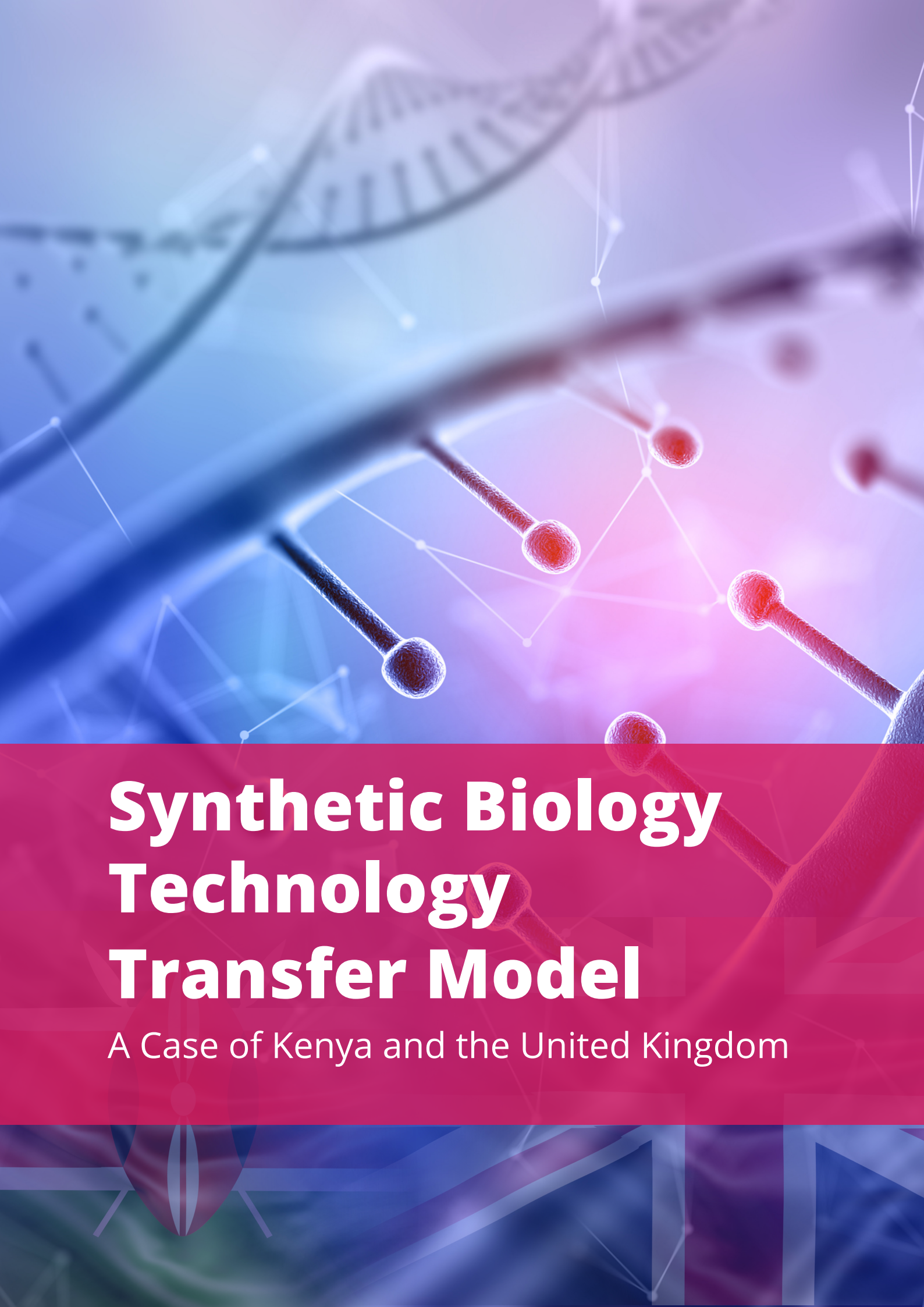


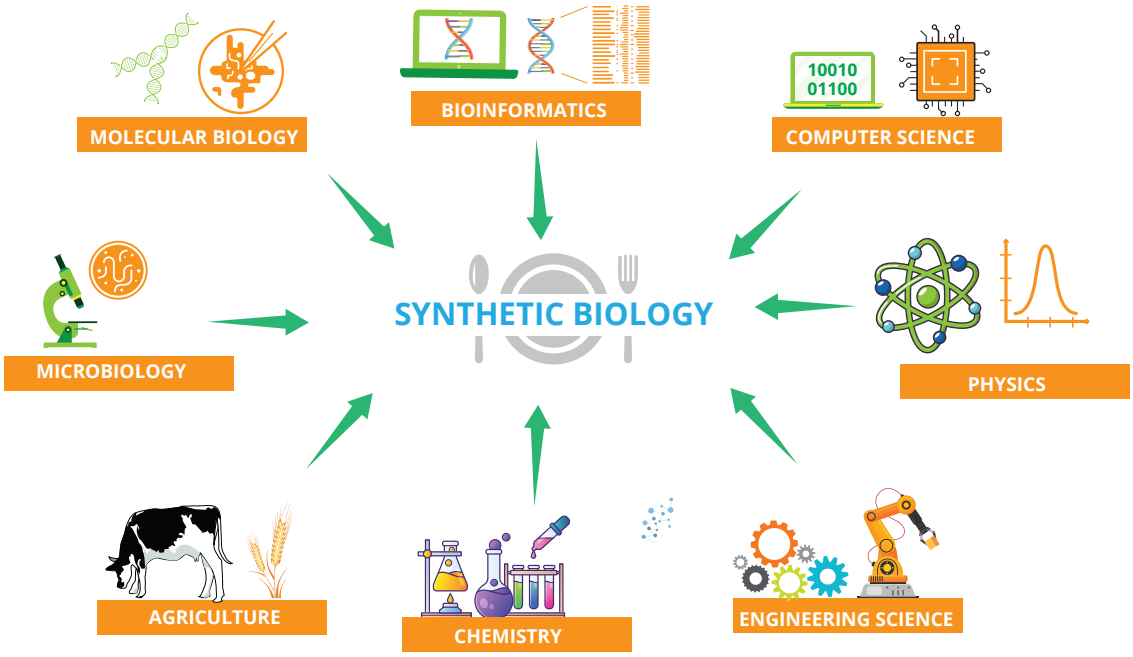
Synthetic Biology Technology Transfer Model

A Case of Kenya and the United Kingdom

Synthetic Biology

Synthetic biology is the systematic design and engineering of biological systems which display functions that do not exist in nature.[1] In essence, synthetic biology has provided mankind with a toolbox of well-defined genetic parts and exciting permutations for building novel or improved functions. This has opened up a world of possibilities in using existing biological building blocks, and/or non-natural building blocks to create useful, functional systems, organisms, and products. Being an engineering discipline, synthetic biology requires standard parts that can be assembled using bioinformatics and simulation tools to build circuits that introduce or modify biological functions.[2] These parts are increasingly being characterized, documented, and availed by synthetic biology research groups.[3]

The ability to predictably combine genetic parts to achieve the desired outcome comes with a host of applications in health, agriculture, industry, and the environment. Moreso, rapid advancements in synthetic biology research are expected to find application in the production of pharmaceutical products, precision drug delivery systems, low-cost clinical diagnostic kits, and biosensors for detection, monitoring, and management of important analytes.



Synthetic Biology: A Multi-disciplinary Field

[1] *Synthetic Biology: Applying Engineering to Biology: Reportof a NEST High Level Expert Group*

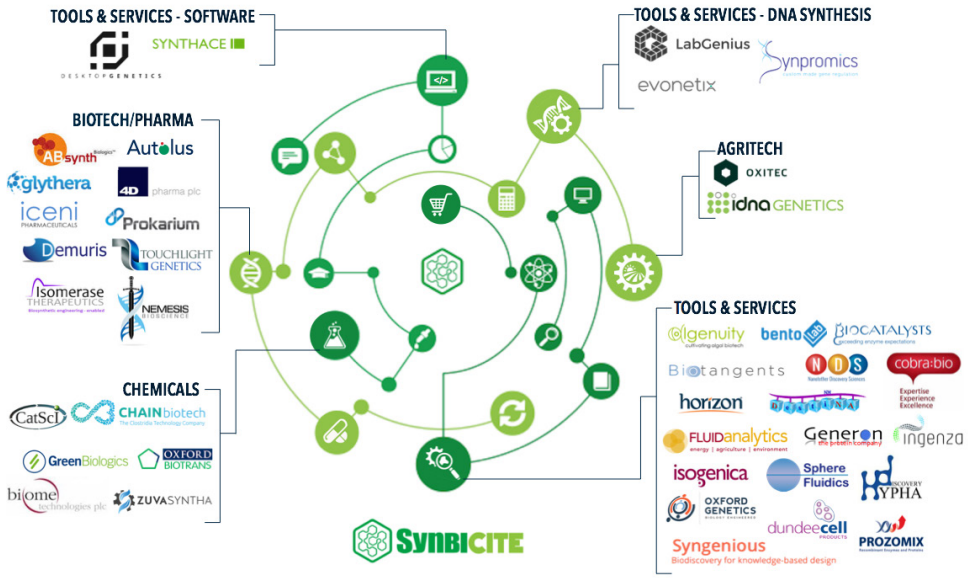
[2] *Molecular Systems Biology 3:158*

[3] *http://parts.igem.org/Main_Page*

Synthetic Biology in the United Kingdom

The United Kingdom (UK) is recognized as a world leader in synthetic biology research and development (R&D). It recognizes the potential of synthetic biology in delivering new solutions to key challenges spanning the bioeconomy. As such, the UK government commissioned the publication of a national Synthetic Biology Roadmap in 2011, to facilitate its commercialization.[4] In addition, the country has made a significant investment in infrastructure to support the R&D capacity, translation, and scaling up of synthetic biology products and innovations. These include Synthetic Biology Research Centres, DNA Synthesis Foundries, Doctoral Training Centres, Innovation, Knowledge, and Business Incubation Hubs. Moreover, start-up contests, mentorship programs, seed funding, and entrepreneurial training programs have all aided in the development of innovative ideas and the transformation of technologies into viable enterprises. This has stimulated exponential growth in synthetic biology innovation, expertise, private sector investment, and business start-ups mainly pioneered by early-career professionals.

To provide leadership in synthetic biology R&D, a Synthetic Biology Leadership Council (SBLC) was established in 2012, bringing together stakeholders from government, funding agencies, academia, and industry. The council published a UK Synthetic Biology Strategic Plan in 2016, channeling focus on processes of research translation and commercialization.[4] Over the past 5 years, the number of synthetic biology start-up companies has increased by 28 percent, with over 140 companies established. This is accompanied by growth in private investment, with 56 synthetic biology companies raising $3 billion in the first half of 2020.[5] Sectors represented by these start-ups include synthetic biology tools and services (e.g. strain engineering, DNA synthesis, research tools), biomedical, industrial chemicals, software, environment, agriculture, and consumer products.[6]



UK Synthetic Biology Start-ups in 2017

[4]*Clarke, L. J., & Kitney, R. I. (2016). Synthetic biology in the UK–an outline of plans and progress. Synthetic and systems biotechnology, 1(4), 243-257.*

[5]*Synthetic Biology Startups Raised $3 Billion In The First Half Of 2020. Synbiobeta 2020.*

[6]*Synthetic Biology Start-ups in the UK and Worldwide, UK-SBLC 2017.*

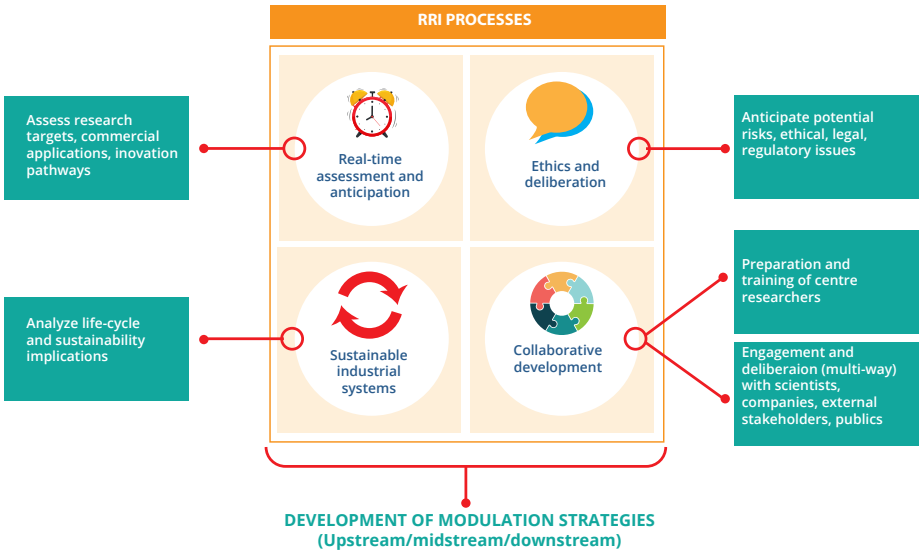
Synthetic Biology Policies and Regulations in the UK

The UK is a host to a growing and vibrant synthetic biology start-ups, spin-outs, and Small and Medium Enterprises (SME) ecosystem. This ecosystem is nurtured by significant financial and infrastructural investment, as well as enabling policies and science-based regulations that foster commercial translation of synthetic biology research. Synthetic biology products may fall within the scope of existing regulations and risk assessment frameworks for genetically modified organisms (GMOs), food, chemical, and medicines. However, questions have been raised as to whether these regulations are appropriate for potential future applications of synthetic biology.[7] Prior to the UK's exit from the European Union (EU), risk assessment of synthetic biology research was covered by two EU GMO directives – Contained Use Directive 2009/41/EC, and Deliberate Release Directive 2001/18/EC. In order to engage stakeholders and build trust in the technology, the UK incorporated a Responsible Research and Innovation (RRI) framework within the Synthetic Biology Roadmap.[8] In addition to safety, RRI enables consideration of other factors such as economic and social concerns. An iterative approach to assessing risk is used, involving social and natural scientists, NGOs, citizens, and regulators. This framework is adopted by the UK synthetic biology community and is embedded in research centers, national center for technology transfer, and the industry. Researchers highlight to regulators where synthetic biology work in the field pushes the boundaries of current regulations and provides a space for discussions.[9] The RRI for synthetic biology requires that:

i. Inescapable uncertainty is acknowledged and measures are put in place to ensure safe, rapid, and effective responses to any unforeseen problems.

ii. The UK maintains and develops its regulatory and enforcement regime for environmental, health, and security risks relating to synthetic biology, and that it does so from an international perspective.

iii. Engagement means genuinely giving power to a wide range of diverse social groups, including those who will be the end-users or presumed beneficiaries of the technologies, taking their concerns seriously, and enabling them to participate throughout the whole pathway of technological development.



[7] *POSTnote 497 May 2015 Regulation of Synthetic Biology*

[8] *EPSRC, Framework for Responsible Research and Innovation*

[9] *A synthetic biology roadmap for the UK*

Synthetic Biology in Kenya

Kenya has established itself as a regional leader in synthetic biology research and development. In 2019, a Kenyan delegation attended a synthetic biology experience-sharing workshop in the UK. The two-day workshop hosted at the Imperial College London (ICL) comprised a series of talks and focused discussions, and was the third workshop to be held between the UK and Kenyan researchers, policymakers, and science communicators. It was preceded by a two-day SynbiTECH conference that served as a primer and a vital eye-opener for the Kenyan delegation to the tremendous opportunities synthetic biology offer in solving intractable challenges in our modern society.

In 2020, a team of Kenyan scientists launched the first-ever government-funded research project on synthetic biology in the country. The 3-years project, funded under the country's National Research Fund, is using synthetic biology to address intractable challenges in food security and healthcare. Led by a multidisciplinary team of researchers, the project titled "Developing low-cost diagnostic tools and biosensors for rapid detection of crop and human pathogens in Kenya" aims at harnessing the power of synthetic biology to provide viable solutions to delayed disease surveillance and intervention in the country. To model the application of this technology, the research team is developing synthetic biology-based biosensors for cassava brown streak disease (CBSD) and cholera, two economically important crop and human pathogens in the country. In addition, the project is evaluating policy and legal frameworks required in adopting synthetic biology innovations, while building a shared public understanding of the opportunities and benefits of the technology through effective communication. The research team is working closely with a research team at ICL in exploring synthetic biology technology transfer models compliant with both countries' standards and regulations. The project is expected to inspire more government and private sector investments in synthetic biology.

Kenyan youth have also taken interest in synthetic biology. This was demonstrated by a team of young professionals who participated in the 2021 International Genetically Engineered Machine (iGEM) competition. The team, Africa Biosynthetic Solutions and Innovations (ABSI), is developing a biosensor that detects common chemical and biological contaminants that can be used by people from the comfort of their homes. Target chemical contaminants are Cadmium, Fluoride, and Lead while microbial contaminants are E.coli H. Pylori and V. cholerae. The biosensor will apply common engineering principles to work, and this will be a great step for affected communities to fight waterborne illnesses.[10]

In 2020, a team of Kenyan scientists launched the first-ever government-funded research project on synthetic biology in the country to address intractable challenges in food security and healthcare.

[10] *https://2021.igem.org/Team:ABSI_Kenya*

Synthetic Biology Policies and Regulations in Kenya

Kenya does not have a defined policy and regulatory framework for governing synthetic biology research and development. Discussions are ongoing on whether the existing policies and regulations including the Biotechnology Development Policy [2006] and the Biosafety Act [2009], among others, are sufficient to govern synthetic biology research, development, and commercialization. Recommendations from stakeholder consultations point towards product-based regulation of synthetic biology applications on a case-by-case basis.

Building a Thriving Bio-economy: Lessons from the UK

The fast-growing population and diminishing natural resources require urgent exploration of alternative sources of food, feed, fiber, and fuel. Moreso, topical challenges including climate change and disease pandemics necessitate the adoption of robust solutions, adaptation and mitigation measures. Synthetic biology presents a biology-based source of alternative solutions to key intractable challenges in food production, healthcare, environmental restoration, and industrial bio-manufacturing.

Building a sustainable bio-economy is imperative to growing the country's GDP, and creating job opportunities for the young generation. Therefore, it is imperative that enabling policies, and science-based regulations that promote innovations are adopted to allow science, technology, and innovations (STI) to contribute to socio-economic growth and development.

This ecosystem should also be bolstered by investment in research, infrastructure, expertise, and translation to commercial products through the scaling up of start-ups, spin-outs, and SMEs. Here, public-private partnerships are essential in bridging the gap between research and business. From the UK Bio-economy Strategy, some of the key factors to consider in the adoption of synthetic biology innovations include; (a) enabling policies, (b) science-based regulations, (c) effective communication, and regular, all-inclusive engagement with the relevant stakeholders, and (d) a proper implementation roadmap.

One of Kenya's main challenges is the missing link between science and politics (policymakers). Scientists rarely have the opportunity to advise the government on policies governing the research, development, and commercialization of scientific innovations. Learning from the UK system, the Prime Minister's Council for Science and Technology provided recommendations on how to enhance the regulatory oversight of technological innovation, identifying key challenges that should be addressed:

1. The need to be on the front foot in reforming regulation in response to technological innovation.
2. The need to build dialogue between society and industry on how technological innovation should be regulated.
3. The need to work with partners across the globe to reduce regulatory barriers to trade in innovative products and services.

One of Kenya's **main challenges** is the **missing link** between **science and politics** (policymakers).

UK-Kenya Synthetic Biology Technology Transfer

1. Needs Assessment	• Identify the challenge. • Classify the challenge - agriculture, health, environment, industry etc.
2. Technology Requirement	• Are there existing technological solutions to the challenge? • If yes, are they efficient? • Why is synthetic biology a better alternative?
3. Technology Scouting	• Are there synthetic biology technologies developed in the UK that could address the challenge? • Score the technology's suitability, ease of use, and cost implication.
4. Enabling Environment	• Are there favorable policies and regulations to allow for technology transfer? • Are there specific standards requirement for the technology?
5. Freedom to Operate	• Is the technology accesible for public use? • Are there IP protection and patent agreements that need to be made with technology developer?
6. Negotiate, Acquire, Deploy	• Sign transfer agreements. • Agree on revenue management of financial returns. • Import, adapt, and adopt technology.

Acknowledgment:

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Citation:

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