, determining a consensual research agenda, facilitating the sharing and dissemination of information, and including an annual review system.

The National Malaria Programme in ***Madagascar*** *is successfully coordinating research use at a national level, using an annual review system where there is a collective discussion before determining the program's annual work plan, which incorporates the lessons learned from previous years* (Jones and al., 2021).

3.2 Involve research institutions in the policy-making process: facilitate the alignment of research with national health priorities and regulations between research organizations and the institutional level.

Box 10 - To explore further

*The Noguchi Memorial Institute for Medical Research (NMIMR) in **Ghana** is a semi-public medical research institute that is closely collaborating with the government, especially during the COVID-19 pandemic* (Noguchi Memorial Institute for Medical Research, 2023; Sam-Agudu and al., 2016).

*In **Kenya**, the state corporation Kenya Medical Research Institute (KEMRI) plays a major role in advising the Health Ministry in matters pertaining to R&D policies and priorities: support for setting the health research agenda, defining norms and standards, formulating evidence-based policy options, and monitoring and evaluating health trends* (Jones and al., 2021; KEMRI 2023).

4. Promote a positive research environment

4.1 Organize and encourage participation in scientific research forums or conferences gathering relevant stakeholders across the country or region: to disseminate findings, raise awareness about R&D, focus on national/regional priorities, create linkages between the public and private sectors, and offer an opportunity to network. Participation in national knowledge translation platforms can be encouraged by awarding research prizes or scholarships for attendance at these conferences (Jones and al., 2021; Musango and al., 2023).

*The government of **Ghana** successfully increases collaboration and meaningful research inputs by fostering the participation of researchers in existing health policy forums, hosting R&D events, or informing their policy counterparts of new research projects early in the process* (World Health Organization & Alliance for Health Policy and Systems Research, 2021).

*The Kenya Innovation Week, organized by the state corporation Kenya National Innovation Agency (KENIA), is a national innovation forum with the purpose to strengthen the research and commercialization practices for greater socio-economic impact in **Kenya*** (Fosci and al., 2019).

Box 11 - To explore further

***Zambia's** Forum for Health Research is an annual conference gathering research and political stakeholders* (Jones and al., 2021).

4.2 Ease access to scientific information to strengthen research culture: by building a national database showcasing the ongoing R&D projects and publications and by allowing researchers to consult them freely in addition to online scientific journals.

*Thanks to agreements signed with publishers of scientific journals by the **Tunisian** government, the "virtual library project" makes available free documentation published in journals such as the Official Journal of the Republic of Tunisia* (Jones and al., 2021).

5. Encourage collaboration with regional or international institutions abroad

5.1 Engage in and encourage academia and private institutions to collaborate: to build high-level capacity for health research skills by enhancing knowledge transfer, networking, and pooling available resources.

The Consortium for Advanced Research Training in Africa (CARTA) *is a consortium gathering eight African-partner universities that aims to train networked African researchers, with complementary research skills and the ability to work in multidisciplinary research environments* (Consortium for Advanced Research Training in Africa, n.d.; R. Wanyenze, personal communication, May 18, 2023).

*In **Peru**, the research University Cayetano Heredia (UPCH) developed international partnerships and funding on relevant topics, indicated by co-authorship of publications* (Glass and al., 2018).

Box 12 - To explore further

*In **Kenya**, The Coalition for Health Research and Development (CHReaD) catalyzes action on health R&D through coordinated advocacy efforts.* (Research and Development for Health in Kenya, 2015).

Conclusion

In conclusion, based on our analysis of the sub-Saharan panorama, we can deduce that the current political and economic context is not yet propitious to the creation of a resilient healthcare R&D system. Indeed, many bottlenecks hamper its sustainable development, such as the difficulty of generating revenue and sustaining funding, retaining skilled human capacity, particularly doctoral graduates, and the lack of incentives for both private and public research. The findings of our research reveal that the priority focus should be on resolving these particular challenges to stimulate and promote R&D in the region. The development of an incentivizing environment could promote competition, innovation, and the production of affordable, high-quality, and effective medicines and other health technologies tailored to local needs.

By following our recommendations, several SSA countries would have the opportunity to produce a comprehensive R&D policy framework, build technological capacity and adequate infrastructure, create economic opportunities, balance public and private funding, and strengthen cooperation within sectors. In parallel, the reviewed existing literature and the experts interviewed all emphasize that sub-Saharan Africa has great potential and skilled minds and that the time has come to capitalize on these assets by working together. Regional partnerships can provide transnational support and help countries build on each other's comparative advantages (N. Mugala, personal communication, May 19, 2023). Sub-Saharan African countries can achieve this ideal, provided they share the same pioneering goal of creating self-sustaining innovations that improve both health and macroeconomic development.

Despite some challenges due to the limited scope of the research and the scarce existing or accessible literature on the topic, we truly believe that the hybrid top-down and bottom-up methodology and the recommendations that emerged from it are relevant and represent a strong basis for the WHO to build its guidance for LMICs to build and strengthen their health R&D systems. Our mapping exercise shows the diversity of pathways through which such recommendations can be implemented and anchors our framework within real-world evidence. This list of policy recommendations is not exhaustive but provides states with flexible solutions that can be tailored and prioritized based on their specific needs and capabilities. Further analytical studies of health R&D systems across the globe are required. To continue this research, we recommend extending the qualitative interview process to truly understand the obstacles each type of R&D actor encounters, and how best national governments can support them. We would also like to highlight that a consequent part of the literature on the topic advances the need for a coordinated global effort and advocates for the solutions proposed by the Consultative Expert Working Group on Research and Development (2011). We, therefore, advance that a future roadmap framework for LMICs to build and strengthen national and regional effective and sustainable R&D systems should be conceptualized hand-in-hand with further discussions on globally coordinated efforts.

Finally, despite the structural obstacles identified in this report, we believe that Africa is a region full of potential and that in, the wording of the 2012 Rio+20 conference, LMICs' ability to conduct cutting-edge and locally relevant R&D will be "a precondition for, an outcome of and an indicator of" their socio-economic development.

Annexes

Annex 1: Recommendation framework

The following framework results from a broad and diverse literature review and aims to synthesize the most important recommendations, applicable at the national level or that can be leveraged by domestic authorities. However, the content of this framework relies primarily on the recommendations of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (World Health Organization, 2011a), as well as the very complete literature review provided by Franzen and al. (2012).

Pillar	*Initiatives/recommendations*	*Indicators/research questions*
Strategic agenda-setting and monitoring	• Undertake a situational analysis and build on existing assets. (Ali and al., 2006; Franzen and al., 2017) • Collaboratively identify gaps, needs, and priorities and develop an R&D agenda and strategic action plan (Dean and al., 2017; World Health Organization, 2011a) • Create a research coordinating body, scientific councils, research/R&D support office or equivalent, coordinating the health research and health R&D strategy and its implementation, regularly assessing needs, effectively reporting to legislative bodies, managing grants, reporting contracts, and supporting information sharing and transparency (Ali and al., 2006; Dean and al., 2017; World Health Organization, 2011a) • Clarify guidelines, and streamline procedures to make them accessible to R&D professionals (Franzen and al., 2017; World Health Organization, 2011a) • Strengthen regulatory and ethical review capacity (Franzen and al., 2017; World Health Organization, 2011a)	• Does the country have a national health ministry and/or a national health strategy? • Does it have an R&D capacity building component? • Is it based on a regular and effective assessment of local health needs? • Is there a clear task allocation and/or national body responsible for health research and R&D?
Building on and taking advantage of global and regional opportunities	• Encourage international cooperation to develop effective policies for the retention of health researchers (Ali and al., 2006; COHRED, 2012; Dean and al., 2017; Kilmarx and al., 2017; World Health Organization, 2011a) • Establish and strengthen national and regional coordinating bodies and develop a regional R&D agenda (Dean and al., 2017; Kilmarx and al., 2017; World Health Organization, 2011a)	• Is the country engaging with existing South-South, regional, or international collaboration initiatives on health-related R&D across sectors? Whether related to information sharing or technology transfer?

	● Establishing a strong health R&D diplomacy by advocating for foreign direct investment and local projects, initiatives, and researchers, when co-negotiating collaboration agreements (World Health Organization, 2011a) ● Identify and invest in areas of comparative advantage, in particular when it comes to traditional medicine (World Health Organization, 2011a) ● Continue to encourage technology transfer both within a North-South and South-South context and provide the necessary training to absorb knowledge (Dean and al., 2017; Kilmarx and al., 2017; World Health Organization, 2011a)	● Is the domestic government engaged with the foreign private sector and actors to encourage and foster investment in local research?
Fostering the application and management of an intellectual property rights regime that promotes innovation and maximizes public health and equitable access	● Identify incentives and barriers, including intellectual property rights-related provisions -at national, regional, and international levels – that might affect increased health R&D and suggest ways to facilitate access to research results and research tools (United Nations Secretary General's High-Level Panel on Access to Medicine, 2016) ● Encourage further development and dissemination of medical inventions and know-how through appropriate licensing policies (such as open licensing and voluntary patent pools) (United Nations Secretary General's High-Level Panel on Access to Medicine, 2016; World Health Organization, 2011a) ● Facilitate widespread access to, and promote further development of, user-friendly global databases that contain public information on the status of health-related patents (Franzen and al., 2017; World Health Organization, 2011a) ● Promote the active participation of health representatives in intellectual property rights-related negotiations, so that such negotiations also reflect public health needs (World Health Organization, 2011a) ● Consider, where appropriate, the use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (World Health Organization, 2011b; World Health Organization, 2012)	● Is the country actively building an evidence-based building domestic enabling IP regulatory framework that fosters innovation and promotes public health? ● What are its practices when it comes to the intellectual property rights of the outcome of publicly funded research (if any)? ● Is the country actively engaging with continental or global initiatives aimed at coordinating work relating to private intellectual property rights and public health?
Creating sustained, sufficient, and intentional financing	● Commit 1% of GDP to government-funded health research of all kinds and research capacity building, based on the recommendations of the African Union. (African Union Commission, 2016)	● What proportion of GDP is directed toward health and innovation? ● Does the country have a track record

schemes and mechanisms	● Create and sustain a finance system using innovative revenue generation, such as transaction taxes, indirect taxes, or direct taxes (World Health Organization, 2011b; World Health Organization. Regional Office for South-East Asia, 2012; World Health Organization, 2012) ● Provide long-term funding and flexible grants within a stated strategic plan adapted to national priorities (Franzen and al., 2017) ● Create incentives for private investment (World Health Organization, 2011a),	of innovative financing mechanisms? ● Is there a sustained balance between public and private funding? ● Is there a national funding commitment and is this investment based on an intentional and long-term action plan?
Improving, increasing, and sustaining research infrastructure and investing in innovative and material capacity	● Upgrade overall public libraries and journal availability, as well as information technology (Dean and al., 2017; Franzen and al., 2017; Kilmarx and al., 2017; World Health Organization, 2011a) ● Invest in modern research equipment (World Health Organization, 2011a), ● Ensure stable power and water supplies while keeping utility costs low (Franzen and al., 2017; World Health Organization, 2011a) ● Support existing and new research and development stakeholders, including regional centers of excellence, in developing countries (World Health Organization, 2011a)	● Did the country recently establish public/private, new/existing research centers, or comprehensive institutional development and support? ● Does its health research system meet the international standard?
Improve, increase, retain, and sustain human capacity with research knowledge, skills, and experience	● Identify skills gaps and core capabilities necessary to conduct health R&D ● Encourage public and private universities to propose research study programs, and open centers of excellence to build capacity (Franzen and al., 2017) ● Make R&D principles and skills key components of undergraduate and continuing professional medical education, using "train the trainer" programs, LMIC-HIC 'sandwich' courses, visiting research fellowships, or increasing e-learning resources (Franzen and al., 2017; World Health Organization, 2011a) ● Develop a variety of research and R&D roles: data managers, statisticians, laboratory personnel, managers, and data collectors, as well as train management and research and R&D institutional support staff (Franzen and al., 2017; World Health Organization, 2011a) ● Create opportunities for junior and female staff to take responsibility within a supportive environment through small grants (Franzen and al., 2017; World Health Organization, 2011a) ● Build a mentoring system by supporting mentors with long-term funded	● Do the national strategic plans have a health workforce and an R&D component? ● Is there locally available, well-promoted, and appropriate R&D training? ● Are there sufficient positions and long-term opportunities) to build on and sustain practical knowledge? Are those positions granted institutional support? ● Does the government advocate for this workforce within collaborative projects?

	positions and recognition and creating institutional or partnerships/exchanges or peer mentorship (Franzen and al., 2017) ● Ensure the involvement of local staff in public or private collaborative projects throughout the process (World Health Organization, 2011a) ● Create incentives for researchers, favor protected research time and longer-term contracts and re-entry grants, higher salaries or guaranteed jobs to offset the 'brain drain', and private-practice incentives (Franzen and al., 2017) ● Enhance recognition through publications, institutional promotion, award schemes, and possibilities for career advancements (Franzen and al., 2017)	
Foster collaboration, allow synergies and efficient management of resources and research effort through network-building and information sharing	● Create or support a national, regional, and/or global platform for data and information-sharing and improve data collection mechanisms (Dean and al., 2017; Franzen and al., 2017; Kilmarx and al., 2017; UNESCO, 2018) ● Create an institutional interface for R&D both for policy-makers to better account for research and for researchers to better navigate the guidelines and institutional demands (Ali and al., 2006; COHRED, 2012; Dean and al., 2017; World Health Organization, 2011a) ● Create knowledge translation platforms to support dialogue throughout the R&D process both domestically and abroad (Franzen and al., 2017; United Nations Secretary General's High-Level Panel on Access to Medicine, 2016; World Health Organization, 2011a) ● Use or develop professional networks, through web-based communities and conferences on locally important topics (Franzen and al., 2017) ● Support the creation of voluntary open databases and compound libraries to develop a durable portfolio of new products and enhance the availability and use of relevant publications by research universities, institutes, or centers (COHRED, 2012; Dean and al., 2017; Franzen and al., 2017; Kilmarx and al., 2017; UNESCO, 2018) ● Make the publication of outputs on information-sharing mandatory and promote such conditions when collaborating with foreign or domestic private actors	● Is there an institutional relation between policy-makers and the domestic research and R&D landscape? ● Does the country participate in and promote information-sharing platforms? ● Does it have any regulations regarding the use and sharing of outputs of publicly funded research?

Annex 2: SWOT Analysis of SSA

Through a SWOT analysis, this section summarizes the strengths, weaknesses, opportunities, and threats of the SSA region that are essential to consider in developing a reliable R&D system. These points were gathered from our literature review[12] and interviews, and mainly summarize R&D capacity in English-speaking SSA countries as little information is available on French-speaking SSA countries.

Strengths	Weaknesses
Strong political interest and national funding commitment amongst SSA governments to improve their local R&D capacity (Al-Bader, Masum, and al., 2010; Masum & Singer, 2010)	R&D policy incoherence: local regulatory frameworks and governance remain poor, limiting an enabling environment (African Union Commission, n.d.; African Union Development Agency (NEPAD), 2019; Coulibaly, 2011)
Majority of SSA countries have established basic drug manufacturing systems and there is a growth in the number of R&D firms relatively successful (yet, underutilized and understaffed) (African Union Commission, n.d.; Kuepfer & Burri, 2009)	Lack of basic infrastructure to conduct research and development to ensure high quality of research and production (P. Guinot, personal communication, May 30, 2023; Wenham and al., 2021)
Increase in the number of training programs, centers of excellence, or universities providing training and education in pharmaceutical innovation and manufacturing (R. Wanyenze, personal communication, May 18, 2023)	Size of the R&D sector in SSA countries varies considerably, with some boasting over 200 research institutions (South Africa, Nigeria, Ghana) and others fewer than five (Cameroon, Swaziland, Lesotho, and Malawi) (African Union Commission, n.d.; Wenham and al., 2021)
The trend of creating government innovation funds for health (African Union Commission, 2012; Wenham and al., 2021)	Weak Intellectual Property rights, and regulatory and ethical oversight to allow fair competition in the R&D sector (African Union Comission, n.d.; Simpkin and al., 2019)

[12] Literature sources for the SWOT: (Simpkin and al., 2019), (Dr Boutsika, 2018), (Wenham and al., 2021), (African Union Commission, 2012), (Al-Bader, Masum, and al., 2010), (Kuepfer and Burri, 2009), (Coulibaly, 2011), (African Union Development Agency (NEPAD), 2019), (The Economist, 2020), (Al-Bader, Daar, and al., 2010), (Shah and al., 2010), (Simiyu and al., 2010), (Kamunyori and al., 2010),

African scientists are involved in well-regarded international research universities and creation of private and public research universities, and the return of professionals from the diaspora (Jones and al., 2021)	Low level of human capital: understaffed ministries and private companies due to the lack of formation in universities and the brain drain of health researchers in the Global North (Al-Bader, Daar, and al., 2010)
Creation of local and regional initiatives, allowing SSA countries and firms to reach regional markets and create research networks (Health Research and Innovation Strategy) (African Union Development Agency (NEPAD), 2019)	Lack of coordination among regional players resulting in fragmented domestic markets, and research conducted in isolation due to poor knowledge of other R&D players (Kuepfer & Burri, 2009)
Low labor costs, especially as Indian labor costs begin to increase(African Union Commission, n.d.)	Unreliable supply and dependent on imports of active pharmaceutical ingredients (mainly from China and India), packaging, and excipients (African Union Commission, n.d.)
	Poor data collection systems: hinders access to data to guide decision-making, share knowledge, and measure capacity and performance (African Union Development Agency (NEPAD), 2019; Coulibaly, 2011)

Opportunities	Threats
Overall rising GDP, increasing political stability, and fast economic development of the sub-Saharan region (African Union Commission, 2012)	Unstable political environment in certain SSA countries: poor governance and risk of corruption (Simpkin and al., 2019)
African population growing at approximately 2.7% per year, expected to reach nearly 2.5 billion by 2050, an opportunity to increase the labor force (The Economist, 2020)	Penetration of sub-standard or counterfeit products (African Union Commission, 2012)

Several North-South and South-South partnerships: can foster knowledge transfer and exchange in addition to providing funding channels (Dr Boutsika, 2018; Simpkin and al., 2019)	Reliance on external funding for training and research programs because of limited availability of national funding. External donor R&D priorities may not match local health needs, and reduce local actors' financial autonomy (Coulibaly, 2011; Simpkin and al., 2019)
Increasing network of SSA pharmaceutical companies involved in R&D in addition to public research institutes (Al-Bader, Masum, and al., 2010)	Lack of incentives for local private companies to invest in R&D: high utility costs, poor collaboration between private companies and government-owned institutions (Simpkin and al., 2019)
Creation of public departments aiming to improve cooperation between public and private sectors (Al-Bader, Masum, and al., 2010)	
Strong will from SSA countries to join regional and local initiatives and create linkages between local actors to improve local R&D capacity (African Union Commission, 2012)	
Expert knowledge of plant medicines: an asset for innovative R&D. Emerging companies in the phyto-medicine[13] market (A. Graham, personal communication, June 1, 2023; Simpkin and al., 2019; Wenham and al., 2021)	
Great number of firms striving to reach international standards, aspiring in a second time to export to international markets (African Union Commission, n.d.; A. Graham, personal communication, June 1, 2023)	

[13] Phytomedicine can be defined as the herbal medicine with therapeutic and healing properties.

Annex 3: Overview of the interview process

All interviews lasted between 45 and 90 minutes and were conducted between May 10 and June 10, 2023. All interviewees gave their consent to being recorded for the purpose of the research and to be directly quoted.

Interviewee list

- **Dr. Philip A. Adeniyi**, Founder of African Young Scientists (AYS);
- **Ms. Odireleng Keipopele**, Patent Examiner, The African Regional Intellectual Property Organization (ARIPO);
- **Dr. Suerie Moon**, Director, Global Health Center, Graduate Institute Geneva (IHEID);
- **Dr. John Arne Røttingen**, Ambassador for Global Health, Norwegian Ministry of Foreign Affairs and founding Chief Executive Officer of Coalition for Epidemic Preparedness Innovations (CEPI);
- **Dr. Rhoda Wanyenze**, Dean, Makerere University School of Public Health in Uganda;
- **Dr. Alexandra Graham**, Former CEO of LaGray Chemicals and Founder of LaGray Financing;
- **Dr. Nanthalile Mugala**, Director of the Africa Division, Program for Appropriate Technology in Health (PATH);
- **Mr. Philippe Guinot**, Chief Technical Officer, IntraHealth.

Question sample:

Our questions varied based on the person interviewed, their area and region of expertise and we tailored the interview to explore the perspective of the sector they come from. However, recurring questions and themes explored were the following:

- Can you describe some of the key challenges and opportunities to build robust national health R&D systems in LMICs and particularly in Africa?
- What can national governments do to capitalize on these strengths and overcome these weaknesses?
- What global and regional initiatives should they leverage or advocate for to best enable their own R&D efforts?
- Through your work and experience, did you identify some best practices across SSA countries that allowed for better collaboration and improved health R&D capacity?
- In your opinion, what are the most promising areas for the expansion of health R&D capacity in Africa, and why?
- Throughout your career how did you see the conversation around health R&D and the ability to conduct it at the national level change and how do you see this global discussion evolve over the upcoming year? Same question for health R&D in Africa, how did the panorama evolve and how do you envision its evolution in the future?

Annex 4: African Initiatives Table Summary

As mentioned above, African initiatives to improve R&D systems in the continent are flourishing. Among other functions, they aim to encourage investment in R&D, build capacity, harmonize regulations, and foster collaboration. These African initiatives are essential to overcome the current challenges facing the SSA region and to enable an environment conducive to a sustainable national R&D capacity.

Name of Initiative	*Role*	*R&D strategies/activities/evaluations*
African Health Strategy (AHS) (2016-2030) by the African Union (AU) (African Union Commission, 2016)	• Document which recognizes the importance of investment in research and innovation for tackling the challenges that the African continent is grappling with • Enhancement of commitments reflected in the global and continental instruments • Cohesive and consolidative document encompassing all such commitments and strategies in the health sector • Emerging regional experts research through strengthening regional research centers, building research networks, and sharing results across countries	• Institutionalized mechanisms for defining, producing, and utilizing African research • Highlighted investment in research and innovation • Member States' commitment to empowering local research institutions, setting up innovation hubs, and allocating 2% of the national budget for research and innovation • It was explicitly stated in the strategy that there will be a Results Monitoring and Evaluation Framework (RMEF) as well as periodic reviews at the national regional and continental levels
African Union Development Agency (AUDA) – New Partnership for Africa's Development (NEPAD) (African Union Development Agency (NEPAD), 2019)	• Coordination and implementation of continental and regional priority projects with UN agencies, African development partners, African Union Member States, and international financial institutions • Advisory support to African Union Member States, regarding national development priorities, policy development, knowledge sharing, partnerships, resource mobilization, application of norms and standards, and development trends	• Publication of reports and action plans on health innovation, i.e. Science, Technology, and Innovation for Public Health in Africa, Health Research and Innovation Strategy for Africa-HRISA (2018-2030): Guide to Member States and RECs on priorities for agenda setting in health research and innovation • Support to Alliance for Accelerating Excellence in Africa (among many initiatives)
The African Medicines Regulatory	• Collaborative initiative among African countries aimed at establishing a harmonized medicines regulatory system	• African Union Model Law on Medical Products Regulation- harmonizing medicines regulatory systems

Harmonization Programme (AMRH) (AMRH Home | AUDA-NEPAD- AMRH, n.d.; Ndomondo-Sigonda and al., 2023; Tanzania Medicines and Medical Devices Authority, 2023)	• Coordination by the regional and international stakeholders • A response to addressing challenges faced by African National Medicine Regulatory Authorities (NMRAs) and ensuring policy alignment • Local/regional harmonization and human and institutional capacity development: provide technical assistance and capacity building to regulatory authorities in African countries to strengthen their regulatory systems	and providing an enabling environment for the development and scale-up of health technologies • Designated Regional Centers of Regulatory Excellence (RCoREs) and Regulatory Pool of Experts Database • Some best practices in AMRH as highlighted by Ndomondo-Sigonda and al. (2023) are (1) communication between heads of NMRA; (2) strong leadership at the NMRA level; (3) strong regulatory reliance and transparency between NMRAs; and (4) sustainable funding
African Network for Drugs and Diagnostics Innovation (ANDI) (Botros & Nwaka, 2009; Nwaka, 2021; Nwaka and al., 2012)	• Establishment of ANDI involved extensive collaboration among African scientists, institutions, governments, and stakeholders members of the World Health Assembly (WHA). • Pan-African institution which supported the development of local health technologies from labs to markets. • "Broker", "facilitator" and "catalyst" in advancing local technologies (affordable, high-quality drugs and diagnostics) with potential for impact in Africa and other developing countries • Promotion in the development of an African-led drug discovery and development enterprise • Network composed of African and international partners	• Some notable achievements of ANDI were as follows: (1) partnerships with African universities to co-fund a training and mentorship program for African scientists, innovators, and entrepreneurs; (2) partnerships with African universities on IP-related training; (3) north-south collaborations; (4) identification of pan-African Centers of Excellence (CoE); (5) Innovation Awards program • ANDI's work was recognized and lauded at the regional and global levels, highlighting the value of an African-led approach to health product innovation • Some local technologies successfully promoted (among many): (1) Integrated Mobile Phone Diagnostics for Neglected Diseases; (2) Biomarker screen for Schistosomiasis Diagnostics; (3) NIPRISAN for the Management of Sickle Cell Disease; (4) Automated Malaria Diagnostic System; (5) and Immuno-diagnostics for Control and Eliminator of Schistosomiasis
The African Regional Intellectual Property Organization (ARIPO) (ARIPO, 2023; Engelbreg, 2019; O. Keipopele,	• Intergovernmental organization established by Lusaka Agreement; implements Harare Protocol • Initially started for IP in English-speaking countries in Africa but expanded to other regions • Patent examination role for member states	• ARIPO Academy which has capacity-building programs for member states on IP-related subjects • Online filing, eForms for IP; examination of IP applications; management of IP databases • Journals/library for patented products

personal communication, May 10, 2023)	• Facilitation, coordination role • Capacity and awareness-building of IP for members • Promotion of the development of IP rights, facilitate the registration of patents, trademarks, and industrial designs, as well as harmonize IP laws among member states • Help to reduce the cost and administrative burden of patenting	• The total number of health-related patents registered in ARIPO as of April 2019 was 3458 • African countries that had health-related patents at ARIPO were Kenya, Mauritius, Namibia, Zambia, Zimbabwe, and Egypt from the Eastern Mediterranean Region (EMRO) of the WHO • Only counts 7 patent examiners among its staff • ARIPO member states also have their own IP legislation that coexists with the Harare Protocol
L'Organisation Africaine de la Propriéte Intellectuelle (OAPI) (Engelbreg, 2019; l'OAPI, 2023; Motari and al., 2021)	• Intergovernmental organization established by Bangui Agreement; serves as both national and central patent documentation party for member countries and for member-states party to the Patent Cooperation Treaty • Patent examination role for member states • Facilitation, coordination role • Capacity and awareness-building of IP for members • No IP legislation in OAPI member states	• The total number of health-related patents registered in the OAPI database as of April 2019 was 2811 • African countries that had health-related patents at OAPI are Burkina Faso, Benin, Central African Republic, Congo Republic, Cote d'Ivoire, Cameroon, Guinea, Mali, Mauritius, Namibia, Nigeria, Senegal, Togo, South Africa and Egypt and Morocco from EMRO • Some specific initiatives are as follows: Denis Ekani Acadamy; Masteral Program in Intellectual Property; Intermediate and beginner trainings in IP-related topics • Unlike in ARIPO, OAPI member states do not have their own Intellectual Property legislation
The Pan-African Network For Rapid Research, Response, Relief and Preparedness for Infectious Disease Epidemics (PANDORA) (PANDORA, 2023)	• Support via technical capacity and partnerships; capacity building/training roles; advocacy roles • Facilitation of collaboration among African researchers and institutions to respond to infectious disease epidemics: a collaboration of 13 African Institutions and 9 European Institutions • Development and implementation of strategies to improve early warning systems, strengthen surveillance and laboratory systems, and enhance community engagement and communication during disease outbreaks	• Training and mentorship covering many areas of research, such as diagnostic techniques, emergency response, financial management, bioinformatics, ethics, and quality management • Per-need projects such as mobile laboratories, evaluations, capacity building, exploratory missions, response missions

	• Consortium supported by European and Developing Countries Clinical Trials Partnership (EDCTP), EU; National Institute for Health Research, UK	
African Young Scientists (AYS) (P. Adeniyi, personal communication, May 22, 2023; Africa Young Scientists, 2023)	• Non-profit and nongovernmental organization which gathers scientists from diverse disciplines across Africa • Empowerment for the next generation of African scientists through unique and non-traditional capacity-building and training strategies	• AYS Mentorship Programs; Mentorship platform; Mentorship Forum Live Webinars • Girls for Science Initiative: an initiative educating girls on science awareness, career development, skills acquisition, mentorship; also providing scholarships, boot camps, and competitions, and workshops • Science Summer Camp which connects secondary school students and young talented scientists with young scientists in Africa to promote science and innovation • Encourages African scientists currently located or studying in HICs to bring back to the country skills and knowledge gained through the mentorship programs
PANdemic preparedness plaTform for Health and Emerging infections Response (PANTHER) (PANdemic preparedness plaTform for Health and Emerging infections Response, n.d.)	• African-led clinical research platform, supporting preparedness and rapid response to emerging infectious disease • Support of research on infectious diseases through the provision of infrastructure, technical expertise, scientific capabilities, and administrative support	• Five-year strategic plan aligned with African public health priorities in preparing and responding to infectious diseases • Operations, legal, financial, and training activities • Site preparedness and scientific and strategic preparedness • Build on ANTICOV Trial's lessons learned
African Vaccine Regulatory Forum (AVAREF) (WHO Regional Office for Africa, 2021)	• Network of African NMRAs and ethics committees that use harmonization and reliance as pillars for capacity building • Governance structure currently being aligned with AMRH • An avenue to accelerate clinical trial applications • Expedites product development without sacrificing safety and quality	• Through the network, medicines and vaccines against meningitis, malaria, rotavirus, pneumococcal pneumonia, and Ebola have been developed • Development of technical guidelines and regulatory tools for clinical trial applications; review and monitoring of clinical trial applications (AFROWHO) • Joint Review Process for Clinical Trial Applications

The African Academy of Sciences (AAS) (African Academy of Sciences Programmes, 2023)	• NGO that promotes scientific and technological advancement in Africa • Provision of support for scientific research and development • Conducts the following: (1) funding and agenda setting; (2) publishing platforms; (3) financial governance • Establishment of partnerships within Africa and globally	• AAS Open (a publishing platform/database) • Global Grant Community • Coalition for African Research and Innovation (CARI) (a sustainability platform or collaborations)
Alliance for Accelerating Excellence in Science in Africa (AESA) (Devex, 2023)	• Initiative of the African Academy of Sciences (AAS) and the New Partnership for Africa's Development (NEPAD) Agency • Funding and agenda-setting platform created to accelerate scientific excellence, leadership, and innovation; Funded by the Bill and Melinda Gates Foundation and the UK's Department for International Development, among others • Main implementation agency of Science, Technology and Innovation programs in Africa • Provision funding, training, and mentoring opportunities to African scientists • Facilitate partnerships between African scientists and international institutions.	• Funding and agenda-setting platform that aims to promote health innovation and research across Africa • Funding focused on building R&D Infrastructure (DELTAS, Africa, H3AFRICA) • Funding focused on Innovation and Entrepreneurship (Grand Challenges Africa, ASET/STEM) • Funding focused on Developing Young Scientists (various Post Doc programs, CIRCLE, RISE, FLAIR, APTI) • Funding focused on Filling Critical Gaps (Think Tank Activities, Community Engagement, Research Management, Science Communication, Open Publishing) • Many other programs established/funded such as (1) Developing Excellence in Leadership, Training and Science (DELTAS) Africa; (2) Human Hereditary and Health in Africa (H3Africa); (3) Good Grant Financial Practice (GFGP) and STEM
Science For Africa Foundation (SFA) (Science for Africa Foundation, 2023)	• Promotion of scientific innovation in Africa to face the complex challenges of the continent • Creation of programs implemented through a grant-making scheme, promotion of scientific excellence, and intra-Africa collaboration • Funding in clinical research and trials in Africa via partnerships	• Clinical Trials Community (CTC) is an online platform to identify African clinical trial sites by providing easy access to feasibility data and regulatory and ethics information all on one platform. • Cross Pharma Capacity Development Initiative (CPCDI) • Health technologies, policies, clinical trials guidelines, knowledge sharing

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