Synthetic Biology Leadership Council

BIODESIGN FOR THE BIOECONOMY

UK Synthetic Biology Strategic Plan 2016

SYNTHETIC BIOLOGY STRATEGIC PLAN 2016

CONTENTS

FOREWORD

The Synthetic Biology Roadmap, published in July 2012, set out a clear vision for synthetic biology in the UK – that it should be economically vibrant, cutting-edge, and of clear public benefit. Recognition of the importance of synthetic biology to the future UK economy as one of the Government's 'Eight Great Technologies' has set the UK as a world leader. Then we saw synthetic biology as an exciting new approach to biological research and innovation. Now, we realise even more acutely the potential growth opportunities for the bioeconomy and possibilities to address global challenges. The harnessing of intracellular biological systems for the manufacturing and processing of bio-molecules is one of the most exciting fields of 21st Century Life Science. By incorporating engineering principles and encompassing cell-free systems, synthetic biology will continue to extend such capabilities and further expand our horizons.

Since 2012 significant progress has been made. The development of the UK roadmap and significant additional public investments to bolster our national capability, such as the establishment of six new Synthetic Biology Research Centres, have put the UK in pole position to seize advantage both socially and economically. We have seen an increasing incorporation of engineering principles and practices in the development of new and modified biological systems. It is this shift towards 'Biodesign' capabilities that will be key to unlocking the commercialisation of applications.

We now need to release the potential developed since 2012 through the next phase of the roadmap. Key to fulfilling our UK vision on the world stage is maintaining exceptional national agility and responsiveness. Technological frontiers continue to advance, attracting new investments and inspiring the formation of numerous start-up companies. Exciting and important new opportunities are being identified and developed across the bioeconomy, including chemicals, advanced materials, energy, health, and environmental protection.

This strategic plan for synthetic biology aims to accelerate the commercial translation of products and services with clear public benefit, building off the strength of the UK's research base. It has been developed with expert engagement from a broad cross-section of interests spanning business and the research community. It focuses on five key areas of related strategic importance: accelerating industrialisation and commercialisation; maximising the capability of the innovation pipeline; building an expert workforce; developing a supportive business environment, and building value from national and international partnerships. This refreshed strategy will provide the touchstone around which all those involved in this exciting scientific frontier can unite, enabling us to press forward with confidence and increasingly realise the potential that synthetic biology affords.


Co-Chairs of the Synthetic Biology Leadership Council
George Freeman MP, Minister for Life Sciences
& Prof Lionel Clarke
February 2016

The UK government has supported the SBLC in its development of this independent strategic plan. The recommendations reflect views gathered from the stakeholder community as assimilated and represented by the SBLC and as such do not necessarily represent UK government policy.

EXECUTIVE SUMMARY

The UK aims to achieve a £10bn UK synthetic biology market by 2030, capable of delivering substantial societal and economic impact nationally and internationally. To achieve this, the UK must commercialise cutting-edge science and technology through a healthy innovation pipeline, a highly skilled workforce, and an environment in which innovative businesses can thrive.

Synthetic biology is capable of delivering new solutions to key challenges across the bioeconomy. Synthetic biology delivers the capability to manufacture complex molecules that are currently very difficult, too expensive or simply impossible to produce. By improving the productivity of biomanufacturing processes it can help generate more sustainable materials, chemicals and energy. Synthetic biology has the potential to generate a broad range of useful applications. It can be applied, for example, to develop smart response systems such as biosensors; to engineer plants for disease or drought resistance; to engineer mammalian cells for drug testing, stem cell production or tissue engineering; to engineer bacteria for human digestive and environmental health, and for waste management. As synthetic biology tools and techniques continue to develop we anticipate many other applications will emerge. The successful commercialisation of such opportunities within the UK will contribute direct benefits to health, security and the economy.

Synthetic biology builds on a rich legacy of research and understanding spanning over sixty years since Crick and Watson's discovery of the structure of DNA. However, funding for the specific development of synthetic biology in the UK spans less than one decade, with the first dedicated synthetic biology research centre, CSynBi, established at Imperial College in 2009. Recognising the considerable potential of synthetic biology and the national strength of underlying research expertise, the UK government commissioned the Synthetic Biology roadmap, published in July 2012. Its recommendations were supported with significant additional investment to bolster the national research and development infrastructure. Total investment into synthetic biology research in the UK is second only to the US and amongst the largest per capita in the world. A comprehensive national network has now been established, comprising synthetic biology research centres, synthesis facilities, centres for doctoral training and an innovation and knowledge centre to drive commercial translation. A vibrant community of start-ups and SMEs engaged in synthetic biology has emerged and a broad range of potential applications is being explored in universities and industry. The formation of a Special Interest Group and ongoing support for open meetings and conferences has developed a thriving nationwide community of academics, industrialists and other stakeholders. The importance of maximising the economic benefits from such investments within a culture of responsible research and innovation is clearly recognised in the roadmap.

Rapid advances in information technology and high-throughput analysis and assembly[1] are making it increasingly possible to address biological system function from a digital rather than analogue perspective, facilitating the continued emergence of synthetic biology. By applying core design and engineering principles of characterisation, standardisation and modularisation to biological systems, predictability and development speed can be increased and costs reduced. Previously intractable challenges can be addressed, and the potential to commercialise useful applications enhanced. As this underlying platform technology becomes increasingly embedded, and the core design-build-test-analyse cycle becomes increasingly automated, so scientists can concentrate more on end uses - shifting the focus towards what we term 'Biodesign'. This will ultimately increase access to synthetic biology approaches from a broader range of non-specialists. By enabling concepts to be translated more rapidly and reliably into commercially viable processes, the cost of market entry may be reduced, competitiveness enhanced and delivery of benefits accelerated.

The UK bioeconomy is currently estimated to be worth around £150bn GVA and capable of rapid future growth. Synthetic biology currently comprises a relatively small component of the bioeconomy as a whole, but lies at its innovative heart. Facilitating the delivery of synthetic biology-based solutions could become an important driver of productivity and UK competitiveness in years to come.

The potential value of synthetic biology is stimulating considerable interest around the world, and rapid progress continues to be achieved through collective global activity. Maximum impact on a global scale will arise not only from UK initiatives but from international

RECOMMENDATIONS

partnerships – connecting expertise and resources to market needs. Universities and companies in the UK are developing international partnerships, and it is notable that a number of major applications currently coming to market aim to provide significant benefits in the developing world.

In view of the significant progress that has been made in the three years since the roadmap was published and an increasing number of potentially commercial opportunities, the Synthetic Biology Leadership Council (SBLC) decided to focus attention on the translation of emerging ideas and the commercialisation of applications. This next crucial phase is necessary for jobs and growth. This strategic plan aims to deliver the original target of a £10bn synthetic biology based platform technology[2] in the UK by 2030[3], with substantially greater value potentially achievable from exploiting future applications in global markets. To realise this ambition, the SBLC has developed a series of recommendations as the basis for a new strategic plan, the key elements of which are summarised here. Full details of these recommendations, along with the key mechanisms for their implementation are described in the Planning the Way Forward section.

This new strategic plan should be viewed in conjunction with the original roadmap, which provides the enduring foundation for this refreshed focus on translation and commercialisation. It builds directly upon - but does not replace - the core principles and initiatives set out in the original roadmap, seeking to accelerate commercial translation responsibly towards the delivery of products and services of clear public benefit for many years to come.

1 Accelerate industrialisation and commercialisation
By promoting investment in, and translation of, empowering biodesign technologies and assets to drive growth in the bioeconomy

2 Maximise the capability of the innovation pipeline
By continuing to research and develop platform technologies that will improve manufacturing efficiencies and unlock future opportunities

3 Build an expert workforce
By distilling the skills required for biodesign and implementing them through education and training

4 Develop a supportive business environment
By ensuring that regulation and governance systems are proportionate and appropriate to the needs of industry and that these are aligned with the needs and desires of stakeholders

5 Build value from national and international partnerships
By fully integrating the UK synthetic biology community to position UK research, industry and policy makers as partners of choice for international collaboration

1. High-throughput methods use automation to conduct huge numbers of experiments in parallel

2. A platform is a group of technologies that are used as a base upon which other applications, processes or technologies are developed

3. A Synthetic Biology Roadmap for the UK, 2012: http://www.rcuk.ac.uk/publications/reports/syntheticbiologyroadmap/

INTRODUCTION

Opportunities for Synthetic Biology

Synthetic biology - a 'platform technology'

For more than a century, industrial production has been dominated by the conversion of fossil oil-based feedstocks[4]. The development of synthetic chemistry techniques in the 19th through to the 20th century provided the 'platform technology' required to create new industrial processes and products using these feedstocks. Synthetic biology may provide the 21st century 'platform technology' required to create new industrial processes capable of producing and using a wider range of bio-based feedstocks, generating a greater diversity of products, and supporting the expanding bioeconomy with innovative solutions.

From Analogue to Digital to Biodesign

Rapid advances in information technology and high-throughput analysis and assembly are making it increasingly practical to address biological systems from a digital rather than analogue perspective. Digital approaches benefit from the massively increased speed and data-handling capacity enabled by these advances. Consequently reproducibility, predictability and development speed can be increased and costs reduced. This allows a range of previously intractable challenges to be addressed and the potential to commercialise useful applications enhanced.
As the underlying platform technology develops for particular applications it may become possible for the core design-build-test-learn cycle to be increasingly automated and managed remotely through computer-aided design systems. This has facilitated the continued emergence of design elements within synthetic biology as proposed in the 2012 UK Synthetic Biology Roadmap[5].

The development and adoption of 'higher-level' language[6] to instruct the required operations will start making the technology accessible to a broader range of non-specialists who can then focus more on the intended outcomes than on the mechanics of the underlying design-build-test-analyse processes. This shift in focus towards 'Biodesign' is already becoming a reality for simpler systems, whilst remaining a significant future target for more complex systems.

Supplying the innovation pipeline

Synthetic biology has only emerged as a practical option in recent years, and capabilities continue to advance rapidly. Consequently it remains necessary to maintain adequate support for the underlying research base, to continue developing the necessary underpinning tools and techniques, and to remain responsive to global opportunities arising whilst continuing to foster responsible research and innovation (RRI) as set out in the 2012 roadmap. This will be needed to supply the commercial pipeline with a stream of innovative opportunities for years to come, akin to how microelectronics continued to advance long after the first applications of the transistor in the 1960s.

Contributing towards the future bioeconomy

Synthetic biology provides a rapidly advancing capability to develop solutions to key challenges across the bioeconomy, spanning health, chemicals, advanced materials, energy, food, security and environmental protection. In recent years, the concept of a bioeconomy has evolved with potential for rapid and significant growth. Several countries have developed explicit bioeconomy strategies, reflecting the potential for biology as an economic force. Although there is currently no official UK bioeconomy strategy, the size of the UK bioeconomy is currently estimated to be worth at least £150bn GVA, potentially increasing by a further £40bn over the coming decade[7]. Synthetic biology currently plays a small role in the overall bioeconomy but lies at its innovative heart. The development of higher-level biodesign capabilities could become a critical component of productivity and UK competitiveness in years to come, especially when international market growth opportunities are taken into account. Close links have been forged between the SBLC and other groups including the Industrial Biotechnology Leadership Forum (IBLF) and the Agri-Tech Leadership Council (ATLC), to ensure alignment between the role and potential value of synthetic biology and this broader vision for the UK bioeconomy.

By enabling concepts to be translated more rapidly and reliably into commercially viable processes, the cost of market entry may be reduced, competitiveness enhanced and delivery of benefits accelerated. This strategic plan aims to deliver the original target of a £10bn synthetic biology based sector in the UK by

2030 - associated mainly with the commercialisation of the underpinning technologies - with substantially greater potential value from the development of applications both within and beyond the UK.

Generating Applications and Benefits

Synthetic biology can help to tackle challenges for which current technology has not yet delivered effective solutions. For example:

- Synthetic biology could speed up drug development, reduce our dependency on animal testing, and increase our ability to respond more rapidly to pandemics or biosecurity threats.

- Early stage development is underway for drugs that tackle antimicrobial resistance and that target specific diseases or parts of the body, such as cancer cells.

- Advanced materials, capable of providing stronger, lighter, biodegradable alternatives to current polymers are being explored.

- Synthetic biology is providing fresh tools to help turn renewable feedstocks into biofuels, transforming wastes back into useful products, and improving the productivity of biomanufacturing processes, helping to reduce our reliance on fossil fuels and to increase sustainability.

- UK-based world-leading research groups are engineering pathways[8] into crops with the aim of reducing our reliance on fertilisers and pesticides, and exploring ways to produce important nutrients, such as omega-3 oils typically found in fish, more sustainably from plants and algae.

Synthetic biology is already allowing companies to manufacture products in novel ways. Novel enzymes have been designed to perform chemical transformations to manufacture previously expensive flavour and fragrance compounds from cheaper, more sustainable, feedstocks. Weakened strains of bacteria are being developed to deliver novel vaccines, and companies are testing innovative and environmentally friendly solutions for insect control, helping to tackle both agricultural pests and those that transmit diseases, such as Dengue Fever and Zika Virus, to humans. Synthetic biology techniques are being used to develop biosensors to improve diagnostics and bioprocesses. The commercialisation of such applications will contribute direct benefits to health, security and the economy.
The relationship between synthetic biology as a platform technology and the role of biodesign in generating innovative solutions and options for the bioeconomy is captured in Figure 1, and exemplar case studies can be found throughout this strategic plan and on the SBLC website.[9] We anticipate that many other ideas remain yet to be imagined and developed.

Linking entrepreneurship with responsible research and innovation

A good understanding of stakeholder interests and potential future market value needs to continue to influence the selection of research topics and to inspire the development of innovative applications. Doing so within a responsible framework ensures effective balancing of societal benefits and commercial value. For synthetic biology entrepreneurship and the principles of responsible research and innovation can, and indeed should, be complementary. A common factor and source of inspiration are grand challenges for which conventional technologies provide imperfect solutions. Such societal benefits attract high quality researchers and applications are already beginning to flow, with new tools and techniques emerging that may assist in tackling longer term challenges. Synthetic biology may provide vital options for tackling such tough challenges.

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4. Feedstock is the raw material or fuel required for an industrial process

5. Synthetic biology is defined in the UK roadmap as 'the design and engineering of biologically based parts, novel devices and systems as well as the redesign of existing, natural biological systems'. Other definitions have been proposed elsewhere for regulatory and other purposes but this original definition continues to capture the core engineering and design focus of synthetic biology as a platform technology

6. In computer programming, 'higher level' languages offer a simpler coding system that is separated from the details of the computer's systems and are therefore easier for non-specialists to understand

7. The British Bioeconomy, Capital Economics, 2015: http://www.bbsrc.ac.uk/documents/capital-economics-british-bioeconomy-report-11-june-2015/

8. A biological pathways is a series of actions (such as enzymatic modifications) that lead to a new product or cellular change

9. Website for the Synthetic Biology Leadership Council Case studies: www.connect.innovateuk.org/web/synthetic-biology-special-interest-group/synbio-case-studies

Operating globally

The intimate relationship between the physical and informational dimensions in synthetic biology permits a new balance to be achieved between centralised and distributed operations, including those across national boundaries. Academic and commercial partnerships will also help accelerate technological progress and help forge mutually beneficial links between global market needs and technological solutions.

The commercial development of synthetic biology will often require the incorporation of other technologies, and its contribution to a final product may range from being essential to its function simply providing a source of insight. Applicable regulations may vary from application to application and from market to market, focussing on either product or process. Dealing with regulatory inconsistency can be a particular impediment for smaller companies. Developing internationally recognised standards, and the establishment of effective governance systems may assist the process by providing common and transferable reference material. A recent study by BSI and synthetic biology stakeholders highlighted the need for best practice in the design of biological manufacturing systems[10] and a guide to the use of standards for digital biological information. Standards will have an important role to play not only in the development of underpinning technologies but also in the commercialisation and governance of synthetic biology.

The importance of coordination

One of the most cost-effective mechanisms to extract maximum value from investments made is to focus the resulting expertise and resources towards a common goal. This was the main purpose of the original roadmap. Synthetic biology is essentially a platform technology, advancing rapidly and with a myriad of potential applications, so the alignment process needs to be dynamic and responsive. The UK Synthetic Biology Leadership Council (SBLC) provides an essential coordinating role. It draws upon the expertise, networks and resources of its stakeholder representatives to identify and address such needs, consistent with the original roadmap vision in which UK synthetic biology is: economically vibrant, diverse and sustainable; cutting edge; and of clear public benefit. The SBLC has compiled the brief case studies from both the research base and industry which appear throughout this document, and more detailed case studies are available on the SBLC website.

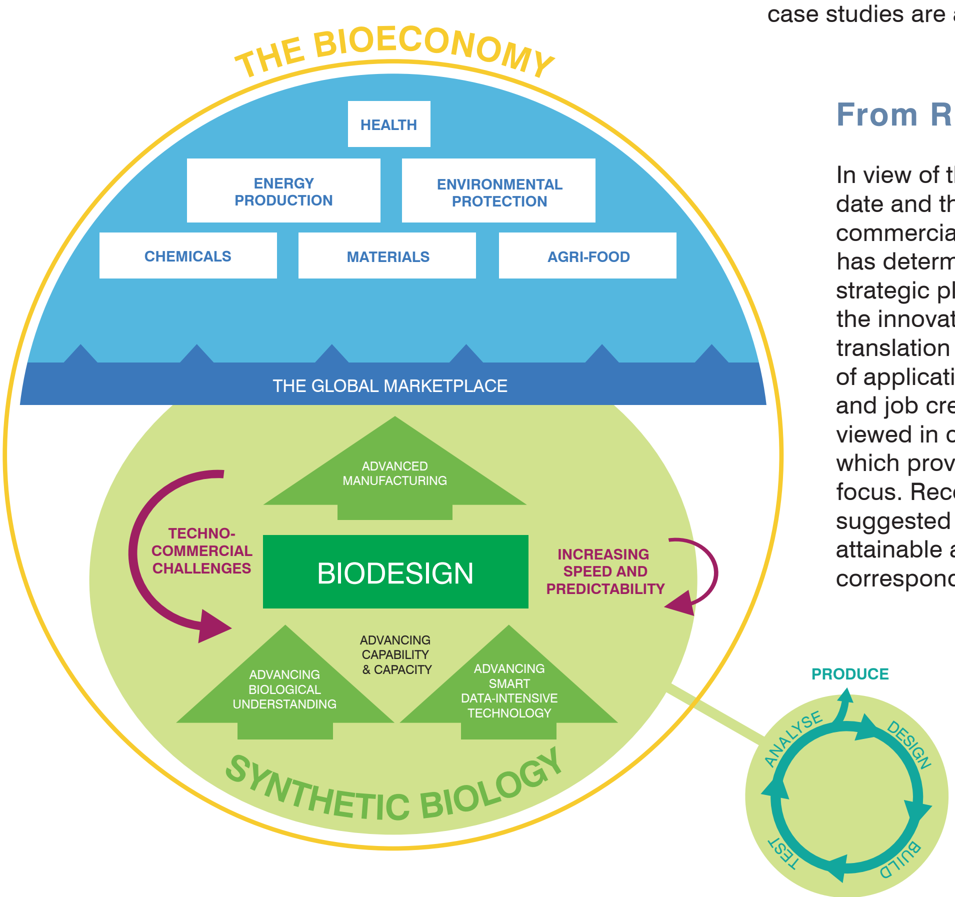

__Figure 1:__ Synthetic Biology is evolving into a biodesign discipline, as accelerating 'design-build-test-analyse' capabilities make outcomes more predictable and robust and increasing attention can be given to the delivery of economic and social benefits. Potential applications span the bioeconomy and a greater understanding of market needs better inform foundational research and training programmes.

From Roadmap to Strategic Plan

In view of the significant progress made to date and the increasing number of potentially commercialisable applications, the SBLC has determined that it is timely to generate a strategic plan focussing particularly on supplying the innovation pipeline[11] and accelerating the translation of ideas and the commercialisation of applications. This will directly support growth and job creation. This new plan should be viewed in conjunction with the original roadmap, which provides the foundation for this refreshed focus. Recommendations and supporting suggested actions which are specific, trackable, attainable and timely may be found in the corresponding sections of this plan.

A FOUNDATION FOR GROWTH

In the UK

Research Infrastructure and Innovation Eco-System

Excellent progress has been made towards delivering the five recommendations published in the 2012 Synthetic Biology Roadmap. UK public sector investment has totalled approximately £300M ($450m) in the last eight years. Six new centres of multidisciplinary synthetic biology research excellence have been added to the original CSynBi centre at Imperial. Together with networks of research groups and smaller centres in more than 30 universities spanning the country, these have generated a UK-wide research and development foundation of international significance (see Figure 2). All centres are committed to research in Ethical, Legal and Social Aspects (ELSA) of their work, with embedded RRI goals and dedicated staff who link the centres, share experience and develop best practice. This dynamic environment for research and training brings together a critical mass of researchers working across the UK, galvanising the higher education sector to make their own significant investments in synthetic biology, and attracting substantial matched funding from industry and from international grants and partnerships.

The UK Government's Synthetic Biology for Growth Programme has made significant capital investments in equipment and facilities for foundational research and development. The Synthetic Biology Research Centres (SBRCs) and the SynbiCITE Innovation and Knowledge Centre (IKC) provide access to leading technologies, ranging from state-of-the-art robotics and automation platforms to high-performance computers and automated workflows for phenotyping and characterisation. DNA synthesis is an essential underpinning technology for synthetic biology as researchers increasingly move from reading to writing the genome. A distributed UK capability in DNA Synthesis Foundries has been established which bring together the whole process from design to production, working with commercial synthesis companies and enabling institutions and industry to work together to overcome bottlenecks in the production of fully characterised DNA constructs.

The SBLC set up its Governance Subgroup (GSG) to provide a dedicated forum to influence the development of an agile and supportive policy and research processes for synthetic biology in the UK. Social awareness alongside technological expertise is now embedded through the framework of Responsible Research and Innovation (RRI) as recommended in the 2012 roadmap. Outreach and community engagement are an important part of the UK synthetic biology effort and have enabled RRI to become an essential feature of research funding.

Translation and Commercialisation

To support the commercialisation of research outputs, two Innovate UK-led collaborative research and development competitions have funded companies to work in partnership with UK universities. There have also been two Dstl-led calls on synthetic biology applications in defence. The synthetic biology Rainbow Seed Fund has been established to fund synthetic biology pre-companies and start-ups, and promising spin-outs are already emerging from the IKC and SBRCs (see figure 2, next page).

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10. http://www.bsigroup.com/LocalFiles/en-GB/standards/BSI-The-ascent-of-digital-biomanufacturing-Executive-Summary-UK-EN.pdf

11. 'Innovation Pipeline' used here to describe the entirety of researching, developing and testing novel processes, products or services, spanning the full breadth of applications, through to commercial launch.

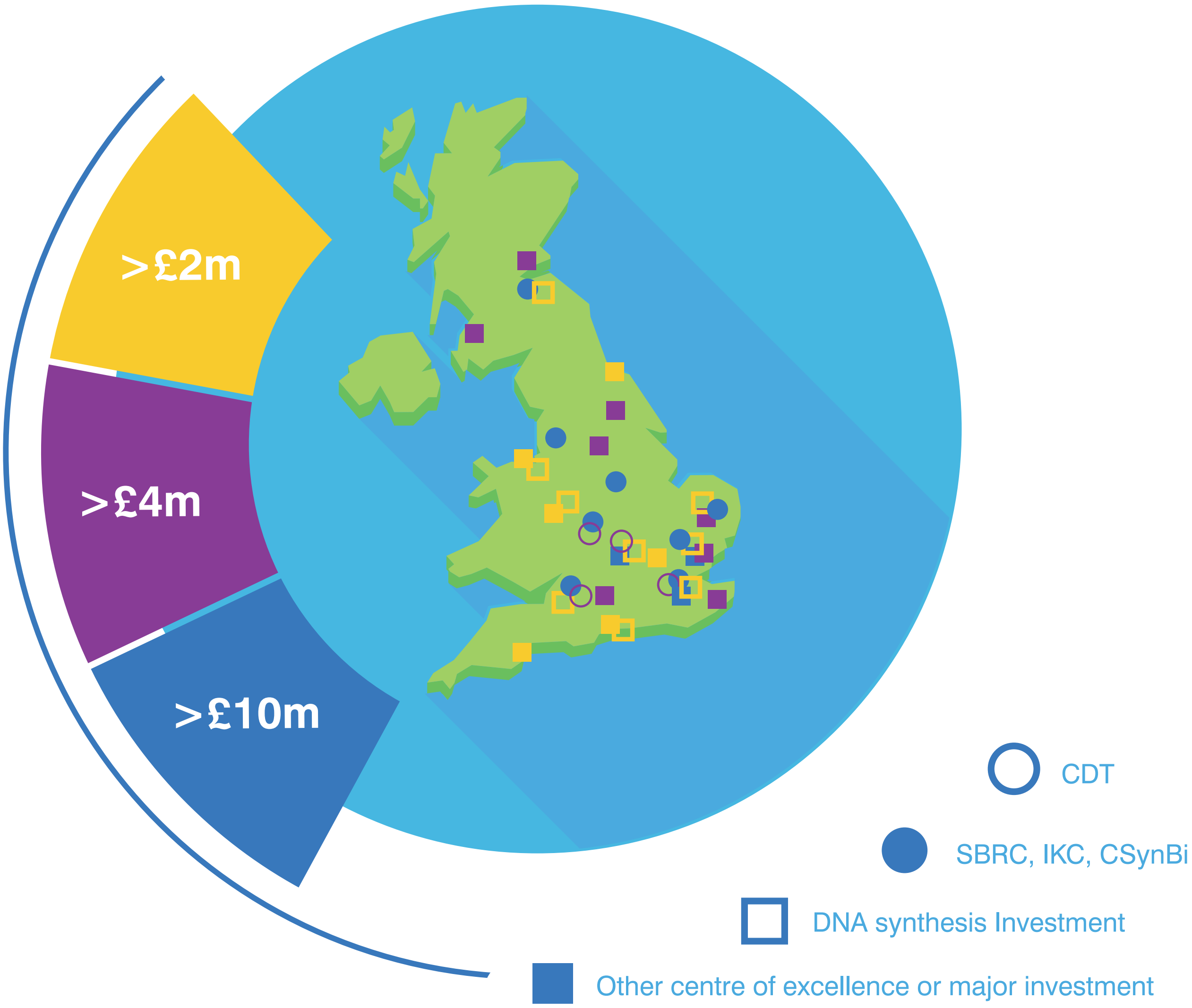

Figure 2: *£300M ($450m) of public investment has established a nationwide network of synthetic biology centres of research excellence in the UK. Each centre contributes a distinctive and complementary field of expertise towards synthetic biology platform technology and application development, whilst joint programmes help build synergies across the network as a whole.*

SYNBIOCHEM
Manchester Synthetic Biology Research Centre for Fine and Speciality Chemicals

The Synthetic Biology Research Centre for Fine and Speciality Chemicals at the University of Manchester will use predictive synthetic biology to develop faster, more predictable, novel routes to fine and speciality chemicals production (including new products/intermediates for drug development, agrochemicals, flavor/fragrance components and new materials), and through industrial collaborations, help propel chemicals/natural products production towards 'greener' more sustainable manufacturing processes.

UK Centre for Mammalian Synthetic Biology

The UK Centre for Mammalian Synthetic Biology Research at the University of Edinburgh is building expertise in cell engineering tool generation, whole-cell modelling, computer-assisted design and assembly of DNA and high-throughput phenotyping to enable synthetic biology in mammalian systems. Applications include tools and technologies for commercial exploitation by the pharmaceutical and drug testing industries, diagnostics, novel therapeutics, protein-based drugs and regenerative medicine.

SynBio
SBRC Nottingham

The Synthetic Biology Research Centre at the University of Nottingham focuses on micro-organisms already able to synthesise fixed-carbon products from single-carbon gases but applies synthetic biology approaches to engineer-in enhanced chemical production for industrial use. Applications include the sustainable production of chemicals and biofuels. This approach reduces reliance on petrochemicals, reduces climate change and exploits waste.

WISB
WARWICK INTEGRATIVE SYNTHETIC BIOLOGY CENTRE

The Warwick Integrative Synthetic Biology Centre addresses specific, industrially relevant design challenges across the scales of biological organisation: genetic circuits, pathways, cells, and multi-cellular systems, also providing us with a better understanding of some of the key mechanistic and evolutionary principles underpinning living systems. Application areas include pharmaceuticals, high-value and commodity chemicals, treatments for disease, environmental bioremediation, bioenergy, and food security.

SynBiCITE

The UK's national industrial centre for synthetic biology is designed to be an effective industrial translation engine, bridging the gap between university-based research and industrial processes to create products and jobs, through industry. It provides a national centre of expertise in technology development and commercialisation - and nucleating point - for the benefit of the UK economy.

OpenPlant
OPEN TECHNOLOGIES FOR PLANT SYNTHETIC BIOLOGY

OpenPlant, a collaboration between the University of Cambridge, the John Innes Centre and The Sainsbury Laboratory in Norwich, is accelerating the development of open technologies for plant synthetic biology and applying these to generate novel plant traits. Applications include metabolic engineering for production of high value products, and foundational work to improve bioenergy sources and enhance photosynthesis and nitrogen fixation.

BrisSynBio
biomolecules to biosystems
from understanding to design

BrisSynBio focuses on applying biomolecular design and assembly in synthetic biology. This includes rational design and engineering of nucleic acids, lipids, peptides and proteins as structural, enzymatic and regulatory components in new biological and bioinspired systems. Applications include: producing agrochemicals, pharmaceuticals and fine chemicals; designing new vaccine platforms; developing products; and establishing new methods to increase wheat yields.

CSynBI
Centre for Synthetic Biology and Innovation

The Centre for Synthetic Biology and Innovation at Imperial College applies a twin track research strategy to engineering biology to develop platform technologies and applications. Platform technologies include: information systems, standards (SBOL and DICOM-SB), protocols for characterisation (BioParts, devices and chassis) and DNA assembly. Application areas include: biosensors, biocomputing, production therapeutics, cell-based therapies, advanced biofuels and biomaterials.

Training

Effective routes for training postgraduate students have been established through two Centres for Doctoral Training (CDTs) at University College London and a collaboration between the Universities of Bristol, Oxford and Warwick. The CDTs are responsible for producing the next generation of synthetic biologists, ensuring they have a strong grounding in core disciplines, complemented by multi-disciplinary understanding and skills in entrepreneurship. In addition, applicable to synthetic biologists at all levels, are courses and programmes aimed at leadership, business, responsible research and innovation and entrepreneurial skills, e.g.: the Synthetic Biology Leadership Excellence Accelerator Programme (LEAP), organised jointly by SYNBERC (USA) and the SynbiCITE IKC (UK). This is developing a community of emerging leaders in synthetic biology to create bold new visions for developing biotechnology, and the Lean Launchpad (run by SynbiCITE), which allows participants to gain real world experience of starting a business.

Building the community

Through the activities of Innovate UK, Research Councils, the Synthetic Biology Special Interest Group (SynBio-SIG), learned societies and others, the community has become increasingly networked, helping to build an effective innovation environment. This has fostered interactions across boundaries, with shared learning, resources and best practice. The recently established academic-led national synthetic biology conference, Synthetic Biology UK 2015, demonstrated the progress made in building a broad-based, world-class community across the UK.

This collective community enterprise is promoting a culture change. Synthetic biology is becoming a truly multidisciplinary field that drives cross-boundary working spanning the life sciences, engineering, medicine, chemistry, mathematics and social sciences. The new and established centres and research groups enable resources and expertise to be drawn from a wide range of sources, whilst operational collaboration contributes to efficient use of facilities and a more collective focus on shared and critical challenges.

The UK is recognised as an international leader in synthetic biology, with strengths across research, innovation and policy. We are a partner of choice for many countries and proactively engage with, for example, the US, EU, China and Singapore. This international reputation positions the UK well to increasingly develop opportunities collaboratively and creatively.

PLANNING THE WAY FORWARD

'Biodesign for the Bioeconomy' is the SBLC's strategic plan for taking synthetic biology through the next phase towards achieving the roadmap vision. Although many years of fundamental research will still be required to unlock the potential opportunities from more complex systems (such as eukaryotes or microbial communities) a number of relatively simpler systems are now becoming commercialisable. It is important to focus attention on the processes that will enhance or could inhibit the translation and commercialisation of these early examples, which should pave the way for accelerating benefits from more challenging systems as they emerge. It addresses key drivers of productivity – providing effective tools and a skilled workforce to use them, appreciating current and future market needs and facilitating a supportive operating environment to streamline delivery – and adapts them to the characteristics of synthetic biology and its current state of development.

Foundations of research and development have been laid over the past decade and set the stage for commercial growth. Reflecting on progress and experience has brought the needs of the next phase into sharper focus, and enabled us to draw out detailed suggested actions. These are captured in the following sections, structured in line with the five overarching recommendations.

Critical to success will be the extent to which these complementary activities are integrated within the overall vision (see Figure 3). The SBLC plays a critical role in helping maintain a strategic overview, and in facilitating the coordination of activities within the UK, but it will be the inspired and tireless efforts of individuals and groups throughout the community and the networks and partnerships formed, that will ultimately determine the rate of progress.

Much of the expertise and resource needed to deliver this strategic plan already exists in the UK. Achieving it will require a continuing resource commitment to partnering and coordination, addressing training and development needs, incentivising inward investment, streamlining processes and upgrading resources as set out in these recommendations.

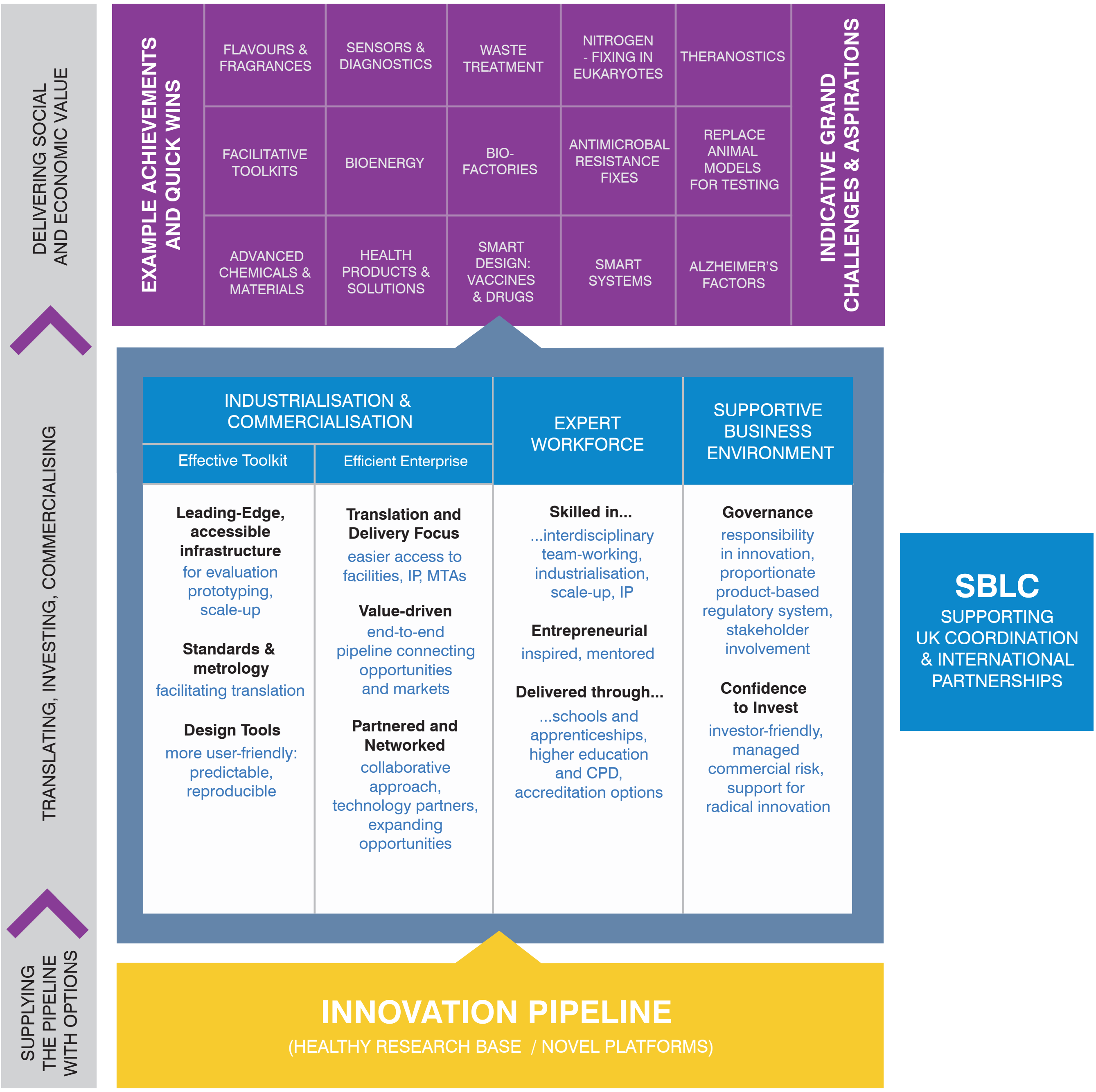

Figure 3: *Outputs from synthetic biology research are already finding their way to market applications. The next stage is to build upon foundations laid, generating a highly productive system for supplying the biodesign innovation pipeline, meeting needs and translating into social and economic benefit in the near and long term.*

1

Accelerate industrialisation and commercialisation

Recommendation 1: Accelerate industrialisation and commercialisation by promoting investment in, and industrialisation of, empowering biodesign technologies and assets to drive economic growth

Synthetic biology today captures the vision of a new era of biology-enabled industries that are already beginning to deliver scientific advances and new products. Rapid progress has focused attention on the increasing importance of digital biology and laboratory automation in unleashing a new business sector of biodesign. Over £300m ($450m) of public funds have been invested in addition to substantial private investments. A focus on translation of this research base is now needed to capitalise upon the competitive technologies that are emerging.

Opportunities for Growth

The industrial biotechnology (IB) sector is one example of pioneering the use of synthetic biology. As our ability to engineer more complex biological systems grows, including mammalian and human cells, the medical biotechnology sector, especially bio-therapeutics, will become a major potential growth area for the UK. As productivity increases and costs reduce, many manufacturing sectors such as health, agri-food, energy and advanced materials will need to be engaged with the synthetic biology technology base.

Companies need to be able to find the best and most appropriate innovations and collaborators in a complex landscape. Industry collaboration is often the most effective conduit for technology transfer, but matching of industry needs and cutting edge solutions can only be enabled and organised efficiently on a national level. There should be a leading role for brokerage and knowledge transfer organisations, such as the Knowledge Transfer Network (KTN), to work dynamically with industry. They can help communicate technical barriers to growth and market insights to the creative research community and promote high value collaborations and effective technology transfer. Tools such as business led technology sandpits and showcase events should play a role promoting solutions to multidisciplinary problems and inspiring firms to innovate. Mentorship from experienced industrialists could also prove valuable. A modest proof of concept fund, building on the success of SPARK Awards[12], to accelerate confidence building would be especially valuable to SME's and could incentivise academic engagement and career planning.

Action 1.1 KTN (together with the IKC) to lead work to match business needs and market opportunities with competitive edge technologies arising from the research base with access to a 'proof of concept' fund to catalyse new research partnerships. In addition, KTN should build closer links with industry to generate greater 'market pull' and to encourage mentorship.

From acorns to oak trees – appropriate accelerators

Start-ups and spin-out companies will be vital to the UK bio-economy. An important strategy for ensuring growing companies are funded is to concentrate on supporting businesses through a range of tools such as accelerator schemes.

There is currently a mismatch between the location of available incubator space and the development of synthetic biology hubs, especially in London and Cambridge, that is impeding the growth of high tech bio-industry clusters. Ambitious companies need space to grow nearby. The growing linkages between the synthetic biology and digital sectors exacerbates location challenges and may require a more flexible approach to land-use planning or the application of more advanced communication options.

Action 1.2 Review the emerging needs of synthetic biology businesses and encourage flexibility in planning and investments to allow new sector co-location to flourish.

12. *Innovate UK SPARK Awards: https://connect.innovateuk.org/web/synthetic-biology-special-interest-group/synbio-spark-awards*

Access to Finance

Financing is one of the main challenges of growing small businesses, especially in new technology sectors where investor experience is still maturing. Small businesses need the skills to access finance schemes that are crucial in making businesses investment-ready. There remains a shortage of risk capital in the seed and early stage (<£10m) investment rounds and the UK must work hard to expand the capital pool available. Venture capital (VC) backed competitive accelerator schemes such as IndieBio and Ycombinator, have been powerful magnets for synthetic biology start-ups in the US, combining upskilling, access to industry insiders and investor exposure and would be invaluable if mirrored in the UK.

Action 1.3 Focus on investment readiness programs, build investor awareness and funding capacity and establish VC backed seed fund competitions in the UK.

Capturing Value & Scaling Up

Much of the economic impact from synthetic biology will come from increased competitiveness from existing production, and new products offered by existing market players. A key challenge is how to engage these companies with synthetic biology and how to manage scale up of their products and processes. Engagement can be fostered through the networks already in place. However the costs of early stage high-risk technology development are high. A mechanism is needed to develop new synthetic biology enabled products at all stages of development.

Process engineering[13] is an existing strength in the UK. The UK has invested in technology centres with capital intensive plants of value to synthetic biology, such as the CPI[14] National Industrial Biotechnology Faciity (Wilton) and the National Biologics Manufacturing Centre (Darlington), both of which fall under the broader Catapult network. However, their commercial clients resource their own project activity and if the UK's scale-up capacity is to be fully utilised a graduated support mechanism will be required.

The UK synthetic biology industry has recommended a flexible, Catalyst-style[15] approach to supporting the promotion and translation of synthetic biology products and processes. It is important that this approach also enables access to critical scale up facilities. The industry demand for synthetic biology commercial and translational support, from early stage enabling technologies to marketplace products is unusually broad and it is important to ensure that a range of funding tools are made available. There is clearly a need for both application-led and industrial technical challenge focused initiatives. For example the Industrial Biotechnology (IB) Catalyst has funded several SynBio IB projects and has seen applications increasing steadily.

Action 1.4 Establish a competitive and graduated support fund for companies to develop synthetic biology products/processes potentially using the existing Catalyst framework or similar. Maintain its operational flexibility reflecting rapid changes in the commercial landscape and alignment with private sector investments.

Case studies

Oxford Biotrans – sustainable grapefruit flavour

The compound which gives grapefruit its distinct flavour, nootkatone, is a very expensive ingredient costing between £1,000 and £5,000/kg. Oxford Biotrans is commercialising its novel process to produce nootkatone from valencene (the major component of orange oil) using an enzyme-catalysed process.

Green Biologics Ltd

Green Biologics is a renewable chemicals company focused on developing and delivering new renewable alternatives for everyday products.

Oxitec

With prior support from both BBSRC and Innovate UK, Oxitec have developed an innovative solution for controlling harmful insect populations through the production of 'sterile', self-limiting insects whose offspring do not survive. In 2015, Oxitec was sold to Intrexon, a US-based biotechnology company, for £102 million. Intrexon will further use Oxitec's technology to combat diseases and agricultural pests worldwide.

Boosting productivity through advanced automation

The availability of synthetic genes at commodity prices, and the possibility of automated and potentially remotely operated laboratories, will transform synthetic biology over the next three years. Allied to a range of innovations in miniaturisation, automation and metrology, this will realise the vision of taking experimental sciences into the design-test-build era and towards a new level of enhanced operability we characterise as 'Biodesign'.

Simple, easy to use, cost effective off-the-shelf laboratory automation is key to boosting productivity at the heart of synthetic biology. The main barrier to uptake is reported as being changes in the approach and skillsets of researchers and easy access to robotics. Although the robotics required by synthetic biology are of modest sophistication they are currently poorly represented in both public and private biological facilities.

Action 1.5 Undertake a study to determine whether or not there is the need for a significantly scaled-up and world class resource investment to train and empower researchers, in academia and industry, to profit from modern robotics, data analysis and experimental design and the associated capital investment in bio-robotics required across the sector.

Action 1.6 If required following 1.5 establish a capital investment or loan-guarantee programme, available to public and private organisations, for them to invest in bio-robotics and laboratory automation.

Standards for SynBio

The development of internationally recognised standards in synthetic biology was recognised very early on as key to the industrialisation of biological 'parts'[16] and processes. The emergence of best practice will be best achieved incrementally, reflecting the pace of development and in anticipation of evolving needs. Innovate UK has funded BSI to produce the first guidance on the use of standards in synthetic biology (PAS 246)[17]. Internationally agreed standards for 'parts' and the associated metrology materials remain an important goal now supplemented by a need for data format standards required for seamless transfer between laboratories. These include remote gene assembly and data analysis hubs. It is important that the UK maintains a central link to global standard setting agencies to ensure UK competitiveness. Industry has a key part to play and its needs should be central in the establishment and international co-ordination in synthetic biology standards.

Action 1.7 The synthetic biology industry should be placed at the heart of UK activities in setting and agreeing technical standards (e.g. in relation to data formats, process automation procedures and tools, and component characterisation). We should formalise links between the UK standards and metrology agencies (e.g. BSI and the NPL) and other global standards institutions (e.g. NIST).

Case studies

Autolus

Spun out from UCL, Autolus is developing cancer treatments by engineering immune cells to more effectively target cancer cells specifically.

Detecting spoiled food with a tricorder

Scientists from the University of Birmingham are developing a 'tricorder' type device which can detect infection of food samples by microbes. A spin-out company to develop the technology, Linear Diagnostics, has been formed by the team.

Sphere Fluidics

Sphere Fluidics has developed a technology which can screen hundreds of thousands of molecules per day for suitability as ingredients in new drugs.

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13. Process Engineering focuses on the design, operation, control, and optimisation of chemical, physical, and biological processes

14. The Centre for Process Innovation: http://www.uk-cpi.com/attachment_data/file/440927/bis_15_352_The_dowling_review_of_business-university_rearch_collaborations_2.pdf

15. Catalysts are run jointly by Innovate UK and the Research Councils and support research from basic science through to pre-competitive industrial research in particular priority areas

16. Biological parts are units of biological activity (normally encoded by DNA) that can be assembled into systems or devices

17. Use of standards for digital biological information in the design, construction and description of a synthetic biological system, BSI, 2015: http://shop.bsigroup.com/forms/PASs/PAS-2462015/

2

Maximise the capability of the innovation pipeline

Recommendation 2: Maximise the capability of the innovation pipeline by continuing to research and develop platform technologies that will improve manufacturing efficiencies and unlock future opportunities

The UK has built a world-class capability in synthetic biology by identifying the field as one of the Eight Great technologies for economic growth and directly injecting funds for research and innovation into the area. synthetic biology - the engineering of biology - results from the confluence of two major revolutions in molecular and cellular biology, and information technology, as illustrated in figure 1. Key to establishing these firm foundations has been a partnership between the Research Councils to jointly fund multidisciplinary research effort at the interface of bioscience and engineering.

Compared to the century or more of evolution of synthetic chemistry, synthetic biology is still at an early stage of its development - with many aspects undergoing rapid change. There is still considerable fundamental, foundational research work that needs to be done and funders will continue to support world-class research vital to maintaining a portfolio of UK synthetic biology projects to ensure a continuous flow of underpinning research and platform technologies to pump-prime the innovation pipeline.

The technology underlying the initial sequencing of the human genome (the ability to read DNA) and the ability to write DNA (DNA synthesis) have been key drivers of the field such that the ability to both read and write DNA accurately, rapidly and cheaply are now important industrial drivers in their own right. This, coupled to other developments – for example the implementation of extensive automation, software (e.g. for design, analytics, process management and control) and genome editing (e.g. CRISPR/Cas9) - is resulting in the rapid development of the field. There is a continued need for the development of tools for synthetic biology. Without these toolkits many commercial applications will not be realised. Platform technologies and early-stage applications are beginning to emerge and are being commercialised (Box 1), whilst the development of toolkits for more complex and challenging systems such as eukaryotic multicellular organisms will require many more years of underpinning research.

In the context of these overall developments, it is essential to continue to enhance national and international collaboration with other academic centres and industries working in the field.

Action 2.1 Drive the ongoing development of effective platform technologies - whether bioengineered, biological or software in nature - through national and international collaborations, to aid the sustained advancement of synthetic biology and the industrial translation of research outputs.

The development of the platform technologies that form much of the basis of industrial translation in synthetic biology benefits from significant advances in related fields that are also being supported through UK research investments. It is therefore vitally important that the innovation pipeline is supported on a continuing basis through investment in the underpinning science and engineering.

In many areas of industry the use of standardised components and processes is central to enhancing productivity. Consequently, the development of new metrology and effective technical standards is essential. The synthetic biology design cycle, based on the principles of characterisation, standardisation and modularisation, is now well established. The challenge is to develop techniques and methodology that can be used across a range of applications. This requires accurate metrology, with the comprehensive use of automation (e.g. laboratory robots), interoperability and technical standards. This also underlines the need for reproducibility - i.e. the ability to repeat precisely the same biological system design and its realisation at multiple locations (including BioPart characterisation), using the same protocols. More recently, the use of comprehensive automation and high throughput (HTP) techniques in the design cycle has helped address the need for accurate reproducibility, and these technologies are becoming increasingly important for the field.

Rapid developments in information technology and HTP analysis and assembly are making it increasingly possible to address biological systems analysis and design from a digital rather than an analogue perspective. Central to the vision of a connected and coordinated synthetic biology workflow is the development of efficient and user-friendly software to enable all parts of the workflow to communicate effectively with each other. The implementation of effective digital information infrastructures will greatly enhance the ability to undertake much more rapid design and implementation of synthetic biological devices and systems. This is particularly pertinent to the development of workflows associated with DNA synthesis and the design, and construction of large functional units of genomic information.

Action 2.2 Integrate software development as a key enabler for the development of new technologies and methodologies, as well as ensuring that all parts of the synthetic biology workflow are able to communicate effectively with each other through information infrastructures.

As new types of chassis[18] are developed and optimised, for example for specific industrial applications, it will be essential to understand their biology. At a fundamental level this will involve the application of systems biology[19], control theory[20] and data analysis to obtain greater understanding of the complexity of biological systems. The development of new chassis will also greatly assist the implementation and controllability of biodesigns and to improve manufacturing efficiencies. One example of this approach is the synthetic yeast genome project, Sc2.0, currently ongoing. Overall, such developments will lead to the more robust and reproducible solutions required for industrial processes.

Action 2.3 Advance chassis characterisation as an important component of the systematic design approach, e.g. the development of new strains for specific industrial applications – using the latest techniques in the synthetic biology toolbox.

A further challenge is the ability to control intracellular function through the deployment of smart, designed, biological information and control systems. This will be enabled by the development of effective, robust biodesign tools that will make the high level design and implementation of synthetic biology solutions more accessible to a wide range of users. Potentially cross-functional technologies are also being developed within the UK, such as in robotics and automation, advanced materials and advanced manufacturing, whilst synthetic biology may in due course provide a valuable contribution into emerging areas of science.

Action 2.4 Apply novel mechanisms to control intracellular function through the development of smart, designed biological information and control systems.

Synthetic biology is still new to many technology providers, requiring a different conceptual approach, specialist skills and understanding. This may have inhibited its rapid adoption by established industries, however this is now changing. For example, there is now clear evidence that synthetic biology is being incorporated in a variety of major chemical and energy applications, for example, in the recent 'Industrialisation of Biology' study by the NRC[21].The development of effective, robust biodesign tools will make the high level design and implementation of synthetic biology solutions more accessible to a much wider range of users in different fields of application. A continued focus on the development of effective platform technologies will ensure the synthetic biology pipeline is expanded and reinforced, and the full potential of applications is realised.

18. Biological chassis are the host cell (such as E.coli or yeast) into which biological parts and added

19. Systems biology uses iterative cycles of modeling to understand complex biological systems

20. Control theory deals with the behavior of dynamical systems with inputs, and how their behavior is modified by feedback

21. Industrialisation of Biology 'A roadmap to Accelerate the Advanced Manufacturing of Chemicals' National Research Council of the National Academies, 2015: http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing

Flowers Consortium

Comprising Imperial College and the Universities of Cambridge, Edinburgh and Newcastle (with Kings College - RRI). The consortium has achieved major results in developing information systems, datamining, CAD standards (SBOL and DICOM-SB), and modelling - as well as detailed reproducible procedures for characterisation (BioParts, devices and chassis) and DNA assembly. Flowers is the only international member of SynBERC.

Sc 2.0 project

The Synthetic Yeast Genome Project, involving an international consortium of researchers, aims to completely synthesise and construct a modern synthetic version of the S. Cerevisiae (baker's yeast) genome. The project hopes to find new ways to synthesise commercially valuable products such as chemicals and vaccines.

Synpromics – the power of synthetic promoters

Synpromics develops customised lengths of DNA, called promoters, which can switch genes on or off in a much more controlled manner than was previously possible. For example, Synpromics technology facilitates higher yields in bio-manufacturing processes, allows tuneable control of protein production and improves the safety profile of novel gene therapeutics

Synthace

Synthace's purpose is universal bioscience productivity. The company's deceptively simple bio-programming language, Antha, effortlessly spreads biological information in a repeatable way, easily linking lab equipment, protocols and processes to bring Design for Manufacturing to bioengineering.

World's first artificial enzymes created using synthetic biology

The world's first enzymes – 'XNAzymes' – made from artificial genetic material not found anywhere in nature have been created by researchers at the MRC's Laboratory of Molecular Biology, capable of cutting up or stitching together small chunks of RNA, just like normal enzymes. These XNAzymes are much more stable too, providing a starting point for an entirely new generation of drugs, diagnostics and therapies.

Plants as bio-factories

Scientists at the John Innes Centre in the UK have developed technology for the rapid expression of proteins in plants. Used under licence, this technology allowed Medicago Inc. to produce 10M doses of H1N1 swine flu VLP Vaccine in just a month, outperforming the traditional method which takes 9-12 months.

The Development of Biological Devices

Advances in the development of biologically-based digital devices have wide ranging implications in medicine and a number of other fields. Recent developments in synthetic biology have allowed the creation of a 'half adder' – a key building block in biological computation - to create custom-made devices, eg advanced biosensors.

Toolkit for a responsive biosensor

A biosensor toolkit for small molecule signalling being developed by researchers at Imperial College London and Astra Zeneca could allow cells to respond to a physiological cue, the presence of disease or pathogen biomarkers for example, with the secretion of a therapeutic compound such as peptide hormones for the treatment of obesity/diabetes.

Mould unlocks new route to biofuels

Researchers at Manchester University have identified the exact mechanism and structure of two key enzymes, isolated from yeast moulds, which provide a new cleaner route to the production of hydrocarbons for biofuels and more sustainable chemical manufacture. Work with the Diamond Light Source (Harwell) provided atomic level insights into the chemical reactions not previously thought to occur in nature.

A sustainable source of omega-3?

Researchers at Rothamsted Research have successfully engineered Camelina plants to produce omega-3 'fish oils' that are associated with health benefits. The new process could release pressure on the oceans and result in more sustainable, land-based sources of omega-3 fish oils.

3

Build an expert workforce

Recommendation 3: Build an expert workforce by developing the skills required for biodesign and implementing them through education and training

Development of a synthetic biology profession

Developing synthetic biology from an exciting basic science discipline into an economically important sector in the UK will require the concurrent development of trained synthetic biologists. Historically the emergence of other "new" scientific disciplines has often been accompanied by an *ad hoc* approach to establishing a trained workforce. This unorganised approach has often led to a reduction in the speed of development in an emerging area. Synthetic biology has always aimed to innovate in a wider area than just the underpinning science, challenging current approaches in training, innovation and regulation amongst others. Uniquely, from its inception the discipline has always viewed synthetic biology training to encompass other essential skills - including entrepreneurship, communication and high-level group working.

The UK needs to support and maintain world leading synthetic biology skills amongst practitioners at all levels. Synthetic biologists require both foundational skills that allow development and application of the pure science itself, and sufficient business skills that provide the tools to accelerate the exploitation of synthetic biology developments in the commercial world, or at least sufficient to engage effectively with industrialists.

Foundational Skills

Synthetic biology intrinsically requires expertise beyond traditional discipline boundaries. A successful synthetic biologist has to posses skills in one or more of maths, engineering, programming, automation, biology, biochemistry and biomedicine. Whilst it is impossible to have significant expertise in all of these disciplines, it is essential that a synthetic biologist can communicate skilfully within multi-disciplinary teams. This flexibility is difficult to teach formally and is more likely to result from working and training within a multidisciplinary environment. Cultural as well as technical differences must be accommodated and assimilated.

Although the application of routine good laboratory practice addresses immediate safety and environmental issues associated with a particular research programme, the roadmap recommends considering the longer-term implications of new research activities. Such awareness is now embedded in all research planning as RRI (see 4: Develop a supportive business environment), a further dimension to the multi-dimensional skillset required of today's synthetic biologists. The establishment of the multidisciplinary synthetic biology Centres for Doctoral Training (CDTs) and multiple research centres have already provided the foundations for such environments. This builds upon a number of established Doctoral Training Programmes in synthetic biology at other universities including University College and Imperial College London.

Action 3.1 The UK Research Councils should work with HEIs and others to develop further programmes that embed student training in multi-disciplinary, challenge-led environments.

About 70 'DIYbio' communities have sprung up around the world, half of which are located in the US[22]. Such 'citizen science' has a valuable role to play in helping to make science more accessible, improving technical understanding and developing an appreciation of associated safety and responsibility issues.

Linking biology through engineering to design is already inspiring and enabling novel multidisciplinary collaborations for example between synthetic biologists, designers, artists and social scientists, aiming to further develop new spaces for practice, cooperation and debate[23].

The development of synthetic biology in the 21st century reflects a fundamental shift in our understanding of biology, from the information in DNA to the function of whole systems. The resulting multi-disciplinary nature of synthetic biology challenges historic differentiation between the life-sciences and physical sciences. To foster the mutual understanding needed to embrace this 'new biology', and to help enthuse and nurture synthetic biologists of the future, we recommend reconsidering such traditional categorisations even earlier within school curricula. The implementation of an advisory body linked to the SBLC and with learned society involvement could provide guidance on biology and information to all educational levels from primary to HEIs. At higher levels, one solution would be to develop a synthetic biology curriculum accreditation. However in a new fast-moving field this may stifle innovative development.

Action 3.2 A joint SBLC-learned society-educationalist working group should be established to rapidly develop a synthetic biology teaching framework and commission resources to enhance synthetic biology teaching throughout the education system.

Business skills

The emergence of synthetic biology from the entrepreneurial west coast of the US and the Boston region has placed entrepreneurism at the core of commercial translation. It was quickly recognised that entrepreneurial skills could significantly accelerate the realisation of economic benefit from synthetic biology. Young scientists are trained in multidisciplinary team working and commercial awareness through the iGEM competition and Biotechnology Young Entrepreneurs Scheme (Biotechnology YES), and the synthetic biology IKC has developed the Lean Launchpad programme to develop entrepreneurial skills in post doctoral researchers. For example, iGEM provides a highly stimulating learning environment, a fantastic recruitment tool for new synthetic biologists and a platform for the development of new innovative uses for the technology (see box). The competition not only illuminates the potential of synthetic biology, but also teaches essential multi-disciplinary team working skills and values[24]. These and other examples represent significant capacity building and future UK plans have to be aimed at filling gaps and ensuring that this upward trajectory is maintained.

Because synthetic biology has emerged so recently, a significant proportion of practitioners (and potentially future leaders) entering business today are represented by recently-trained students (to date over 18,000 have participated in iGEM alone). The core values of responsible research they have assimilated during their training and take forward with them in their future careers should be an important factor through the innovation pipeline. In synthetic biology, entrepreneurship and the principles of responsible research and innovation can, and should, be complementary. Providing relevant support materials and continuing access to resources for those who transfer from educational establishments to business may further assist this process.

Action 3.3 A synthetic biology education fund should be established to enable the further development and adoption of successful synthetic biology scientific and business skills programmes (e.g. iGEM, Lean Launchpad, Biotechnology YES, RRI training) by the wider community.

A key aspect of business training involves embedding new students in industry to provide an opportunity for the student to immerse themselves fully in business culture. So-called 'Skills Schools' provide short intense training of students and postdocs in an industrial environment. The skills schools provide industry relevant training over a one-week intensive course, which focuses on both industrial science and management training.

Action 3.4 Relevant scientific societies & academies and academic centres of excellence should form a working group to consider developing a Skills School provision for synthetic biology students and postdocs.

In addition to developing a programme that ensures that the new generation are skilled in new synthetic biology approaches, established researchers in related disciplines will need to be up-skilled. The transfer of skills, knowledge and expertise from other disciplines into synthetic biology will accelerate the development of the discipline and encourage the uptake of synthetic biology in relevant commercial sectors. The provision of trained experts and the subsequent development of industrial careers will ensure that UK industry continues to lead in this field.

Action 3.5 Relevant scientific societies & academies and academic centres of excellence should develop a unique continued professional development programme to encourage cross-discipline career development and the movement of people between academia and industry to facilitate maximum knowledge exchange.

The development and support of people with the technical and vocational skills needed by industry is critical to ensure the successful uptake of synthetic biology methods and innovation. This will promote stronger productivity and support the needs of the whole synthetic biology community. Many of these skills will be more vocational than those obtained through postgraduate degree courses, but have the potential to equip businesses with substantial synthetic biology capabilities. This could consolidate existing continuing professional development courses, such as the synthetic biology module within the Modular Training for the Bioprocess Industries (MBI®) delivered at UCL[25] and the Edinburgh University masters course in Management of the Bioeconomy, Innovation and Governance[26].

Action 3.6 Relevant Trade Associations should support the development of Apprenticeships, including Degree Apprenticeships within synthetic biology to encourage vocational technical training in synthetic biology in support of synthetic biology-utilising industries.

Case Studies

iGEM (the international genetically engineered machine competition)

iGEM started in 2004 with five undergraduate teams from US universities, but has expanded very rapidly in response to growing worldwide interest. Teams of students work over the summer to produce biologically-based devices – frequently of a very high standard. British teams have been highly successful in the competition. Cambridge were overall winners in 2009, developing targeted parts for biosensors. Imperial College has been in the top six teams every year since 2006, coming second out of 268 teams in 2014 with a water filtration system based on biologically produced cellulose. A significant proportion of graduates starting synthetic biology careers have been inspired by taking part in iGEM and ten companies have already formed directly from iGEM projects, with four of these in the UK.

Investing in emerging leaders

The Synthetic Biology Leadership Excellence Accelerator Program (SynBioLEAP) invests in the next generation of leaders in synthetic biology. In its first year, SynBioLEAP, a joint programme devised between Imperial College and Stanford University, brought together 23 fellows (7 from the UK) to develop the skills needed to lead responsible synthetic biology development in a global context.

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22. http://diybio.org/local/

23. Synthetic Aesthetics - an experimental, international research project between synthetic biology, art, design and social science to explore designing, understanding and building the living world. http://syntheticaesthetics.org/about

24. http://igem.org/About

25. Modular training for the Bioprocess Industries: https://www.ucl.ac.uk/biochemeng/industry/mbi/courses/index/edit/cob

26. http://www.sps.ed.ac.uk/gradschool/prospective/taught_masters/h_n/msc_management_bioeconomy_innovation_governance

4

Develop a supportive business environment

Recommendation 4: Develop a supportive business environment by ensuring that regulation and governance systems are proportionate and appropriate to the needs of industry and that these are aligned with the needs and desires of stakeholders

The application of excellent basic science at industrial scale will require an agile, supportive and proportionate governance approach, including government policies, development of standards, regulatory systems and public and stakeholder engagement and dialogue.

The SBLC is well placed to give leadership on these issues, given its experience over the past three years, and the broad range of expertise on which it can call including through its Governance Subgroup. The agility of the supportive environment we create to govern future developments in synthetic biology will be one of the main factors determining UK success in innovation. A responsible approach to research and innovation will be a key component, embedded within that environment. Responsibility in its broadest sense will be crucial to the successful delivery of the benefits of synthetic biology.

Policy and Regulatory Developments

The SBLC, with support from its Governance Subgroup (GSG), has advised UK Government Departments on relevant regulatory and policy developments and we expect the range and immediacy of such opportunities to increase in the next three years. This contribution will be vital for the delivery of the desired benefits from the UK's investments in synthetic biology. This will include advising on cases where regulatory adaptation can influence the direction, cost and timescale of development of innovation at a lower cost to the public purse.

There is growing pressure for policies and regulatory systems to become more adaptive to the needs of innovative industry without sacrificing quality, safety and efficacy. This is particularly the case in agriculture, energy and health sectors. In the health area adaptive regulatory systems are already speeding the translation to markets of innovative new technologies. With such benefits in mind, the SBLC and its GSG have engaged with the British Standards Institute (BSI) on the opportunities to identify interactions between standards and regulatory systems to support governance approaches that can adapt more rapidly to new opportunities, or to the emergence of new unexpected hazards. Extending this to development of sector or industry specific standards, or guidelines that complement the respective regulatory system, will facilitate translation of a wider range of products and applications.

Whilst synthetic biology derived products have been developed to respond to global threats (e.g. engineered drug therapy for treatment of patients during the Ebola epidemic), as with many emerging technologies, there are concerns over potential unethical use in civilian or military applications such as engineered pathogens. It is therefore important that a supportive governance structure is in place to ensure that civilian use of materials can be appropriately developed to maximise benefit and minimise risk.

Action 4.1 Through the SBLC and its GSG, establish a working group involving a pool of sector-specific regulators and practitioners to share experience of developing adaptive regulatory systems, to support proportionate and effective regulation.

Action 4.2 The SBLC and its GSG should continue working with BSI to identify opportunities for standards to contribute to more adaptive regulatory systems that meet the needs of rapidly evolving industry sectors while retaining high standards of safety and efficacy.

The timely development and introduction of technical standards, including the role of bodies such as BSI in generating effective guidelines, is key to accelerating efficient commercialisation and delivery. Such standards should streamline the global development of synthetic biology as a platform technology, and also help to provide a common baseline of data for regulators and facilitate the integration of technologies and their commercialisation within different markets. The development of technical standards for synthetic biology (e.g. SBOL and DICOM-SB) is underway through international collaboration that has already achieved significant technical development. Regulations will need to be framed to accommodate continuously evolving frontiers of knowledge and understanding, and the application of technical standards may complement this approach by providing more effective mechanisms to address particular issues. Such standards, regulations and governance systems will ultimately need to be developed and agreed internationally.

Action 4.3 Innovate UK to support and draw upon the relevant interests and expertise in technical standards and standard-setting within the UK to ensure that we can make an effective and well-grounded contribution to international discussions.

Responsible Research and Innovation

An important component of future governance of synthetic biology will be implementing responsible research and innovation (RRI). RRI includes aspects of anticipation, reflection and engagement. The need to engage positively and proactively with stakeholders is now widely accepted and is one of the core principles of RRI. The aim should be for broad awareness and mutual understanding of synthetic biology across public and stakeholder groups, and for research and innovation communities to build public trust through being open about their motivations and aims.

UK Research Councils, Innovate UK and EC research programmes are considering how best to conduct public engagement as part of a RRI approach, The SBLC will take an active part in these developments. There is a generally perceived need to ensure that all key actors, including policy makers, regulators and civil society, as well as researchers and innovators, are aware of the broader implications of their actions and understand what acting responsibly would mean for them.

Recent research has contributed to our understanding of the effectiveness and pitfalls of different approaches to stakeholder engagement and dialogue and to delivering RRI. This evidence base will contribute to well-informed choices on the optimal approaches to stakeholder engagement in the near future. The need for such engagement is increasingly urgent, given the accelerating pace of scientific developments in synthetic biology and the expanding range of potential future applications. A complementary requirement will be the availability of balanced and accurate information on synthetic biology that is readily understood by non-specialists. Most citizens are not well informed about synthetic biology but are interested in the potential applications and implications. An important part of the SBLC's strategic approach should be to support the provision of information by the media and other sources that is balanced and accurate.

Action 4.4 The SBLC and its GSG to build on recent and current initiatives on engagement and dialogue, involving representative stakeholders, to ensure that RRI is incorporated as a core value in decision making on synthetic biology, and to continue to develop appropriate standards for RRI.

Action 4.5 The SBLC, working through relevant organisations, should support provision of balanced and accurate information on synthetic biology research and future innovative developments, particularly issues attracting strong media interest.

Protecting against misuse

Measures being taken to address the potential for accidental or deliberate misuse are kept under review through established protocols that apply far beyond synthetic biology alone. Laboratory biosafety and managing the risk of accidental release is addressed through the relevant regulatory processes, which apply equally to accredited academic and industrial laboratories, as to citizen science 'DIY' spaces. It is generally agreed that the risks remain extremely low[27], nevertheless UK industrial providers remain vigilant. For example, consortia of providers have instigated gene synthesis order-screening procedures[28], and the recently established DNA foundries in the UK have signed-up, or are in the process of signing-up, to such consortia.

One of the best defences against future accidental or deliberate misuse, or indeed against a much more likely naturally occurring pandemic, is to have appropriate diagnostics, vaccines and antibiotics already available or able to be developed in a very short timescale. Synthetic biology tools, along with appropriate regulatory adaptation to facilitate rapid response, are the key to delivery of this defence.

The increasingly 'digital' nature of the technology and the processes of storing or transmitting data electronically make it especially important to address the issue of cyber-security, not least from the perspective of protecting commercial security. This is a risk not confined to synthetic biology and relevant guidelines have been issued by the UK government[29].

Action 4.6 Academic and commercial operations in the UK should ensure that adequate security measures are in place to safeguard the storage and flow of information and materials associated with their synthetic biology programmes, regularly reviewing procedures and sharing best practice.

Case Studies

Creative ways of generating dialogue around synthetic biology

Synthetic Aesthetics, an international project led by Edinburgh and Stanford Universities, brought together artists and designers with scientists, to beautify or better communicate the science of synthetic biology. The project led to new language and metaphors to better articulate the implications of the field to a wider range of people.

Standards for engineering in plants

Researchers at OpenPlant SBRC have established a ratified standard for Type IIS cloning methods. Defining a common syntax of fusion sites, the standard enables exchange and assembly of DNA parts for plants, which could be applied for genome editing and engineering of new traits.

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27. Workshop report - Synthetic Biology and Biosecurity: https://www.kcl.ac.uk/newsevents/news/newsrecords/docs/Jefferson-et-al-2014-Synthetic-Biology-and-Biosecurity.pdf

28. Screening framework guidance for providers of synthetic double-stranded DNA: http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf

29. Policy, Cyber security: https://www.gov.uk/government/policies/cyber-security

5

Build value from national and international partnerships

Recommendation 5: Build value from national and international partnerships by fully integrating the UK synthetic biology community to position UK research, industry and policy makers as partners of choice for international collaboration

National coordination

Substantial national investments have helped establish a highly competitive R&D base in the UK. This could be further strengthened by optimising linkages between the research base, enabling the UK to demonstrate national science excellence, and supporting synergies across and between novel UK technologies. We should, where appropriate, capture best practice in standards, contributing to establishing the UK as a leader in particular areas of strength.

Action 5.1 Synthetic biology institutions should coordinate joint activities and projects to share best practice, benefit from the latest technological developments and build a coherent UK offer to showcase their world leading and truly cross-disciplinary capability.

Whilst the research excellence of the UK must be maintained, this strategic plan shifts the focus towards the rapid translation of opportunities into clearly defined applications, and accelerating their commercialisation. The KTN's synthetic biology Special Interest Group has gathered over 1,000 members in three years and membership continues to rise at a steady pace. This membership reflects the strong interest in the topic, however it is currently dominated by those with extensive existing knowledge. To further expand, the community needs to develop broader industrial engagement. In particular, KTN should target sectors where synthetic biology can help to realise opportunities not otherwise possible.

Action 5.2 KTN's synthetic biology group should be expanded through further cross-disciplinary connections and engage with those companies and organisations that operate in target market applications.

In July 2015 the Dowling Review reported that public support for the innovation system is too complex. Innovate UK and KTN are already working to simplify the innovation landscape, making it easier to access information, digital tools, people and funding. In the context of this refresh, KTN will specifically address the needs for the synthetic biology community, and act as a community resource.

Action 5.3 KTN will make public resources for synthetic biology more visible and accessible by providing tools and mechanisms to allow business and stakeholders to engage with UK assets more proactively.

The SBLC seeks to represent the main stakeholder groups within the UK either directly (through its members), or indirectly (through sub-groups and representative constituencies). It oversees the implementation of the roadmap and provides independent advice to policymakers (including but not limited to BIS, UKTI, Defra, the Health & Safety Executive (HSE) and GO Science). The role of the SBLC, resources for its support and integration with its representative stakeholder groups needs to be reviewed to reflect the delivery needs of this strategic plan and the changing UK and international policy landscape.

Action 5.4 The membership and terms of reference of the SBLC should be periodically reviewed to reflect the changing needs of UK synthetic biology.

Coordination and guardianship, as managed via the SBLC and its sub-groups, is critical to maintaining momentum. But success will only come from the collective efforts of all stakeholders.

For example, the co-chair of the SBLC has engaged with his counterparts in the Industrial Biotechnology Leadership Forum (IBLF) and the Agri-Tech Leadership Council (ATLC) to develop shared messaging on the bioeconomy. More recently connections have also been made with the Chemistry Growth Partnership (CGP) and Medicines Manufacturing Industry Partnership (MMIP). Co-ordination of strategic leadership across the bioeconomy will be key to unlocking the potential of synthetic biology and the roadmap vision.

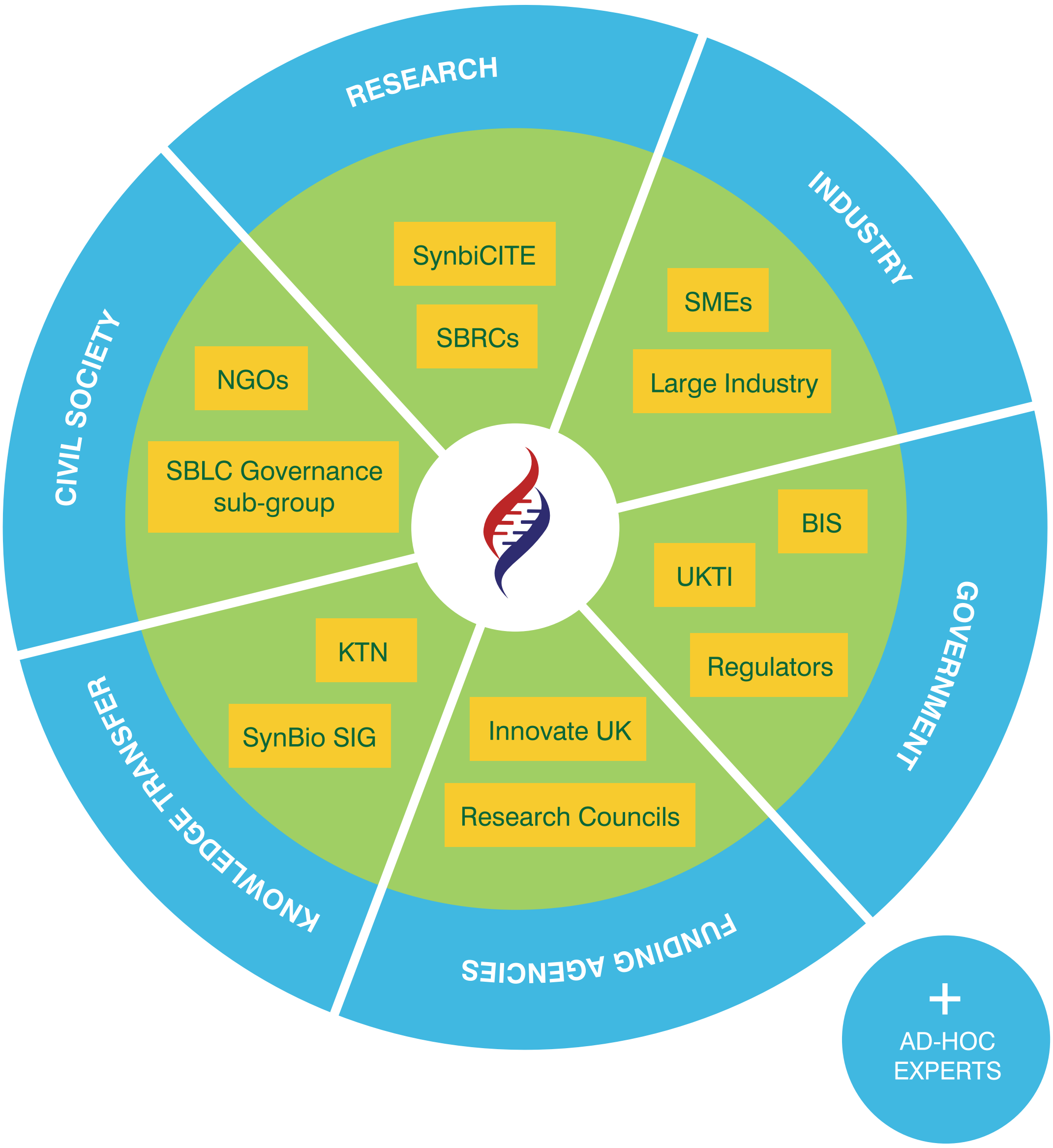

Figure 4: The UK SBLC representation (December 2015). Glossary: KTN - Knowledge Transfer Network; SynBio SIG – Synthetic Biology Special Interest Group; NGO – Non-Governmental Organisation; SBRCs – Synthetic Biology Research Centres; SynbiCITE – Synthetic Biology Commercialisation & Innovation Translation Engine; SMEs – small & medium sized enterprises; UKTI – UK Trade & Investment.

Intellectual property

Much of the Intellectual Property (IP) in synthetic biology resides in the products or specific elements of biosynthetic pathways rather than underlying tools. There is a clear need to promote exchange of biological building blocks though more open exchange. Formal standards allow the creation of reusable tools that will promote innovation. In order for these to have maximum impact in the commercial sector, there must be freedom to operate - to promote technology transfer to new businesses, and potentially explore new business models. At the same time, this must be balanced against the need for businesses to subsequently establish proprietary positions to secure investment and to build and maintain their competitive edge. The UK is already home to four of the world's top ten universities and is ranked as the best place in the world to obtain, exploit and enforce intellectual property rights by the Taylor Wessing Global IP Index.[30]

Given the ongoing rapid discovery in platform technologies and the considerable breadth of application opportunities including many as yet unimagined, the greatest overall stimulus to innovation and the long-term benefits it can ultimately deliver is likely to derive from encouraging greater open exchange at the platform technology level whilst developing approaches to technology transfer more responsive to business needs.

Many industries rely on trade secrets as a more feasible proposition than patents, considering the complexity of biological processes. Know-how is an asset that is best transferred as part of industry collaborations rather than licensing to the highest bidder. Another aspect is the increasing digitisation of biology, making data exchange rather than materials transfer the principal monetisation route. The shift from patent to the protection of digital material needs serious consideration to protect UK synthetic biology assets and investments.

SBLC representatives have already initiated and contributed to both national and international workshops[31 32], and will continue to assess whether traditional IP protection adequately meets the needs of emerging synthetic biology assets.

Action 5.6 The SBLC should continue to review, refine and act upon IP-related recommendations developed from on-going workshops and discussions.

International Partnerships

The UK synthetic biology research community is highly networked with other world-leaders in the field and has played host to major international synthetic biology events such as SB6.0, held at Imperial College in 2013, and one of the 'six academies' US, UK, China meetings in 2011. The SBLC has engaged with and advised delegations from the US, China, France and Canada, amongst others, to compare policies and strategies. This reflects the reputation the UK has generated as a world leading exponent of synthetic biology. The UK must continue to collaborate and engage to learn, share and help establish common standards, values and best practice.

Leading edge research is currently concentrated within a limited number of countries, but interest in its potential is increasingly global. Operational aspects of the technology can be distributed, and it is notable that a number of applications now being developed could deliver specific benefits within the developing world. There is a clear opportunity for the UK and international partners to collaborate to build capacity and allow synthetic biology solutions and their associated benefits to become more widely accessible. The aim should be to facilitate mutually beneficial partnerships that stimulate new global value chains, linking technological capabilities with market needs and interests.

Action 5.7 SBLC representative organisations should continue to participate in mutually beneficial engagement with key international delegations to develop (i) effective technology partnerships, (ii) policy alignments, and (iii) priorities for collaboration based on mutual needs and capabilities, generating value both in the UK and globally.

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30. *Taylor Wessing Global IP Index, http://united-kingdom.taylorwessing.com/ipindex/about.html*

31. *EU workshop on synthetic biology – IP, standards and regulatory issues, October 2013: https://connect.innovateuk.org/documents/2826135/9165366/EU%20SB%20Report%20FINAL.pdf?version=1.0*

32. *UK-US summit, October 2014: https://connect.innovateuk.org/documents/2826135/22810104/UK_US_Summit_Summary-21Jan15_FINAL.pdf?version=1.0*

Stimulating Inward Investment

The UK has very recently been ranked as the second most innovative country in the world. The Global Innovation Index (GII) has placed the UK above the USA, Singapore and Germany for the third year running, recognising the UK's standing in the field of innovation[33]. The UK possesses a healthy ecosystem for new and established business (ranked in the top 5% of countries for 'ease of doing business' – World Bank Survey 2011), supported through a firm government commitment to encouraging long-term investment, and promoting a dynamic economy[34]. However more could be done to make it even more attractive to inward investment in synthetic biology, including private investment and the location of new businesses. For example, HEIs in the UK frequently expect to take a greater share of start-up values than is typically the case in leading US academic institutions. The expectations of the HEIs and role of their technology transfer offices should be reviewed to establish if a reduction in start-up share, easier access to resources, facilitation of IP licensing, and other factors could create a more vibrant environment for start-ups. Greater attention to identifying and capturing IP from the academic research base would also add value, if combined with processes to facilitate access to UK-based companies and research, building upon the already very successful 'patent-box' process. Building on this and the recommendations from this strategic plan, the UK synthetic biology market is well placed to attract investment from both the UK and overseas.

Action 5.8 The HEI/industry/start-up interface in synthetic biology should be reviewed to determine if any barriers could be removed. In addition, UKTI should to continue to promote UK synthetic biology assets as attractive opportunities for inward investment.

Case Studies

Synthetic biology health impact for developing countries

Arsenic in drinking water is an enormous public health issue in South Asia, with more than 100 million people at risk of poisoning and death. A research consortium led by Cambridge and Edinburgh Universities, in extensive consultation with local people, government organisations and NGOs, has developed a whole cell biosensor for arsenic detection, and results can be shared via a mobile phone app.

Plants help clean up explosive-contaminated land

Pollution from explosives like TNT can pose a risk to both the environment and public health. Plants engineered by researchers at the University of York to contain the degrading abilities of certain bacteria are able to remove explosive contamination from soil and water, a more sustainable alternative to current decontamination methods that are expensive and environmental damaging.

KTN's Synthetic Biology Group

Membership of the KTN's Synthetic Biology Special Interest Group has risen to over 1,000, of which half are from academia and a third are from industry. The group is a focal point for news, events and activities pertinent to the community, and provides introductions to build consortia for collaborative projects.

__33.__ Global Innovation Index 2015 http://www.wipo.int/econ_stat/en/economics/gii/

__34.__ Fixing the foundations: creating a more prosperous nation https://www.gov.uk/government/publications/fixing-the-foundations-creating-a-more-prosperous-nation

CONCLUSION

Synthetic Biology is a rapidly advancing technology, with the capacity to generate a wide range of important and useful applications spanning the bioeconomy. In recognition of this considerable potential, 'a Synthetic Biology roadmap for the UK' was published in July 2012. The roadmap set out a vision for the sector and included a set of recommendations that were subsequently supported in full by the UK government. The main goal, consistent with government's approach to the 'Eight Great Technologies', was to give heightened attention to the accelerated translation of cutting-edge research and development into significant commercial and public benefit.

Synthetic biology has only recently emerged as a platform technology, becoming practically possible since the turn of the 21st century. It has been specifically identified in the UK for research funding only since 2006, with its first dedicated centre established at Imperial College in 2009. Consequently, relatively few of the applications coming through the 'innovation pipeline' were commercially-ready at the time of the 2012 roadmap. This provided a rare opportunity to look well ahead, to anticipate, deliberate and address issues across the entire 'eco-system' that could potentially enhance or inhibit future progress. Building a broad and networked community was identified as an essential starting point, to gather together relevant expertise, experience and interests, actively seeking to establish and share core values including responsible research and innovation. All the infrastructure initiatives recommended in the 2012 roadmap are now being implemented. Investments have expanded the network of multidisciplinary research and training centres in addition to establishing an 'Innovation and Knowledge Centre' focused on translation and commercialisation.

Since 2012, considerable progress has been made, not least in the promising flow of potential entrepreneurial applications and the formation of numerous start-up companies. This has provided highly valuable experience and many learning opportunities relevant to translation and commercial application. The SBLC has gathered information and perspectives from which a number of fresh recommendations have been drawn. By supplementing each core recommendation with a series of actions, we indicate how the intentions behind each recommendation may be realised. Whilst the long-term vision and core values set out in the 2012 roadmap remain a constant thread, the recommendations in this new strategic plan provide a reference point for the next phase.

Synthetic biology is now the subject of research and development globally, with potentially transformative opportunities and benefits for both the developed and developing world. Future success will be dependent on partnerships forged, nationally and internationally. The underpinning platform technologies and opportunities for application will continue to advance at a rapid pace. The actions in this strategic plan will inform our steps, but it will be important for the SBLC and other stakeholders to remain vigilant to fresh opportunities as they arise to respond with the agility necessary to realise the vision.

RECOMMENDATIONS

Recommendation 1: Accelerate industrialisation and commercialisation by promoting investment in, and translation of, biodesign technologies and assets to drive economic growth

Actions

1.1 KTN (together with the IKC) to lead work to match business needs and market opportunities with competitive edge technologies arising from the research base with access to a 'proof of concept' new research partnerships. In addition, KTN should build closer links with industry to generate greater 'market pull' and to encourage mentorship.

1.2 Review the emerging needs of synthetic biology businesses and encourage flexibility in planning and investment to allow new sector co-location to flourish.

1.3 Focus on investment readiness programs, build investor awareness and funding capacity and establish VC backed seed fund competitions in the UK.

1.4 Establish a competitive and developmentally tiered support fund for companies to develop synthetic biology products/processes potentially using the existing Catalyst framework or similar. Maintain its operational flexibility reflecting rapid changes in the commercial landscape and alignment with private sector investments.

1.5 Undertake a study to determine whether or not there is the need for a significantly scaled-up and world class resource investment to train and empower researchers, in academia and industry, to profit from modern robotics, data analysis and experimental design and the associated capital investment in bio-robotics required across the sector.

1.6 If required following 1.5 establish a capital investment or loan-guarantee programme, available to public and private organisations, for them to invest in bio-robotics and laboratory automation.

1.7 The synthetic biology industry should be placed at the heart of UK activities in setting and agreeing technical standards (e.g. in relation to data formats, process automation procedures and tools, and component characterisation). We should formalise links between the UK standards and metrology agencies (e.g. BSI and the NPL) and other global standards institutions (e.g. NIST).

Recommendation 2: Maximise the capability of the innovation pipeline by continuing to research and develop platform technologies that will improve manufacturing efficiencies and unlock future opportunities

Actions

2.1 Drive the ongoing development of effective platform technologies - whether bioengineered, biological or software in nature - through national and international collaborations, to aid the sustained advancement of synthetic biology and the industrial translation of research outputs.

2.2 Integrate software development as a key enabler for the development of new technologies and methodologies, as well as ensuring that all parts of the synthetic biology workflow are able to communicate effectively with each other through information infrastructures.

2.3 Advance chassis characterisation as an important component of the systematic design approach, e.g. the development of new strains for specific industrial applications – using the latest techniques in the synthetic biology toolbox.

2.4 Deploy novel mechanisms to control intracellular function through the development of smart, designed biological information and control systems.

Recommendation 3: Build an expert workforce by developing the skills required for biodesign and implementing them through education and training

Actions

3.1 The UK Research Councils should work with HEIs and others to develop further programmes that embed student training in multi-disciplinary, challenge-led environments.

3.2 A joint SBLC-learned society-educationalist working group should be established to rapidly develop a synthetic biology teaching framework and commission resources to enhance synthetic biology teaching throughout the education system.

3.3 A synthetic biology education fund should be established to enable the further development and adoption of successful synthetic biology scientific and business skills programmes (e.g. iGEM, Lean Launchpad, Biotechnology YES, RRI training) by the wider community.

3.4 Relevant scientific societies & academies and academic centres of excellence should form a working group to consider developing a Skills School provision for synthetic biology students and postdocs.

3.5 Relevant scientific societies & academies and academic centres of excellence should develop a unique continued professional development programme to encourage cross-discipline career development and the movement of people between academia and industry to facilitate maximum knowledge exchange.

3.6 Relevant Trade Associations should support the development of Apprenticeships, including Degree Apprenticeships within synthetic biology to encourage vocational technical training in synthetic biology in support of synthetic biology-utilising industries.

Recommendation 4: Develop a supportive business environment by ensuring that regulation and governance systems are proportionate and appropriate to the needs of industry and that these are aligned with the needs and desires of stakeholders

Actions

4.1 Through the SBLC and its GSG, establish a working group involving a pool of sector-specific regulators and practitioners to share experience of developing adaptive regulatory systems, to support proportionate and effective regulation.

4.2 The SBLC and its GSG should continue working with BSI to identify opportunities for standards to contribute to more adaptive regulatory systems that meet the needs of rapidly evolving industry sectors while retaining commitment to safety and efficacy.

4.3 Innovate UK to support and draw upon the relevant interests and expertise in technical standards and standard-setting within the UK to ensure that we can make an effective and well-grounded contribution to international discussions.

4.4 The SBLC and its GSG to build on recent and current initiatives on engagement and dialogue, involving representative stakeholders, to ensure that RRI is incorporated as a core value in decision making on synthetic biology, and to continue to develop appropriate standards for RRI.

4.5 The SBLC, working through relevant organisations, should support provision of balanced and accurate information on synthetic biology research and future innovative developments, particularly issues attracting strong media interest.

4.6 Academic and commercial operations in the UK should ensure that adequate security measures are in place to safeguard the storage and flow of information and materials associated with their synthetic biology programmes, regularly reviewing procedures and sharing best practice.

Recommendation 5: Build value from national and international partnerships by fully integrating the UK synthetic biology community to position UK research, industry and policy makers as partners of choice for international collaboration

Actions

5.1 Synthetic biology institutions should coordinate joint activities and projects to share best practice, benefit from the latest technological developments and build a coherent UK offer to showcase their world leading and truly cross-disciplinary capability.

5.2 KTN's synthetic biology group should be expanded through further cross-disciplinary connections and engage with those companies and organisations that operate in target market applications.

5.3 KTN will make public resources for synthetic biology more visible and accessible by providing tools and mechanisms to allow business and stakeholders to engage with UK assets more proactively.

5.4 The membership and terms of reference of the SBLC should be periodically reviewed to reflect the changing needs of UK synthetic biology.

5.5 The SBLC should continue its strategic alignment with other leadership councils and organisations to enhance coordination, efficiency and generate opportunities for innovation, particularly addressing end-users and other 'Great Technologies'.

5.6 The SBLC should continue to review, refine and act upon IP-related recommendations developed from on-going workshops and discussions.

5.7 SBLC representative organisations should continue to participate in mutually beneficial engagement with key international delegations to develop (i) effective technology partnerships, (ii) policy alignments, and (iii) priorities for collaboration based on mutual needs and capabilities, generating value both in the UK and globally.

5.8 The HEI/industry/start-up interface in synthetic biology should be reviewed to determine if any barriers could be removed. In addition, UKTI should to continue to promote UK synthetic biology assets as attractive opportunities for inward investment.

ACKNOWLEDGEMENTS

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To develop this strategic plan, the SBLC engaged with a cross section of UK synthetic biology stakeholders to garner their thoughts on how best to refresh the UK Roadmap for Synthetic Biology. During summer 2015, workshops were held in Edinburgh, Birmingham and London. Further input was encouraged through an online survey and the SBLC discussed their ideas with delegates at their annual open meeting in July.

In addition to these activities, this strategic plan has been shaped by the collective experience of the SBLC members over the last three years. In particular, the on-going commitment of the SBLC Governance Sub-Group (chaired by Prof Joyce Tait and involving SBLC members Prof Janet Bainbridge, Prof Lionel Clarke, Dr Tim Fell, Alastair Kent, and Prof Richard Kitney, plus non-SBLC members Linda Brooks, Martin Cannell, Matt Goode, Julian Hitchcock, Sir Roland Jackson, Michael Paton, Prof Nick Pidgeon, and Hilary Sutcliffe). Further engagement with the academic community is managed via the SBLC Science & Technology Sub-Group (chaired by Prof Richard Kitney and comprising SBLC member Prof Dale Sanders plus non-SBLC members Prof Paul Freemont, Prof Jim Haseloff, Prof John McCarthy, Prof Nigel Minton, Prof Anne Osbourn, Prof Antonis Papachristodoulou, Prof Susan Rosser, Prof Nigel Scrutton, Prof John Ward and Prof Dek Woolfson).

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The recommendations and associated actions captured here reflect priorities in the UK at the current state of development. Recognising the dynamic nature of the field, stakeholder involvement and deliberation will continue to play an on-going and integral role in shaping future UK synthetic biology developments.

The recommendations reflect views gathered from the stakeholder community as assimilated and represented by the SBLC and as such do not necessarily represent UK government policy.

Synthetic Biology
Leadership Council

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