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Synthetic Biology Regulatory Opportunities and Gaps in Kenya: Expert Perspectives and Expectations

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Abstract:- Debates around Synthetic biology (SynBio) adoption, like previous advancements in biotechnology, remain highly polarized. Proponentsemphasizethe immense benefits of SynBio to sustainable development especially to low and middle-income countries (LMICs) like Kenya which continue to lag behind in terms of Science, Technology and Innovation (STI). The anti-biotechnology faction emphasizes the potential risks of SynBioas the basis to call for a global-wide moratorium on adoption of SynBio. This tensed debate has characterized biotechnology development in Kenya and is the context within which the 2011 ban on Genetically Modified Organisms (GMOs) occurred. To bolster her bio-economy in accordance with her STI commitments envisaged in Kenya Vision 2030 and 'Big Four Agenda' and to reap from the revolutionary 'promises' of SynBio, Kenyacommissioned a milestone yet infamous *National Research Fund for Synthetic Biology Project.* This notwithstanding, it remains fuzzy whether the current biotechnology development and regulatory landscape is robust enough to facilitate this ambitious quest and allow Kenya to join the global SynBio league as an equal state player. Building on expert surveys conducted between March 2021 and September 2022, corroborated with available secondary data, this paper argues that in the context of the ensuing antivis-a-vis pro-biotechnology discourses,expert-guided and evidence-based policy and programmatic interventionswill play a central role in facilitating smooth adoption and implementation of SynBio in Kenya. Mixed-methods purposive-expert and snowball research designs were employed. Stratified sampling design was used to draw 83 participants from: academia, media & communications, medical, research, policy, governance & regulatory bodies, and industry. Quantitative results were analyzed through descriptive statistics using SPSS v.26. Qualitative data were sorted using Nvivo Software and analyzed thematically.The study revealed that with requisite and sustained political will buttressed with an enabling infrastructurefor SynBio, Kenya can successfully transition into, and reap the 'promises' of SynBio. Key opportunities revealed include: a) overwhelming (over 90%) favorable perception on the capacity of local scientists and regulators to undertake SynBio-related activities atglobal standards; b)favorable rating of the robustnessof mandates of key biotechnology-related institutions in light of the scope of SynBio: NACOSTI was rated at 86%, KALRO at 67%, KEMRI at 60%, and NBA at 60%. Underlying gaps revealed included: a)inadequate public awareness and education, b) potential negative impacts on religious, socio-cultural and ethical beliefs and practices, c) unnecessary bureaucratic procedures hindering commercialization of biotechnology products for public benefits; d) technical challenges within critical organizations like NEMA (rated lowest at 39.8%), and lack of structured and coordinated inter-organizational approach to biotechnology development. These revelations are intended tobe a critical ingredient tobiotechnology stakeholders–especially to those in research, policy, regulatory & governance, media, medical, academia and industry/business sectors – who would be the primary actors insofar as framing an evidence-based public biotechnology discourse is concerned.

Keywords:- *Kenya, synthetic biology regulation, opportunities and gaps, expert perspectives and expectations.*

I. INTRODUCTION

Synthetic Biology (SynBio) is perceived both as a multi-disciplinary field of study and a steadily emerging yet very disruptive technology (Reagan et al., 2022; Ning, Aggarwal, Poh, et al.,2020; Andy, 2020; Kolodziejczyk&Kagansky, 2017). It is a branch of science that encompasses a broad range of methodologies from various disciplines, such as biology, biomaterials, material science/engineering, genetic engineering, molecular biology, molecular engineering, systems biology, membrane science, biophysics, chemical and biological engineering, electrical and computer engineering, control engineering and evolutionary biology (National Aeronautics and Space Administration [NASA], 2020). The field of SynBio is one of the fastest-growing fieldswithin the domain of emerging STIs. In 2016 over 350 companies across 40 countries were actively involved in SynBio-related applications and had a net worth of $3.9 billion. In 2021 the net worth of global SynBio market had risen to $10.07 billion, a figure expected to rise to $13.11 billion this year; this constitutes a compound annual growth rate [CAGR] of 30.2%. By 2026, SynBio market is projected to hit $33.63 billion (ReportLinker, 2022). Perhaps this is why Bueso& Tangney (2017) writing in the *Trends in Biotechnology*declared SynBio as*the driving seat of bioeconomy*.

While advanced nations and their companies - either in the form of public, public private partnerships (PPP) or purely private - continue to dominate the global SynBio market, there has been a systematic attempt by LMICs, including my country Kenya, to explore possibilities for adopting and implementing SynBio, not only as a technology that can ensure their industrial transformation and provide solutions to endemic plant, animal, and human diseases and other challenges, poverty, environmental and other chronic problems facing their populations; SynBio also presents the opportunity to enhance their competitive advantages on the international scene and increase their bargaining prowess in the continuously asymmetrical global

political economy. As a matter of fact, what should be the biggest concern for LMICs like Kenya, is whether the projected steady global market share boom of SynBio will open up opportunities for them to bridge the historically disadvantageous global political economy, or worsen it; rendering them more dependent importers of new technologies rather than producers and exporters. Evidentially and analytically, LMICs like Kenya must pay proper attention to Susan Strange's greatest political economy question -*cui bono*? (Whoto stands gain?) (Strange, 1994). For example, in February 2022, USA produced 9 out of 10 of the world's leading SynBio companies; while USA, UK and China reaped the most in total market share (Report Linker, 2022). This suffices the need for such a perspective to pervade policy, public and intellectual discourses concerned with technology transfer, especially in the context of emerging and disruptively promising technologies such as SynBio. The ultimate goal of this paper is to argue that with proper evidence-based policy and programs, Kenya can join the likes of USA, UK and Singapore as an equal player rather than as a joyrider. Utilizing expert opinions, the paper reveals the opportunities and gaps that should inform biotechnology stakeholders in their quest for structures for adopting and implementation SynBio in Kenya. With the understanding that there is an ongoing synthetic biology project funded by the Kenyan government at the time this study was conducted, and particularly that the new president of Kenya, Dr. William SamoeiRuto has publicly pronounced himself to lift the GMO ban, this study could not be more timely and topical.

SynBiooffers innovative methods for engineering new biological systems or re-designing existing ones for customized beneficial purposes. Synthetic biology is the "world wide web of the last century" declares the founder of International Genetically Modified Machine [iGEM] (iGEM, 2016, p. 1). The revolutionary nature of the technology emanates from its ability to bring the physical, the biological and the digital worlds to a convergence; enabling the design of biologically-based parts, novel devices and systems or the redesign of existing biological systems (Moniz, 2020; UK Parliamentary Office of Science and Technology, 2015; Keiper&Atanassova, 2018; Trump, 2017; Andy, 2020). These novel products of SynBio- are expected to deliver applications with a wide range of usage across multiple sectors of the bioeconomy such as healthcare, agriculture, manufacturing, and the environment (NASA, 2022; Bojar, 2018; Wesseler & Demont, 2011). The most recent and celebrated application of SynBio is the ability of scientists in the developed world to manufacture COVID-19 vaccine; a revolutionary encounter which hitherto was impossible (Andy, 2020). Many other 'revolutionary' promises and have been extensively documented of SynBio have been documented debated (and goes beyond the scope of this paper), including designer babies, golden rice, and possibilities for complete treatment of cancerous cells in and HIV/AIDs in humans (see Supan, 2017; Jayanti, 2020).

However, there is yet to be a consensus that SynBio is purely a good and transformative technology and should be adopted. In fact, the most critical challenge, particularly to the new-comer countries into the SynBio league like Kenya, is the double-edged sword perspective accorded toSynBiolike her predecessors like GMOs. Hence, despite the high 'hypes', the optimistic 'revolutionary promises' way of framing it and the open facts proving a steady and fast growing market share of SynBiopainted by the proponents of biotechnology/SynBio(Keiper&Atanassova, 2018), some scientists and environmental activists - especially international environmental non-governmental organizations (IENGOs)have very stood firm that SynBioadoption should wait (Wesseler&Demont, 2011; Wellhausen, &Mukunda, 2009).

This has led to polarized and tensed debate. On one hand, scientists, and international SynBio companies and organizations[1] are busy producing high-end products and tools and are pushing and engaging in high panel bilateral and multilateral dialogues with Governments to showcase the need for them to create space for SynBio and to adopt these products(Moniz, 2020; Long, 2021; Simon, 2021; Bojar, 2018; Gronvall, 2015; UK SynBio Leadership Council, 2016; US Bioeconomy Strategy, 2012). Developed countries, the leaders in the global SynBio market share, have testified that SynBio is the new avenue for an innovation-led economy and an enabler of a "science supper power". Through formulation of robust development plans, and adapting existing biotechnology regulatory mechanisms to SynBio buttressed by very decisive Government Ministries, Departments and Agencies (MDA) countries like USA, UK, and Singapore, have been able to reap greatly from SynBio-enabled technologies, enabling them to bolster their bioeconomy sectors (Ning, Aggarwal, Poh, et al.,2020; Andy, 2020; Kolodziejczyk &Kagansky, 2017) even amidst counter-arguments from anti-biotechnology factions. USA is already exploring and implementing applications of SynBio in the national security infrastructures, and has launched a SynBio space program. Developing countries must be decisive in their quest for adopting SynBio. The insights of this paper is a key step toward buttressing such decisions with experiential evidence from experts of multi-sectorial origin.

On the other hand, there has emerged a global anti-SynBio movement which insists that all forms of SynBio research, and development, or adoption and implementation in late comer countries like Kenya, not excluding the West, should stop until all related regulatory and ethical issues are settled in policy and other mitigation measures. For example on the 13th of March 2012, a group of 100 civil society

[1]These include established and respected research companies and regulatory-cum-research organizations such as the J. Craig Venture Institute, Thermo Fisher Scientific Inc., GenScript Integrated DNA, Amyris, Twist Bioscience Corporation, New England Biolabs, Synthetic Genmics, Gynko Bioworks, and Intrexon, E. in the USA; Novozymes in Denmark, Synthetic Biology (SynbiCITE), A*STAR, London Biofoundry, and the Imperial College Translation Innovation Hub, in the UK, among other on top of pushing for SynBio agenda within their host countries and concertedly, in targeted and strategic manner, in the Third World. The UK institutions are particularly in the forefront of East Africa, especially Kenya's SynBio discussions.

groups working on environmental-related objectives or with a special interest in social aspects of emerging technologies were spearheaded by Friends of the Earth, the International Centre for Technology Assessment, and ETC Group to issue *Principles for the Oversight of SynBio*which is a call to a worldwide moratorium to the release and commercialization of SynBio organisms until proper and functional risk measures are put into place. Such voices continue to inform the framing of SynBio discourses even in the USA (Supan, 2014) and other parts of the world Third World Network (2017). The regulatory and potential risks issues permeating this anti-SynBio discourse hinge on five major issues. First is the feeling that SynBio products may be used as bioweapons, even along race lines, to cause massive unimagined destruction to mankind and the environment. This is widely discussed under the concept of biosecurity, particularly within the scope of dual-use (see Secretariat to Convention of Biology Diversity [SCBD], 2021). A second issue relates to environmental impacts, particularly the fear that SynBio products may upon interacting with natural occurring counterparts portend horizontal genetic exchange and alter the functionality of such products and that SynBio products may pose toxicity to living creatures in the ecosystem (ReportLinker, 2022; SCBD, 2021; Trump, 2017). Third is from the economic perspective, which is informed by the argument that upon accepting SynBio within industrial, agricultural and other sectors, labor-intensive work may be rendered a thing of the past. This has been used to paint SynBio as a tool for unemployment rather thansustainable development as proponents would argue.

Fourthly, anti-SynBio arguments point to the possibility of massive negative impacts on religious, ethical, social, and cultural fabrics of societies. Important in this debate is the argument that SynBio gives scientists the chance to play God (SCBD, 2021; Trump, 2017). Lastly, anti-biotechnologists argue that bio-safety risks should be a key reason to put a moratorium to SynBio. These health risks include illnesses, and allergies in humans (ReportLinker, 2022). Proponents' counterarguments to these issues have neither been conclusive nor straightforward. Trump argues that an adaptive anticipatory governance [AAG] framework would suffice to ensure that as countries engage in adoption, implementation and even commercialization and massive industrial production of SynBio products, anticipatory mitigation measures are put into place to suppress any potential risks whenever and wherever they may exist. This is mostly the perspective of many scientists and governments (Moniz, 2020; Ning, Aggarwal, Poh, et al.,2020; Andy, 2020; Kolodziejczyk&Kagansky, 2017; UK Parliamentary Office for Science and Technology, 2015; US Bio-economy Strategy, 2012). Kasera et al. (2021) have applied this framework in their review of key bio-economy policies and legislations and made important ways through which stakeholders can create such a framework to ensure adoption and implementation of SynBio is not hindered, while at the same, remaining prepared to respond to potential SynBio risks. The scope of the current study is not to reiterate the findings in Kasera et al. (2021) but to enhance their review through insights from fresh data based on expert's survey. It aims to provide power to Government of Kenya biotechnology policy makers to be more decisive on rallying different sectors to support adoption and implementation of SynBio to attainment of the Kenya Vision 2030 and the "Big Four Agenda"[2].

Although responses to anti-biotechnology voices have not be not been straightforward, proponents have given their responses anyway. These are worth noting. Proponents argue that it is a disservice to the humanity to stop adoption of a highly disruptive technology as SynBio on the basis of fears of dual-use because history of STI, particularly of the Information, Communications Technology (ICTs) have taught us that regulatory frameworks to counter unintended outcomes of innovations can emerge and be better informed by practice. Moniz (2020) argues, in this line, that cyber security,for example, is only a recent innovation despite computers having emerged in the early 1990s. Secondly, environmental impacts of any products should be based on scientifically proven and verifiable evidence. This is largely lacking in the anti-SynBioarguments (CDB, 2017) though scientists too agree that there are potential environmental and health/biosafety risks hence the need for an AAG approach. Thirdly, proponents of SynBio continue to argue that the net expected benefits of SynBio will overcome joblessness in Africa rather than worsen it. This is through providing techniques to improve plant and animal production, provide avenues to incur high yields by small-holder farmers within very small pieces of land; hence solve the problems increasingly reducing land under farming and related products. Reagan et al. (2022) have engaged in an extensive analysis of the benefits of SynBio, providing evidence to this assertion. Lastly, bio-engineers argue that they construct life to make human life better. They don't create life, and thatto do so is purely God's work (Andy, 2020). It is important that these issues are brought to light even as Kenya draws nearer to adopting and implementing SynBio. The present study is a work in this direction. It will show what experts perceive as opportunities and gaps, and what they expect to be done going forward in terms for smooth adoption and implementation of SynBio in Kenya.

Kenya has not been immune to these debates. According to biotechnology experts, while GMOs were officially launched in Kenya in late early 2000s, disagreements between the real benefits and risks of GMO products have witnessed zero products being allowed into the Kenyan market. This is despite experts reporting that these products met the procedural requirements about health and environmental safety tests by legally established institutions (Pamela, 2006; Mugo et al., 2017). The peak of the anti-and pro-GMOs debate in Kenya was in 2011 when, based on a later on disqualified and retracted journal article that proved that GMOs foods caused tumor in rats, one of the then policy makers from the ministry of public health declared a ban on importation of all GMO foods. While SynBio is yet to be adopted in Kenya, such experiences may reoccur in the era of SynBio. Using secondary data and

[2] The Big Four Agenda is now a defunct development blueprint owing to power transition from but this study makes reference to it because it was the context within the study was undertaken.

mixed-methods expert surveys, the present study will generate important insights that will preempt and inform this impending debate. This will be achieved through an analysis of expert opinions on the current opportunities and gaps and the manner in which policy makers and researchers can pursue necessary directions to buttress on the opportunities and bridge such gaps; to increase chances of successful adoption and implementation, as well reduce opportunities for mythmaking and non-scientific oppositions as witnessed in 2011.

The Government of Kenya has officially financially committed to her quest of joining the SynBioLeague of Nations, currently dominated by the UK and the USA. In this regard, shecommissioned a SynBio study in 2020, dubbed the National Research Fund for SynBio Project (NRF-funded SynBio Project)[3]. The project should produce two SynBio products: biosensors for the detection of the Cholera-causing pathogen, and the virus causing the Potato Brown Streak Disease (PBSD) which affects the production of a key staple food crop in Kenya. With this the Government aims to enhance her national science capacity for the attainment of her long-term vision of "a newly industrialized middle-income economy" (Ministry of State for Planning National Development and Vision 2030, 2012). Two primary sectors are targeted as stated in the Big Four Agenda: food security and universal healthcare. However, it has been suggested that for countries yet to adopt SynBio like Kenya, that the first and foremost step in this direction is to assess the current gaps in national capability in terms of biotechnology regulatory environment; biotechnology policies and law, and biotechnology expertise that will facilitate effective adoption and implementation of SynBio (Reagan et al., 2022; Trump, 2017). This assertion has been voiced in other expert quarters commenting on policy needs for SynBio. For example, in a 2017 meeting held in Nairobi and sponsored by the UK Government brining key actors from Government and private research institutions, a key output was the need for proper messaging and outlined policy frameworks to steer the talks about SynBio into actions (ISAAA AfriCentre, 2017). A second meeting held on the 29th of March 2021, reaffirmed the need to assess and explore gaps in current biotechnology regulations. The workshop pointed out to the need to "establish stakeholder's perceptions and policy/regulatory requirements for advancement of synthetic biology in Kenya" (ISAAA AfriCentre, 2021).

Recently, Kasera et al. (2021) documented the specific gaps in the policies and regulatory frameworks through the lens of the potential risks factors around which regulatory debates are being discussed at the Convention on Biological Diversity (CDB) and other platforms (Keiper & Atanassova, 2018; Moniz, 2020; Mukunda, Oye, Mohr, 2009; Presidential Commission for the study of Bioethical Issues, 2010; National University of Singapore [NUS], 2015; Oye, 2012; Pauwels, Stemerding&Vriend, 2011; Ning, Aggarwal, Poh, et al.,2018; Trump, 2017; UK Parliamentary Office for Science and Technology, 2015; Howard, Murashov& Schulte, 2016). The findings are part of the critical evidence needed to inform the formulation of a robust biotechnology policy (and revise concerned legislations) that will include the biosecurity, biosafety, ethical and social risk assessment issues. Kasera et al. (2021) review is a good step forward in heeding to the research gaps identified in the SynBio meetings of 2017 and 2019 identified above; particularly in informing the polarized biotechnology discourse and reorienting the debate toward the extreme positive side through evidence generating through systematic analysis of key policies and regulatory legislations. However, the study needs to be corroborated with primary evidence. Building on analysis of experts own assessments of the current development and regulatory environment, this study will attempt to fill this gap.

In the backdrop of the foregoing, this study specificallyexplored perspectives and expectations of Kenyan biotechnology experts on the opportunities and gaps that may facilitate and hinder, respectively,SynBioadoption and implementation in Kenya. Based on the study findings, this papers claims and then argues that in order to facilitate smooth adoption and implementation of SynBio in Kenya, policymakers and regulators need be guided by evidence. This study attempted to generate such evidence by conducting expert surveys on a sample of experts who have learnt important lessons from both transgenic and modern biotechnology in Kenya. Expert perspectives on issues that, in authors' view, would influence SynBio adoption in Kenya were explored along four thematic areas, namely; Perspectives on Current Local Capacity, Risk Impressions of Synthetic biology, and perceived impacts on religious and ethical beliefs and practices; Role and Significance of Actors in Regulatory and Policy Processes; Robustness of Current Biotechnology Research and Regulatory Institutions; and last but not least Perspectives on Government Versus Private Regulators.

A. The Structure of the Paper

The paper is divided into six main sections. Section 1 has introduced the paper, presented a summary of the literature upon which the study is grounded, and communicated the research niche the paper will attempt to fill. Section 2 presents the methods and techniques employed in the study and the rationale behind choices. Section 3 will present the quantitative findings. Section 4 will present make sense of the quantitative findings by triangulating quantitative and interview (qualitative) results and making possible interpretations. Section 5 will conclude by recasting the main opportunities and key gaps in current biotechnology landscape, and give pointers to what can be done as a way forward. Lastly, section 6 will highlight key recommendations to the GoK and other biotechnology/synthetic biology stakeholders. The last three non-content sections will appreciate research gaps for future studies, contributions of the 7 authors to this paper, and acknowledge the support of key people accorded to the primary author of this piece. The research objectives are as stated below:

[3]The NRF Synthetic Biology Project, which this study is part, aims to produce synthetic biology –based biosensors and rapid diagnostic kits to be used in improve agriculture and health sectors in Kenya, respectively. The Project should end in 2022 during which Kenya is expected to adopt these SynBio tools.

B. Study Objectives

- To explore expert perspectives and expectations on current opportunities in the biotechnology development and regulatory frameworks in the context of Synthetic biology adoption in Kenya;
- To explore expert perspectives and expectations on current gaps in the biotechnology development and regulatory frameworks in the context of Synthetic biology adoption in Kenya in Kenya and lastly;
- Discuss the possible avenues upon which the current biotechnology development and regulatory frameworks can be fashioned to facilitate adoption and implementation of synthetic biology in Kenya.

II. THE STUDY METHODOLOGY

A. Research Design

This study used exploratory mixed method design as the overall research design. The design enabled triangulation of qualitative and quantitative design (Bhattercherjee, 2012; FoodRisc Resource Centre, 2021; Kothari, 2004). To analyze qualitative data we employed descriptive design to put into perspective the data collected through focus group discussions, and key informant interviews. To analyze quantitative data collected through Likert scaled survey questionnaire, we used simple descriptive statistics through the help of SPSS v.26. The study employed stratified, purposive non-random sampling, and snowballing techniques. Based on a biotechnology stakeholder's survey and net mapping hosted by ISAAA AfriCentre in June 2021, there are six important categories of biotechnology stakeholders who may influence the adoption of SynBio technologies: academia; research; policy, governance & regulation; media & communication; medical and industry sectors. Following from the stakeholders net mapping, a total of 83 experts participated in the study from academia, 21 from research, 19 from policy, governance and regulation, 4 from media and communication, 11 from medical and 4 from industry.

B. Research Instruments

Both qualitative and quantitative instruments were employed. The qualitative instruments entailed undertaking 22 Key Informant interviews (KIIs) and 4 Focus Group Discussion (FGDs). The KI and FGD guides contained questions meant to explore expert stakeholders' perspectives and expectations along four thematic areas. Likewise quantitative questions were derived from each of these thematic areas. These: Perspectives on Current Local Capacity, Risk Impressions of Synthetic biology, and perceived impacts on religious and ethical beliefs and practices; Role and Significance of Actors in Regulatory and Policy Processes; Robustness of Current Biotechnology Research and Regulatory Institutions; Perspectives on Government Versus Private Regulators. Mixed method design was useful in the study since the researcher was able to triangulate and discuss the quantitative finding and make nuanced interpretations.

C. Response Mode Scoring Guide

A five point response scale was used to describe expert stakeholders' perceptions and expectations on the synthetic biology regulatory gaps as shown in table 1. In the presentations and discussions, we have perceived 5 (strongly agree) and 4(agree) as "at least" or "had favorable opinion" and 2 (disagree) and 1(strongly disagree) as "at least disagree" or "had unfavorable opinion".

Numerical Rating	Verbal Description	Scoring Guide
5	Strongly Agree	"At least agree"/"had favorable opinion"
4	Agree	
3	Neutral	Fair
2	Disagree	"At least disagree"/"had unfavorable opinion"
1	Strongly Disagree	

Table 1: Response Mode

D. Research Locale and Respondents

This study was conducted in Kenya across five Counties from where the experts were drawn namely, Nairobi County, Kisumu County, Kakamega County and Kisii Counties. The study scope was not defined by the geographical scale but rather by the subject under investigation; hence the researcher's focus was to get the information needed from the experts identified. Purposive and snowball sampling were used. Purposive allowed the researcher to only recruit with in-depth knowledge on the subject under investigation. Snowballing enabled the researcher to reach to experts who were referred by their colleagues during interviews and who and a wealth of knowledge on the subject. Zoom platform was used to convene some KIIs and FGDs wherever it was the most convenient to thesampled experts. The socio-demographic variables of the respondents are summarized in the table 2. The socio-demographic factors reflect the cadre of population we targeted; experienced regulators and or scientists in the biotechnology and related fields. The expertise is reflected by their years of experience, and academic qualifications.

Profile	Factor	Frequency	Percentage
Gender	Male	61	73.50
	Female	22	26.50
	Total	83	100.0
Education Level	Diploma	5	6.02
	Bachelors	12	14.46
	Masters	23	27.71
	Doctorate	43	51.81
	Total	83	100.00
Age	18-45	37	45.00
	45-70	45	54.00
	70-100	1	1.00
	Total	83	100.00
Institution/Sector of Affiliation	Academia	24	28.92
	Research	21	25.30
	Policy, Governance & Regulation	19	22.89
	Media & Communication	11	13.25
	Medical	4	4.82
	Industry	4	4.82
	Total	83	100.00

Table 2: Respondents Demographic Information

Source: Researchers (2022).

E. Data Collection

Data collection involved five main stages. 1) Expert stakeholders' net-mapping and stratification. This involved a meeting held by ISAAA AfriCentre whereby all the Teams under the NFR funded SynBio Project convened to map out key stakeholders to be engaged in the study and other components of the project. 2) The second stage entailed seeking of consent/permission and recruitment of experts into the study. After successfully mapping out the stakeholders, the researcher was able to retrieve the stakeholders list and purposefully reach out to the selected participants from each of the six categories, these were then reached through phone contacts provided by NACOSTI and ISAAA AfriCentre. Consent forms were then sent on their emails or submitted physically to enable them understands the study before interviews and administration of questionnaires. 3) The third stage involved the collection of qualitative data through FGDs and KIIs. The collection of qualitative data before quantitative enabled the researcher to refine the questionnaires and accordingly to capture issues emerging from the interviews more precisely4) The fourth stage involved collecting quantitative data through administration of survey tool through flexible/convenient techniques such as Google-forms, physical self-administered surveys, and fill-and-revert on email, depending on the needs of different experts.

F. Data Analysis and Presentation

Qualitative data was gathered from secondary materials and through FGDs and KIIs. FGD and KIIs data were captured by way of audio recording were transcribed into text, sorted, and categorized thematically. The Nvivo Software enabled the sorting and thematic analysis of the cleaned qualitative data. Primary quantitative data was analysed using SPSS v.26. The software enabled the researcher to enter, clean, test for missing data, and analyze the data through simple descriptive statistics of frequency tables, pie charts, bar charts, and cross-tabulation. The intension was not to correlate the findings but to establish the needed signposts on the missing links for proper regulation of SynBio in Kenya.

G. Ethical Considerations

The study was bound by all the ethical codes guiding social science studies as enumerated in the European Union's (2018) *Ethics in Social Science and Humanities* and any other reviewed official Social Science Research Ethics Manuals. Data collection was only initiated upon receipt of authorizations, that is from Maseno University's School of Graduate Studies (SGS) and a research permit from NACOSTI. Secondly, the researcher sought consent and voluntary participation of target respondents via the use of a consent form emailed to prospective participants before the surveys and interviews. The form explained the intent of the study into detail. Thirdly, the study understood that some experts work within very strict institutional guidelines and which may make them fear diverging important information to the researcher. Such confidential issues were mitigated by ensuring that these experts were recruited at individual capacities rather than as representatives of the institutions they hail from. The researcher made all possible attempts to ensure that the information given was kept anonymous making it difficult for such information to be traced back to them through coding FGDs into 1st, 2nd, 3rd and 4th and by not including participant names in verbatim quotations. Fourthly, no vulnerable participants targeted by the study and no minor were engaged. The study was thus not affected by ethical issues involving engaging vulnerable groups like children, PWDs, or women facing violence.

Fifthly, the data collected through notes, audio tapes and any other means was entirely kept by the researcher and only analyzed and interpreted information has been shared through one journal publication which has no reference to any individual names. Lastly, the findings of this study will

be made public for public consumption and will be published and shared through free access journal articles and through Government ministries, especially, NACOSTI which is a collaborator in this study and the Kenyan government's focal institution SynBio.

III. RESULTS

A. *Perspectives on Current Local Capacity, Risk Impressions of Synthetic biology, and perceived impacts on religious and ethical beliefs and practices*

Under this thematic area, the study used three questions to understand experts' perspectives on current local biotechnology capacity, impressions on potential risks from SynBio, and the perceptions on SynBio impacts on religious and ethical beliefs and practices in Kenya. First inquiry, the study explored whether Kenyan scientists are perceived as capable to undertake SynBio research within the global standards. The study found that majority (90.16%) at least agreed that the Kenyan Scientists possess the needed expertise to produce SynBio products for both local and international consumption. 6% had a fair opinion and about 3% at least disagreed on the preparedness of Kenyan Scientists to produce SynBio products of global standards.

To establish risk impressions on SynBio, the researcher asked the question: "what is your impression about the risks and benefits of SynBio". The study found that 57.8% agreeing that SynBio benefits outweigh its risks, while 32.5% and 9.4% said "benefits equal risks" and "risks outweigh benefits", respectively (figure 1).

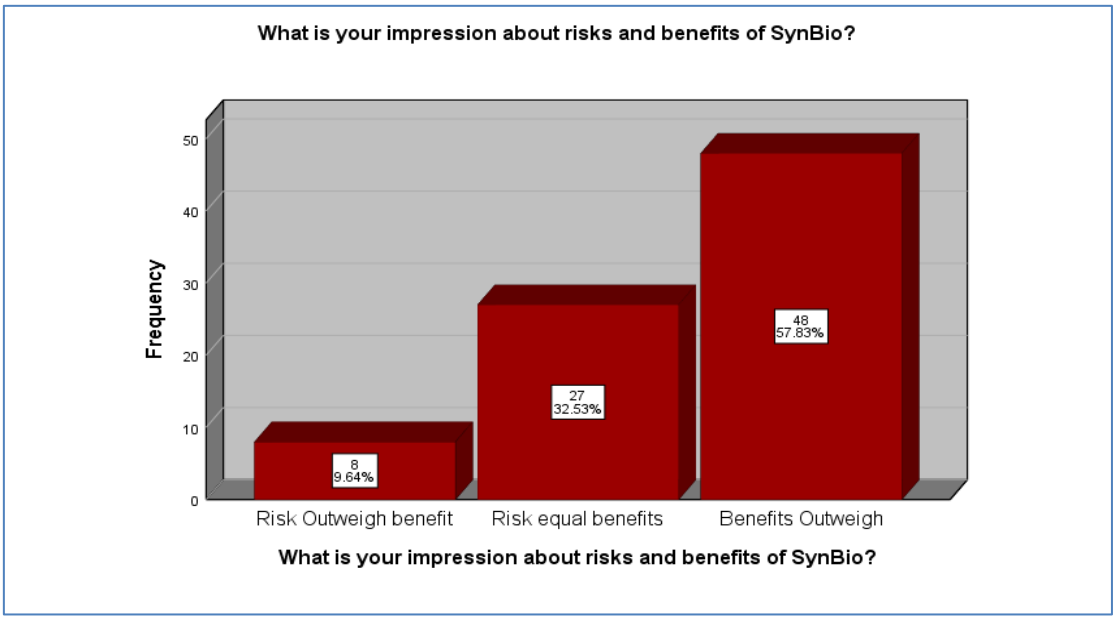

Fig. 1: Expert Impressions on Risks & Benefits of SynBio

Source: Researcher (2022).

Last question in this category aimed to explore experts' perspectives on the implications of SynBio on religious belief systems. We asked this question to understand how such notions as "playing God" as a critical ground for anti-SynBio campaigns would play out in the Kenyan context, within the prism of regulatory gaps. The study established that a majority of 59.04% of the experts at least agreed that in one way or anothertheir religious beliefs are at stake when SynBio is adopted and implemented in Kenya, 27.71% had a fair opinion while 11% disagreed SynBio would impact on their religious beliefs and practices.

B. *Role and Significance of Actors in Regulatory and Policy Processes*

This second thematic area aimed to explore the expert perspectives on the significance and role of actors in biotechnology and SynBio specifically. Based on their past experiences, experts from research, academia, medical, regulatory and other cohorts would be able to rank role and significance of actors. The first actor we explored their role and signifance perception were the political actors. The study found that 18% had a favorable opinion that political actors in deed would play a role in policy processes concerning SynBio, majority (43.3%) had a fair opinion, and a cumulative 38.6% expressed an unfavorable opinion about the role of politicians in SynBio related policy processes.

The study also sought to explore would-be role and significance the business community could play in policy processes concerning SynBio. Unlike politicians, the study revealed a tremendous support to the leadership role that the business community can bring on board. The study established that only 2.4% had unfavorable opinion with the statement, 13.41% of the respondents had a fair opinion, and an overwhelming 84.1% had a favorable opinion that the business community can play a lead role in SynBio policy processes (table 3).

The business community plays a lead role in policy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly Disagree	1	1.2	1.2	1.2
	Disagree	1	1.2	1.2	2.4
	Neutral	11	13.3	13.4	15.9
	Agree	38	45.8	46.3	62.2
	Strongly Agree	31	37.3	37.8	100.0
	Total	82	98.8	100.0	
Missing	System	1	1.2		
Total		83	100.0		

Table 3: Role of Business Community in SynBio Policy Making

Source: Researcher (2022).

Lastly, the study explored the role and significance of the research community as a player in SynBio policy processes. The study established an overwhelming support for the involvement of the business community in SynBio processes. 90.36% supported that the research community should play the primary role in the provision of the needed evidence to inform policy making and implementation; 6.34% had a fair opinion and only 1.20% had an unfavorable opinion. Compared to the other actors, this was the highest rating on actor role and significance. This shows the key role that Kenyan researchers have to play in giving direction and working collaboratively with other categories of stakeholders to define an adaptive anticipatory governance environment through evidence-based policy making, and programming for SynBio.

C. Robustness of Current Biotechnology Research and Regulatory Institutions

The third thematic area of the study aimed to explore respondents' perspectives on the overall sufficiency of regulatory institutions currently concerned with biotechnology regulation and research. These institutions would be the primary institutions for research and development as well as regulation of SynBio in Kenya and expert perspectives and expectations on their preparedness to meet these new obligations would be very important in charting relevant evidence-based policy initiatives. Such institutions in Kenya include and not limited to National Biosafety Authority (NBA), National Council on Science Technology and Innovation (NACOSTI), National Environmental Management Authority (NEMA) and Kenya Agricultural and Livestock Research Organization (KALRO), and Kenya Medical Research Institute (KEMRI) and Kenya Plant Health Inspectorate Services (KEPHIS).

The researchers first asked a general question on the overall expert assessment of the sufficiency of the regulatory systems in Kenya in terms of regulating SynBio. The study established that most respondents (48.19%) had a fair opinion; cumulative 24.09% expressed a favorable opinion on the overall sufficiency of the regulation systems; and cumulative 27.71% expressed an unfavorable opinion on the overall sufficiency of the current biotechnology regulatory systems. This prompted further investigation on specific institutional mandates.

We went further to explore particular gaps in the regulatory system through the lens of the regulatory `institutions. Our exploration of the experts' perspectives and expectation on the current mandates of revealed high level of optimism on the level of preparedness of the organization. 86% of the experts engaged supported that NACOSTI current mandates are good enough to embed and govern SynBio. Only a meager 3% had an unfavorable opinion and 11% expressed a fair opinion. NACOSTI is the national research regulator established under the ST&I Act 2013. Other than regulating all types of tertiary research, the institution is a key advisor to the Kenyan Government on matters ST&I and the kind of priorities which the country should pursue, hence this perspective shows a lot about available institutional capacity to facilitate adoption and implementation of SynBio in Kenya.

Respondents' perspectives on the preparedness of KALRO was also fairly good but lower than that of NACOSTI. As summarized in the figure 2below, cumulatively, 67.47% held a favorable opinion that KALRO is prepared to conduct SynBio research; 24.10% had a fair opinion of the preparedness of KALRO while 8.43% said KALRO was unprepared.

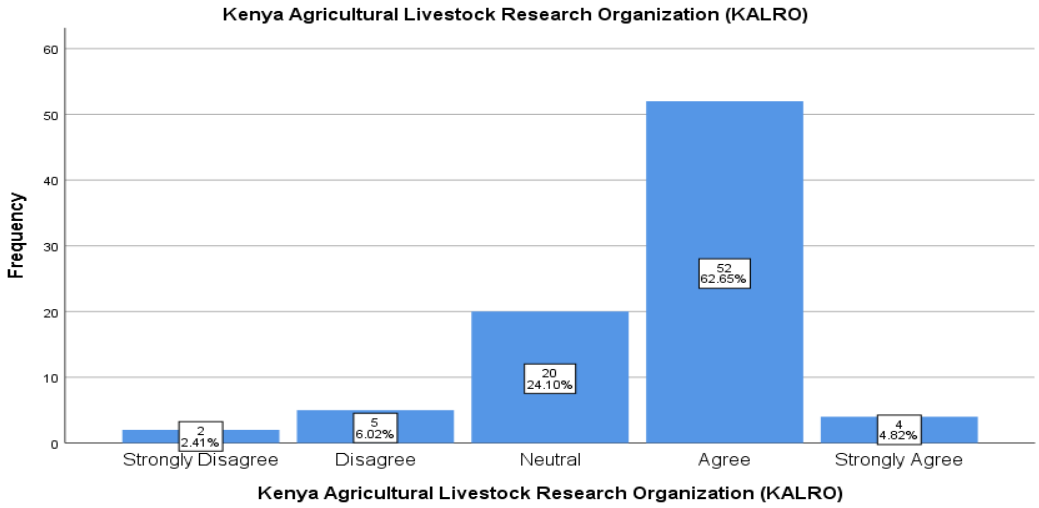

Fig. 2: Robustness of KALRO's Current Mandate

Source: Researchers (2022).

Another institution whose preparedness was investigated was the NEMA. The study established that a whole 45.78% expressed a fair opinion implying that they were neither sure of what role NEMA can play in SynBio regulation nor were they sure of the gaps and opportunities within NEMA that will hinder or facilitate SynBio adoption and implementation. 39.75% had a favorable opinion that NEMA was prepared to regulate SynBio, while the rest (14.46%) disagreed that NEMA had any form preparedness to regulate SynBio research and development.

The second last institution we explored her preparedness was KEMRI. The results from respondents surveyedshowed that 10.84% rated KEMRI's preparedness at 5/5, 49.40% rated it at 4/5, 32.53% had a fair opinion about its position while 4.82% and 2.41% rated it at 2/5 and 1/5 respectively. This statistics revealed some good support for the kind of preparedness KEMRI has in place since a cumulative of 60.24% had a favorable opinion that KEMRI was prepared to take the SynBio research forward.

The last institution we explored her preparedness was the National Biosafety Authority (NBA). As we summarized in figure 18 below, most (60.24%-those who agreed and disagreed) respondents felt that NBA's mandate is robust enough to cover SynBio issues. Only 28.92% remained neutral and about 10% said NBA is not prepared to undertake SynBio regulation.

D. Perspectives on Government Versus Private Regulators

The final thematic category had questions that explored the notion of the typology of the regulator envisaged by Kenyan experts as key in the regulation ofSynBio. We explored whether experts perceived and/or expected the private sector to play the greatest role in SynBio regulation or whether the Government and its institutions were better positioned for the same task. These are the main actors/regulators from the literature on regulation (see, e.g., Hart Research Associates, 2013). The study established that only 4.82% strongly agreed that SynBio can be regulated by private institutions and actors in the SynBio industry. 30.12% 'agreed' and a majority (45.78%) expressed had a fair opinion on the role of the private sector while 19.27% an unfavorable opinion about private sector playing the central role in regulating SynBio. This implied an overwhelming support for government of Kenya as playing the central role in regulating SynBio. This finding is in tandem with other previous studies, as will be highlighted in the discussion section.

IV. DISCUSSIONS

The foregoing section on the presentation of findings has largely answered the question: what are the perspectives of the biotechnology experts on current biotechnology development and regulation landscape in light of SynBio regulation. This section on discussion will try to reveal expert expectations. The section on results presented quantitative data emerged from survey. This section will utilize qualitative data from FGDs and KIIs to triangulate the quantitative and qualitative results and expand the discussion in a nuanced manner. The discussion will follow a thematic approach as adopted in the previous section.

A. Perspectives on Current Local Capacity, Risk Impressions of Synthetic biology, and perceived impacts on religious and ethical beliefs and practices

The survey results revealed an overwhelming (over 90%) expert support that Kenyan scientists are well capable to undertake SynBio research of global standards. FGDs and KIIs revealed that ongoing relevant work on GMOs is a key reason for this optimism and rust on the capacity of Kenyan scientists. It emerged that there has been, from around 2001, ongoing biotechnology research and development which has led to production of three GM awaiting commercialization these include, Bt Corn/Maize, *Bt* Cotton, and lately Cassava which have been successfully produced through Kenyan scientists, proving that have the needed capacity even to produce SynBio products and components. These previous exposures are aimed to influence positively scientists' uptake of SynBio research. The understanding was prominently expressed by the scientists involved in the NRF – funded SynBio Project. Who particularly expressed that it is due to their previous engagements in GMO studies that

they were able to conceive and undertake the said project as lead/principal researchers.

However, most interviews also revealed that biotechnology research and development (R&D) in Kenya has not been driven from within and that experts have only been involved for their expertise by the external funders. This has contributed to the slow pace of biotechnology development as well as slows pace local capacity building because projects have not been born from within and only a handful of scientists have been engaged in the few projects, limiting the scale of involvement of Kenyan scientists. Two important demerits of an externally driven biotechnology research expressed by most experts were as follows. First that this has always led to conflicts of interest between the Government and donors where the Government has been emphasizing public interest such as safety of products while donors have been interested in facilitating quick production and commercialization of GM products. This is congruent with Pamela (2006) study which evaluated the implications of such conflicts during the *Bt Maize* project funded by an external donor.

Secondly, interviews revealed that donor-driven biotechnology studies has led to a situation where local expertise has not been properly developed because there have been at any given time only a few or one mega biotechnology study going on. This is despite the fact that Kenya produces hundreds of biotechnology graduates yearly. In this regard, experts were overly in support of the ongoing NRF SynBio project, funded by the government and implemented 100% by Kenyan scientists through a public-private partnership arrangement, through the ISAAA. One interview excerpt captures this quite aptly:

…I think this is why we have very brilliant scientists in biosciences in the country but whose names cannot feature anywhere in terms of original thinkers or innovators. Maybe the NRF SynBio Project is an opportunity to place Kenyan scientists on the global biotechnology radar. We have the capacity and what we need is more locally funded projects, led by Kenyans, aiming to solve Kenyan problems (Key Informant Interview with a Biochemistry Lecturer, 12th Dec 2021).

On the question of impressions on potential risks of SynBio products and technologies, the study revealed that almost 60% of the experts who participated in the study believed that benefits of SynBio outweigh its risks. This is an implication for a supportive expertize in terms of Kenya's need to invest in SynBio R&D. Nevertheless, key to policymakers, from this finding, is the fact that there is still need to identify and reduce to negligible levels the fears concerning safety and risks of SynBio because those pessimistic attitudes can negatively affect adoption, implementation and further R&D of SynBio. This could have an implication for R&D of SynBio because if more people have safety reservations about the technology, they would likely not support its adoption an implementation or take part in related research studies. On the other side of the argument, if more people report that they feel the benefits of the technology outweigh its risks then it could be a pointer to smooth adoption, implementation and further investment in R&D of SynBio in Kenya, because this could imply that the technology may make tremendous contributions to the many challenges facing Kenya's bioeconomy sectors[4].

The last question under the first thematic area, ethical and religious implications of SynBio, about 60% felt that their religious and ethical beliefs and practices would be at stake upon adoption and implementation of SynBio in Kenya.Across the globe, there have been claims that SynBio presents an opportunity for scientists to "play God" by "creating life" which is a reserve only for God (see, e.g., Andy, 2020). While scientists-especially genetic engineers, have responded to these claims by differentiating between the concepts creating and constructing (*Ibid*), by asserting categorically that they are not creating but "constructing life" for the betterment of humankind which is the primary intension of the creator, who is God himself, religious suspicions still remain high on what exact impact complex SynBio innovations such as the notion of "designer babies" (Jayanti, 2020), "synthetic pigs" or customized (DNA-sensitive medication and pharmaceutical products) may mean for the supernaturalness* of God (see, e.g., EU, 2012).

The message to policymakers and regulators from this finding is that the religious community is an important stakeholder in SynBio R&D. A senior scientist expressed:

The religious community cannot be ignored. In fact when it comes to issues of biotechnology, is you ignore churches like the Catholic Church, you may do all your things in the laboratory but end up with them rejected by the public primarily based on the anti-science perspective perpetuated by the Church. What we have been doing and what policy makers and Kenyan regulators should do is to involve them from the very beginning of such studies (Key Informant Interview with a Senior Research Scientist from a key International Research Institution based in Kenya, 18th Feb 2022).

The message to policymakers and regulators is that the religious community is an important stakeholder in SynBio R&D, particularly on issues related to public awareness creation and education. The excerpt below summarizes the extent to which experts believe the religious community must be engaged for successful and seamless adoption of SynBio in Kenya.

The religious community cannot be ignored. In fact when it comes to issues of biotechnology, is you ignore churches like the Catholic Church, you may do all your things in the laboratory but end up with them rejected by the public primarily based on the anti-science perspective perpetuated by the Church. What we have doing and what policy makers and Kenyan regulators should do is to involve them from the very beginning for such studies (Key

[4] In their "The Knowledge Based Bioeconomy (KBBE) in Europe: Achievements and Challenges", Albretch et al. (2010) defines the concept as The bioeconomy is the sustainable production and conversion of biomass, for a range of food, health, fibre and industrial products and energy, where renewable biomass encompasses any biological material to be used as raw material."

Informant Interview with a Senior Research Scientist from a key Research Institution based in Kenya, 18th Feb 2022).

B. Role and Significance of Actors in the Regulation, Research, and Development of Synthetic biology in Kenya

The survey revealed a rather unexpected perception among experts on the role of political actors in regulation, research and development of synthetic biology in Kenya. Since public policy making is first and foremost the role of the political leaders, since political will is a critical element as already revealed in the first thematic category, political leaders would be expected to play a key role. The study explored this contradiction further through interviews. What emerged was that the history of biotechnology in Kenya has been mired with policy red tapes and what some experts called "unnecessary regulatory bureaucratic bottlenecks". Explaining the events leading up to the GMO import ban in Kenya which was affected in 2011, one key informant expressed that

…take for example; we have had challenges with the commercialization of GM crop despite completed field tests and environmental impact assessments done by experts that proved the products to be safe. This is partly because the biotechnology policy does not come clear on the extent to which key political actors such as the Minister for Public Health can or should play. Concerning the GMO import ban which we operate under to date, it was the cabinet minister who due to lack of knowledge on GMOs as a political rather than an expert appointee to the docket of a Cabinet Secretary of Health imposed a ban based on an invalid journal paper which tried to prove that GMO foods caused tumors in rats. The paper was later removed from the journal because it was unscientific. So politicians have actually been creating "unnecessary policy and regulatory bureaucratic bottlenecks" instead of supporting biotechnology development in Kenya (Key Informant Interview with a Plant Genetic Engineer).

As the country moves on from the era of GMO 1.0 to GMO 2.0 or SynBio era (TWN, 2018) such lessons learnt from traditional and modern biotechnology should inform the formulation of robust policies and laws that will be devoid of regulatory dilemmas, by spelling out very clearly the roles of individual institutions on the specific stages in the life cycle of SynBio products development, and setting the limits to which appointees to the political offices make critical decisions that require high level of expertise.

The second actor the study explored the role and significance was the business community. As seen from the results section, over 80% supported that notion that the business and industry sector must play a critical role if the SynBio processes must thrive. From interview results three main expectations and observations account for this positive perception:

- Experts reiterated that biotechnologists and researchers and academicians and the related industries have been working in a vacuum. Hence, study revealed that the lack of involvement of the business and industry sectors is a key issue and the "missing link" to unlocking biotechnology potentials in Kenya. SynBio policy and related processes, this should involve the business/industry fields as key actors.
- The business community understands the real gaps about innovative solutions to solving societal problems. They should actually be ones pushing for the adoption of SynBio and other bio-innovations as opposed to researchers whose objectives are usually short-term, ending as soon research funding is depleted.
- That working with the business community will solve the challenges of the many unemployed and wasted students graduating with biotechnology, genetic engineering, and related fields but end up working in the supermarkets and other unprofessional fields because there are no industries to absorb them. One expert said:

Involving biotechnology related industries and businesses, and building their capacity will create job opportunities and enhance innovativeness of biotechnology students and experts to pursue product development pathways which are businesses/industry oriented (A medical officer from KEMRI, during the 1ST FGD).

The last category of actors whose significance was explored was the research community. The over 90% support by the experts sampled that for the study implies that the research community will play a critical role in enabling the development of SynBio products. The interviews revealed two different directions but both of which are in congruent with the quantitative result. First, study found that researchers have been at the center of the previous successes in biotechnology development. Those engaged in the study reported to have played a part in one way or another in the development of the*Bt* Maize, *Bt* Cassava, and *Bt* Cotton, but also through other research endeavors going on at KALRO, KEMRI, KEPHIS and others. This way, experts feel that just like biotechnology successes was primarily due their input, so will SynBio.

Secondly, experts expressed that despite their critical role in biotechnology processes in the country, they have not had the kind of space they need as academicians to exploit their full potentials. This is due to factors already discussed such as; a number of biotechnology funding coming from external donors, political appointees blocking their scientific products from reaching the market among other factors. In this manner, experts expressed that the GoK need consider borrowing a leaf from other countries such Singapore, UK, and USA where these governments have formed SynBio Consortia that brings together academia, industry, and leaders of critical public sectors suchas Civil Service Organizations (CSOs), religious opinion leaders and so. For example, in Singaporean government has put into place the Agency for Science, Technology and Research (A*STAR) to convene members of the academia, industry and government to discuss and advice government decision makers and members of the industry on best innovative ways to implement SynBio within the public interest. The result has been improved capacity for SynBio development, and creation of a technology pipeline that connects industry, academia, government, and the society (Trump, 2017). A*STAR is a statutory board under the Ministry of Trade and Industry of Singapore. The agency supports R&D that is

aligned to areas of competitive advantage and national needs for Singapore (https://www.a-star.edu.sg). In the UK, A*STAR exists in the name of UK Innovation and Knowledge Centre for Synthetic Biology (SynbiCITE) and provides a very important framework for engagement between scientists, the government, and the industry (Trump, 2017).

An important discussion that also emerged in the course of this exploration at the qualitative level was the need for the government to explore the best ways to establish a synthetic biology bio-foundry. According to Farzaneh& Freemont (2021), "biofoundries are a nucleating hub for industrial translation". In simple language, a bio-foundry is the sure way of translating biology, engineering, bioinformatics and all other knowledge fields that conglomerate to be called synthetic biology, into usable products. In the UK, biofoundries include the London Biofoundry, and the Imperial College Translation & Innovation Hub. These are like a one stop shop for all the experts in these related fields well-furnished with state of the art equipment to translate knowledge into usable industrial products. Our interviews captured this as recurrent theme from experts. The government should explore the best ways to put this revelation into practice.

C. Robustness of Regulatory and Research Institutions

This sub-section discusses the results on the expert rating of the robustness of current mandates of institutions concerned with biotechnology development and regulation; and hence will be concerned with development and regulation, and research of Synthetic biology technologies. The task is achieved through triangulation of the qualitative data with qualitative data from the FGDs and KIIs.

a) The National Commission for Science, Technology and Innovation (NACOSTI) and the Emerging Inter-organizational conflict

NACOSTI was one of the organizations we explored the robustness of her current mandates. Created as an entity with corporate rights under the Science, Technology and Innovation (STI) Act of 2013, the institution serves as the key advisor to the Government of Kenya (GoK) on STI matters and doubles as the national STI regulator. From the results above, NACOTI received the highest rating of (86%).When we explored the reasons for this high rating on NACOSTI current mandate, expert narratives can be categorized in three main reasons. Firstly, our expert sample asserted that NACOSTI has several departments and experts leading those departments including for biotechnology. For this reason, NACOSTI may only need to rearrange her departments and fit and equip a SynBio department. Secondly, within the NACOSTI, there is already an expert who represents Kenya at the global debates about SynBio within the frameworks of the CBD. This expertise makes NACOSTI a unique entity because the regulatory and R&D issues, which are still alien to even many of the biotechnologists, and biotechnology research and regulatory institutions, are well known to the NACOSTI through that specific individual, and the NACOSTI collegiate fraternity generally.

However, it was never a straight forward answer that NACOSTI would be the best fit to host SynBio. As Pondy (1967) discussed very extensively in his masterpiece, *Organizational Conflict: Concepts and Models*, organizations usually want to have the biggest share of government funding and this is usually achievable first and foremost if they host mega projects requiring mega funding. This argument was witnessed when several of the organizations from whom we draw experts tried to justify why they were the best suited (discussed in the paragraphs below).

Experts from the private research, industry/business sectors and were particularly of the opinion that Ministry of Industrialization, Trade and Enterprise should host and spearhead the SynBio agenda. Such perspectives were largely justified based on the practices in the UK, a key partner in Kenya's SynBio agenda[5], where the business sector is actually the leading actor (see, e.g., SBLC, 2016). Another reasoning behind such a perspective was that this would correct the research-industry differentiation which most of our interviewees felt was a key reason for the slow pace of biotechnology development in Kenya. Still, others felt that the Institute of Primate Research (IPR) was better placed to spearhead SynBio. To justify this position, our experts from IPR pointed to the milestones they have made in SynBio and related studies and the collaborations which they have managed to foster with external and internal donors and researchers; as the key grounds making them more prepared relative to other GoK research-based institutions. Ours is to reveal that there exist divergent views on who is prepared to undertake SynBio research as the primary referent institution. Other than that, we leave it to the concerned actors to assess the real capacities, including of the NACOSTI, of which institutions are strategically placed to undertake SynBio research, in the context of the argument put forth by Pondy (1967).

Kenya Agricultural and Livestock Research Organization (KALRO)

KALRO is one of the major research organizations in Kenya dealing in biotechnology and related issues**.**Kenya Agriculture and Livestock Research Act of 2013, the institution is a fully-fledged GoK corporate entity and directly implements Agriculture and Livestock policies. From the survey results and in terms of general rating, KALRO came second at about 70%, following NACOSTI. KIIs and

[5] The UK, through the Imperial College London and her experts have been in the forefront in supporting Kenya's pre-NRF SynBio activities beginning in 2017, and culminating in a major stakeholders meeting held on 29th March 2021 brining government and private sector actors bring East African countries to chart and consolidate the processes for adopting and implementing SynBio.

FGDs conducted helped the researchers to put a meaning to this overwhelming on KALRO's preparedness to undertake SynBio related activities in Kenya. One key informant's response summarizes the gist of experts' perspectives and expectations on the role and preparedness of KALRO. She explained:

I think generally speaking, KALRO is very well equipped to take the work it has been during with agriculture and livestock biotechnology to the next level. SynBio builds from biotechnology work, and because we have been doing that for quite sometimes now, we have some tools, we have over 2000 employees' researchers, and whatever is still missing is what we can get to spearhead the new area-SynBio. Actually, as we speak, there is an ongoing collaborative study with an external university and funders which entails gene editing, though the gene editing is done outside Kenya. That explains how seriously we are prepared as an institution (Key Informant Interview with KALRO-based Research Scientist, 19th Feb 2022).

b) National Environmental Management Authority (NEMA)

Third organization we chose for expert evaluation was the NEMA. As the national environmental protection agency, the institution is concerned with any biotechnology (and therefore SynBio) products which would be taken into the environment. It is charged, under the EMCA Act, 2012, to undertake environmental impact assessment of all products going in the Kenyan environment, in effect rejecting or allowing the introduction of those products into Kenya's environment. As such it will be a key regulatory institution in the regulation of SynBio upon its adoption in the country. Whether it is fully prepared or not will thus affect SynBio adoption and implementation. For example, if NEMA lacks the needed capacity to undertake risks assessment of SynBio products but still goes ahead to undertake such tasks, the decisions may be unscientific and either way may lead to introduction of unsafe products into the environment or the disallowing of SynBio products which can help solve Kenya's challenges leading to economic development. The respondents' perspectives and expectations on NEMA revealed a lot of reservations or rather pessimistic role and preparedness of this key institution in biotechnology (and SynBio processes). As the quantitative results show in section 3.0, only about 40% agreed that NEMA within the context of her current work and how it has undertaken such a mandate may be capable to bolster SynBio processes relevant to its mandate. It is important to note that this was the lowest compared to the ratings given to the other institutions such as NACOSTI, KALRO, KEMRI, and NBA. The excerpt below captures the rationale behind a negative feeling of NEMA's preparedness to guide SynBio processes.

It is simple…regulation in any country, should be there to facilitate not prohibit research. That when a product is created, the responsible institution should help explore best ways to go through the entire technology development cycle. But I think the approach that regulation and regulators have taken in this country has been really to prohibit. The way NEMA…you see, NEMA, if you walked into any rivers in Nairobi, the rivers are polluted, the polluters are there doing that every day and we don't see them taking any steps and clearly massive pollution is there. On the other hand, they have taken it upon themselves to block GM crops, any importation, or use of such crops, despite NBA approving them on safety grounds; there are even documents on the safety of the crops. They find it interesting and easier to block GM products than to follow with the industries and factories that pollute the rivers not just in Nairobi but across Kenya. The institution is unprepared to undertake SynBio research if fundamental revisions on its work and structure are done (FGD Interview, 9th Dec 2021).

Another rationale that emerged during the qualitative research was the fact the manner in which institutions such as NEMA have been engaged in biotechnology processes have not followed a properly designed intra-institutional engagement framework, for this reason, an expert narrated for example that:

You see, us, as Programs for Biosafety Services [PBS] have been at the core of promoting GoK's regulatory frameworks for SynBio and we have engaged very broadly with a number of institutions. However, the core reason to NEMA's failure to deliver on biotechnology mandates is informed by the fact that the institution sent a non-biotechnology expert into the inter-organizational forum where we, in the private sector meet with the NBA, NACOSTI and others to discuss ways forward. Such a mistake has meant that NEMA is left behind in these processes because a non-expert will obviously lack the technical capacity to report deliberations, as well as push for their institutions pro-active involvement (Zoom-based Key Informant Interview with an M&E Officer from the PBS).

Such pessimistic rating and stories about NEMA are not very detached from global practices of environmental regulators. For example, the 39.8% rating is in tandem with Hart Research Associates (2013) finding that established that the American public's confidence in the various concerned institutions with the regulation of SynBio was lowest for Environmental Protection Agency (EPA) rated at only 36% (closer to our figure which is 39%) relative to USDA (60%), FDA (57%), and US Department of Energy (52%). The FGD excerpt below can help put these pessimistic perspectives on NEMA into their correct perspective.

Important for policy maker going forward is to take seriously these revelations about the underlying factors hindering NEMA's effective functioning in biotechnology development and regulation, and explore possible ways to make the institution more functional. One such expectation is to plant within NEMA, a SynBio expert and allow this person to be the one representing the institution in inter-organizational meetings and deliberations.

c) Kenya Medical Research Institute (KEMRI)
KEMRI is another critical health and medical research institute in Kenya. The institution engages in multimillion projects many of which are closer to SynBio research (Stakeholder Roundtable/FGD, 18th Nov 2021), and for example is currently undertaking studies around malaria, cholera and tuberculosis detection, treatments and even diagnostics. It also hosts nearly all international medical collaboration studies hosted in Kenya. For example it is currently hosting the PRiSMA study which aims to detect pregnancy related diseases using the placenta of a newly born child and through which it is also monitoring pregnant mothers from conception to delivery (Key Informant Interview with a KEMRI-Based Scientist, Kisumu, 19th Nov 2021). This places the institution as a would-be key player in SynBio research especially those that would concern medical and health aspects. These relevant work tov health dimensions of SynBio perhaps are what informed experts to rate KEMRI at over 60% preparedness, much higher than even NEMA.

However, experts narrated that the work of KEMRI like many other institutions doing bits of relevant activities to biotechnology (and hence will to SynBio related activities) are largely happening in silos, and there has not been an integrated platform where these organizations can have a common platform to implement projects in a manner that will avoid redundancy, increase effectiveness and achieve national goals economically.

d) National Biosafety Authority (NBA)
Established under the Biosafety Act, 2009, the National Biosafety Authority (NBA) is charged with regulating biotechnology research and development in terms overseeing the bio-safety of biotechnology products before they are commercialized. In sections 18-22, the Act gives the NBA the power to authorize the use and introduction of GMOs and prohibits any such activities by persons or groups without such authorization (The National Law Reporting Commission, 2009). The Act lays out the process of authorization of persons who wish to work with or introduce GMOs in Kenyan namely: a) the person should apply to the NBA after which the NBA informs the public via two national newspapers; b) the public is given 30 days to respond by submitting their views within 30days from the date of posting the application; d) if the application is validated, NBA, as outlined in section 27, will conduct a risk assessment or audit the risk assessment that the applicant submitted to it. The Act gives latitude for the participation of other departments such as Department of Veterinary Services concerned with GMO animals, the Department of Public Health concerned with GMO foods as well as the Kenya Plant Health Inspectorate Service (KEPHIS) concerned with GMO plants. In section 28, the NBA is given the power to skip the risk assessment stage in a case where it believes that there exists a shred of vast evidence that available information is proof enough that the GMO to be introduced or used is safe. With the assumption that our expert sample understood the mandate of NBA as outlined in the Act, but also in the manner in which NBA has lived up to her mandate, we asked them to help us explore its robustness vis-à-vis the biosafety, biosecurity and environmental concerns concerning SynBio.

With the third highest rating (60.24%) compared to the other institutions, it can be concluded that NBA's work in relation to SynBio is clearer to the experts than that of NEMA and KEMRI. This in deed is true to the extent that KALRO has been the primary organization conducting agricultural biotechnology of the three GM crops so far produced in Kenya, namely; *Bt* Maize, *Bt* Cotton, and *Bt* Cassava, followed by NBA which has been regulating these GM crops processes and in deed our experts expressed that it has done so very promptly. Three key reasons underlined the above average support for the preparedness of NBA.

Firstly, experts expressed that the NBA is the only organization which deals directly with GMOs and their biosafety. Hence, because SynBio is primarily a modification or advancement from GMO science, the institution has a better standing to regulating and facilitating development of SynBio technologies. Secondly, experts also emphasized that the NBA has been very prompt in clearing up biosafety tests, a role it should play under the Biosafety Act. On this, most respondents compared NBA against NEMA. About the latter, it emerged that it has been acting as a stumbling block to successful commercialization and release to the public of GMO products, despite NBA clearing them. Moreover, NEMA processes are said to be too long hence cause delays to researchers, and achievement of national goals such as food security when promising GM crops are not commercialized. Thirdly, most experts interviewed emphasized that unlike other relevant bodies to the biotechnology regulation in Kenya, NBA has been effective largely because the top employees have been those who qualify, i.e., have been properly trained on issues biotechnology, bio-engineering, bio-chemistry and related fields.

The study also explored the reasons for the reservations about the preparedness of NBA. Two main lines of reasoning were deduced. Firstly, most respondents argued that the NBA has not been keen on awareness creation and public education. One respondent summarized this point, thus:

It is the NBA, they have a big role in regards to public awareness creation but they just seem not to know what they are supposed to do. They should create awareness of these things. That awareness should involve telling the population what the technology is about, why is the technology important, what are its harmful sides and how significant is the harmful sides (Zoom-based Key Informant Interview with Animal Genetic Engineer).

This assertion is an important point to note going forward. It shows the need for a clear framework of public awareness creation and education for what exactly SynBio is, what products can it lead to and what facts and myths accompany the public perceptions about the technology. While the country has the Biotechnology Awareness Strategy, experts felt that this strategy has not led to expected concerted efforts by the Government to promote education and awareness on biotechnology issues, and much of the publicizing work has only been done by the private sector. Additionally, experts emphasized awareness and sensitization about biotechnology and now synthetic biology should not simply be targeted at the general public or consumers but also critical leaders at the agencies concerned. This is because most critical persons in other relevant Government departments and even agencies who should promote biotechnology in the country, have failed to do so. An expert explained this as follows:

I have had several interactions with most of the lead officers in government agencies like public health, KENIA, and many others. One thing which I know for sure is that the level of awareness of biotechnology (let alone SynBio which is now new) is very low. This has affected biotechnology development because key people who should support biotechnology ideas from private scientists and even government-donor collaboration projects have stood against those projects and are simply disinterested. That is why one policy maker burned GMOs in 2011 without any scientific foundation (Zoom-based KI Interview with an Expert from A Private Research Institution).

Another expert expressed during one FGD that such key person should be the target especially if SynBio is aimed to facilitate radical changes in Kenya's bioeconomy. He argued:

What should be done before even we think of educating and creating awareness to the public is to sensitize this critical population and win their support. Awareness and support at this level is what will count because the public are actually looking up to these people, if they believe in the myths surrounding SynBio and biotechnology and they take negative positions such as the GMOs import burn, we can only expect that the public will not accept the technology as well (Zoom-based KI Interview with Senior Environmental Scientist and Researcher)

The second loophole experts reported affects NBA work and would influence its effectiveness to the regulation of SynBio was that as it is today, it concentrates much on plant and agricultural biotechnology. A key informant said:

What is happening is that the Biosafety Act was enacted with only plant and agricultural biotechnology as the priority biotechnology areas. So if the NBA was created by the Act, it cannot perform more than that. This will affect SynBio development and regulation because SynBio cuts across plant, animal, and human, and we cannot say that the NBA is prepared to cover these other areas of biotechnology (KI Interview with Senior Environmental Scientist and Researcher).

Related to the issues of concentration on agricultural biotechnology is the theme of biosecurity. Under this sub-theme most participants reported that the Biosafety Act covers GMOs within the understanding that these are safe products once the cycle of testing and other procedures are met. In regards to SynBio, however, experts expressed fear that risks go beyond just biosafety to include biosecurity; that synthetic biology products and components can be used by careless scientists as weapons of mass destruction. This is also a recurrent theme in SynBio regulation literature (Trump, 2017; National University of Singapore, 2015; Kuiken, 2015; Marris& Calvert, 2018; TWN, 2017; Wikmark et al., 2017; Kolodziejczyk & Kagansky, 2017). An academic-cum-researcher expressed that:

So am saying when I think about the Biosafety Act, I feel like there is a problem in Kenya because it only covers biosafety as it relates to plants-agriculture. But laboratory biosafety which involves SynBio generally is not covered. It is not covered under the biosafety act, it is covered under the bacteriological weapons convention (BWC). So for that reason in terms of the regulation when you want to regulate SynBio I don't know which one now will be revised, the act alone or the others too, and then I don't know if we have a domesticated version of BWC and that is an area that is in dire need. Yes. It is true Kenya has acceded to those but we don't have an act, so we are likely to create a new act and anchor all these biosecurity issues related to SynBio (Physical Key Informant Interview with a Biotechnology and Public Health Lecturer, Kenyatta University, Nairobi).

D. Who should regulate?

An important question in public perceptions and impressions on SynBio surveys (Hart Research Associates, 2013) is the question of whether the Government of the private sector should lead the process and to what extent. As observed in section 3, only about 35% had a fair opinion about the private sector and processes playing a lead role in the regulation of SynBio. This is evidence to that it may not as yet clear on the minds of the experts whether the private

sector can properly regulate the weighty SynBiopotential risk issues such as biosecurity which by and large, is currently regulated through the international regimes especially the bacteriological/biological weapons convention of 1972 (International Committee on Red Cross, 2014). Nonetheless, the private sector is already playing a key role in the regulation of SynBio across the globe. For example, Voluntary Protocols laid out by institutions dealing in DNA Synthesis have laid out the so-called Harmonized Screening Protocol with provisions aimed at stopping the sales of DNA synthesis to individuals who may reuse them as biological weapons by ensuring that customers and persons making orders are properly screened and their details documented. Additionally, evidence show that 80% of the high profile DNA Synthesis private, public and public-private organizations have subscribed to be bound by the guidelines (UK Parliamentary Office for Science and Technology, 2015), with this statistic dated 7 years, it can only be expected that more than 80% have subscribed. The role of the private entities cannot be, therefore, gainsaid. Further, despite the low rating of the role of Private sector as a key regulator, the study revealed that the business sector and industry, which is a critical part of the private sector has great role (rated at 83%) to play in SynBio policy formulation and implementation rated much above political actors (18%)and closest only to the research community (rated at 90%) in terms of generating evidence for formulating and implementing SynBio policies.

On the other hand, experts expressed a lot of support (65%) for the government as the key regulator of SynBio. Interviews revealed the major justification for a government-led SynBio is the security issues about SynBio. These security issues include biosafety, biosecurity, and bioethical concerns (Trump, 2017; Jayanti, 2020; Supan, 2014; Douglas &Stemerding 2014; Fatehi& Hall, 2015; Keiper & Atanassova, 2018; SCBD, 2021; Marris& Calvert, 2018) about SynBio. The most critical issue as to why the government should be the key regulator was reported as the potential biosecurity risks of SynBio products. Biosecurity has been perceived as what literature calls the 'dual-use dilemma'[6] (Rodemeyer, 2009) or sometimes called Do-It-Yourself Biology[7] (DIYB) (Pauwels, Stemerding&Vriend, 2011). Dual-use as a governance consideration issue relates to fears that SynBio may result in unintended harmful consequences, for example, that SynBio applications may be used as toxins and biological weapons of mass destruction (BWMD). From this perspective, the advent of SynBio if not properly regulated may pose terror threats greater than the famous 9/11 attacks executed on USA territory (Pauwels, Stemerding&Vriend, 2011). This is not to overthink the potential 'real-world uses' of SynBio (SBRWG, 2012). Pauwels, Stemerding&Vriend (2011) report that a 2008 USAReport of the Commission on the Prevention of Weapons of Mass Destruction stated that "terrorists are more likely to obtain and use a biological weapon than a nuclear weapon" (p. 15). Such biosecurity threats which come with and are tied to terrorist groups and other transnational organized crimes is core reason why the government has been perceived as the most reliable and capable regulator of SynBio, notwithstanding, however, the complementary role of private sector. The study findings on high confidence in government as the key regulator of SynBio are also in tandem in with previous studies. For example, in their findings, Hart Research Associate (2013) found that 52% of their sample population supported a regulation led by the Federal Government Agencies as opposed to only 36% who supported that voluntary guidelines and private actors could properly regulate SynBio.

V. CONCLUSIONS: GAPS, OPPORTUNTIES AND WAYS FORWARD

Based on the research questions, the following conclusions can be made from the study findings. The study has unpacked several opportunities and gaps from the findings. This section highlights two major opportunities (study objective 1) and 4 key gaps (study objective 2) from the ensuing discussions; the key opportunities are then used as pointers for what can be done(study objective 3).

Regarding opportunities for adoption and implementation of SynBio, Kenya has the capacity to transition from GMO to synthetic. This due to the existence of an overwhelming feeling among the experts that Kenyan scientists and regulators have got what it takes to undertake Synthetic biology research, regulation and related activities, even to the global standards. This is important, particularly in the current context where most (if not all) biotechnology projects are donor funded implying only a few Kenyan scientists will be involved at any given time. This revelation is key because it shows that synthetic biology presents an opportunity to grow Kenya by Kenyans, hence a step-forward to the clarion call "African Solutions to African Problems" (ASAP). Secondly, this study makes the conclusion that there exists the requisite institutional infrastructure to spearhead SynBio but mainstreaming SynBio, and explicitly realigning their mandates is key for smooth and structured SynBio-led bio-innovation. The study established that most of the institutions directly concerned with biotechnology, hence SynBio, such as NACOSTI, NBA, KALRO, and KEMRI are perceived to possess the requisite capacity within their current mandates to transform Kenya's bio-economy through SynBio. At the same time, previous studies (Kasera et al., 2021) have pointed to the extant gaps in current mandates of all these institutions occasioned by the lack of explicit statement in their stated institutional mandates to guide development and regulation ofSynBio.

Concerning development and regulatory gap in current biotechnology landscape, two are key to pint out. To begin with, there is a consensus among experts that political will has been lacking and is a critical determinant of the current

[6]Science is primarily used to benefit humanity, but particular scientific technologies can be misused, presenting scientists and others with an ethical quandary known as the dual-use dilemma (Rodemeyer, 2009).

[7]This refers to "Dual use" concerns raised by synthetic biology, whereby research with legitimate scientific purpose may be misused to pose a biologic threat to public health and/or national security, threatens to undermine public confidence'' (CBD Series on Synthetic Biology, 2021, p. 12).

biotechnology development in Kenya. Study revealed that the top leadership and key political positions such as the ministry of Public Health have not been supportive in taking up scientists calls for increased funding for biotechnology projects as well as following up to see into it that cleared products are successfully commercialized. Secondly, religious and ethical issues surrounding SynBio remain a matter of concern even among the experts/scientists themselves. This is a pointer to the need to have engagement frameworks with key religious opinion leaders and the need for proper public education and awareness creation on the opportunities but also limitations – actual or potential- of SynBio technologies and products. This should be done in lieu of eliminating mythical perspectives that may hinder SynBio adoption. GoK and other stakeholder can accomplish this by expanding the scope of existing biotechnology awareness strategy to include SynBio-focused messaging strategies. Thirdly, the study has revealed certain challenges within key institutions that will determine success or failure of SynBio processes in Kenya. The revelations about the challenges facing NEMA should be considered to inform policy makers on the form of organizational restructuring and reorientation in terms of mandates and inter-organizational engagements. Important to consider under this category of gaps is the challenge where the work of concerned biotechnology research and regulatory organizations are largely disconnected leading to redundancy and lack of structured cost-effective and harmonized funding schemes to biotechnology organizations. Such approach will go a long way to improve the design, implementation, and evaluation of SynBio processes. Fourthly, most biotechnology experts still think SynBio portend certain risks. This may hinder public acceptance and support for the SynBio technologies once officially adopted. A recast of the current biotechnology communication strategy in line with SynBio is a critical first step in laying remedial mechanisms for this challenge.

Five – key but in no way conclusive - ways forward can be isolated from theseconclusions. Firstly, GoK should invest in local projects undertaken under public-private partnerships (PPP) frameworks. The research community should concertedly spearhead the call on the government to regularly allocate resources to SynBio projects and consider expanding the current allocations to STI projects related to SynBio. Secondly, Synthetic biology should be mainstreamed into the work of all concerned organizations. Going forward, any institution undertaking SynBio activities should be doing so because it is her explicitly stated objective in their mandates. This will avoid double implementation, and unnecessary organizational conflicts that may hinder SynBio adoption, implementation and related processes. Thirdly, stakeholders should push for only the qualified persons to be appointed into critical political dockets such as Director General Positions in institutions such as KEMRI, KEPHIS, NEMA, IPR, NACOSTI, and government ministries such as agriculture and public health among others. This will solve problems of misguided, non-scientific political decisions such as the GMO ban as well as provide the environment upon which biotechnology policy brokers to successfully push for SynBio/biotechnology agendas in the country. Finally, a working and enabling infrastructure for biotechnology should include reconsidering the current biotechnology communication strategy. As we transition into 'GMO 2.0' –SynBio (TWN, 2018), public education and awareness creation must be reinvigorated. Experts feel awareness remains very low among the common Kenyan, and worse, even scientists from certain quarters and key leaders in critical government dockets (with the capacity to determine uptake of biotechnology/synthetic biology) have joined the anti-biotechnology voices. The media must be properly used and in a targeted manner. The Twitter handles of concerned organizations must be used to deconstruct mythologies surrounding GMOs and synthetic products. Scientists must strategically appear in media broadcasts to perform this task.Issues surrounding ethics, religion, dual-use/biosecurity, risks perspectives, environmental, health and economic factors relating to SynBio should be clearly spelt out in such revised strategy. Ways of reaching out to concerned sectors of Kenyan societies properly spelt.

VI. STUDY RECOMMENDATIONS

The study makes four main recommendations as follows:

- Explore best avenues for having an overarching framework for SynBio, such as a Bioeconomy Strategy. One viable way is to commission studies to benchmark from existing practice in UK, USA, Singapore among others with a SynBioBioeconomy is place. This will act as the roadmap, and guide further regulatory processes such as enacting legislation, a targeted policy and so on.
- Explore the necessities for establishing a SynBio Consortium in Kenya that will bring stakeholders from industry, academia and government with inclusion of key stakeholders from the general public such as leaders of inter-religious associations. Such a consortium has proved to work well in countries like UK and Singapore, even acting as the government informant and consensus building platform on issues SynBio.
- Mainstream SynBio into the research undertaken in tertiary research and learning institutions. This will a) provide a critical mass of experts of SynBio; b) enable the GoK to invest in multiple projects at the same time. Important under this point is explore best ways to expand the share of the 1% GDP for STI to biotechnology. Investing in biotechnology, particularly in such a disruptive version as SynBio should be treated very seriously. This study recommends that SynBio be given a proportionately higher share matching its potential.
- Explore how the works of KALRO, NEMA, Institute of Primate Research (IPR), NBA, KEBs and KEPHIS and all other concerned institutions can be realigned accordingly to capture SynBio regulation and R&D in a manner that will solve the unnecessary regulatory bottlenecks, reduce possibilities for redundancy or replication of projects and enable for a nationally smoothly run SynBio pipeline. This should include a clearly spelt out institutional mandates and scopes of work for each institution. One way of doing this, maybe be through enacting SynBio legislation and formulating a policy, in line with a Syn Bio Bioeconomy Strategy. The policy/legislation should anticipate political interference and lay out frameworks for remedying such.

- Explore the manner in which a SynBio bio-foundry can be implemented. Questions relevant to such an exploration should include: who will play what role? Where will the bio-foundry located/hosted? Does Kenya possess the needed human and non-human resources to sustainably run the bio-foundry?

VII. SUGGESTIONS FOR FUTURE STUDIES

Based on the foregoing presentation, the following are areas requiring further investigations.

- The findings and conclusions made out of this study were based on a survey of respondents who had diploma education and above and were largely experts involved in biotechnology-related activities. There is need for future studies to explore perspectives of the unemployed and biotechnologically uninformed general public, such as farmers, who are also the majority of the would-be consumers of SynBio products.
- Secondly as it emerged that political has been a hindrance of biotechnology development in Kenya, there is need study that will help establish the cause-effect of such a scenario and explore avenues for remedying it. Specifically, it should be explored how biotechnology brokers (see, Kingiri&Hall, 2012) should particularly target the political class to create sustainable political support for biotechnology in this country.
- Thirdly, there is need for a study to explore the various causes and nature of inter-organization conflicts and hindrances between the biotechnology regulatory, researches, policy and other concerned agencies which are responsible for the slow pace of biotechnology development in Kenya.
- A cost-benefits and risks-benefits analyses of synthetic biology for the Kenya economy is critical. This should include a global markets survey of current SynBio innovations being produced, analyze the extent to which Kenya is better positioned to undertake such with an industrial and finding solutions to local problems mindset. Such analysis should also cover regulatory questions (discussed in-depth in Kasera et al., 2021) among other issues. Finally an analysis should be comprehensive and integrated so as to leave no actors and sectors out.

AUTHORS' CONTRIBUTIONS

Mr. Odhiambo Alphonce Kasera is the first author of this article. He has undertaken this study the said NRF-funded SynBio Project as a policy student researcher. He conceptualized the study, collected data, analyzed the data, and compiled the article. Dr. Michael OmondiOwiso was the university supervisor and the immediate supervisor of this work. He has read drafts leading to this paper with critical input. Dr. Mburu led the Policy Objective of the NRF SynBio Project and co-supervised the thesis study from which this particular paper was extracted. He has read previous drafts of this work and made important improvements. Prof Miano, Dr. Margaret Karembu, Dr. Margaret Muturi and Mr. Geoffrey Ngure conceived and wrote the NRF SynBio Proposal which was subsequently approved by Kenya's National Research Fund, and through which this was funded. Dr. Calvince Barack was useful in this output and made critical observations on this article which improved the quality of the paper.

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The primary author declares no conflict of interest during the process and the compilation of the final product of this paper.

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