Developing a Strategy for Industrial Biotechnology and Bioenergy in the UK

Prepared for 4 BBSRC Networks in Industrial Biotechnology and Bioenergy (BIOCATNET, C1Net, CBMNet, and P2P), and led by the Crossing Biological Membranes Network (CBMNet), University of Sheffield

Landscape Review Report

October 2017

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GLOSSARY

ASHE: Annual Survey of Hours and Earnings
BAP: Biotechnology Action Programme
BBSRC: Biotechnology and Biological Sciences Research Council
BDC: Biorenewables Development Centre
BEIS: Department for Business, Energy & Industrial Strategy
BEP: Biomolecular Engineering Programme
BIA: Bio Industry Association
BIV: Business Innovation Vouchers
BRIC: BBSRC Bioprocessing Research Industry Club
BRIDGE: Biotechnology Research for Innovation, Development and Growth in Europe
BSBec: BBSRC Sustainable Bioenergy Centre
CGP: Chemistry Growth Partnership
CPI: Centre for Process Innovation
DMFC: Direct Methanol Fuel Cell
DSP: Downstream Processing
EBRI: European Bioenergy Research Institute
EIA: US Energy Information Administration
EMA: European Medicines Agency
EPSRC: Engineering and Physical Sciences Research Council
ERDF: European Regional Development Fund
FDA: Food and Drug Administration (US)
FET: Future and Emergency Technology
FTE: Full-time equivalent
GDP: Gross Domestic Product
GVA: Gross Value Added
HE: Higher Education
HEFCE: Higher Education Funding Council for England
HEIF: Higher Education Innovation Fund
HVM: High Value Manufacturing
IBBE: Industrial Biotechnology and Bioenergy
IB-IGT: Industrial Biotechnology Innovation and Growth Team
IBioIC: The Industrial Biotechnology Innovation Centre
IBLF: Industrial Biotechnology Leaders Forum
IBSIG: Industrial Biotech Special Interest Group
IBTI: Integrated Biorefining Research and Technology Club
ICT: Information and Communications Technology
IKC: Innovation and Knowledge Centre
IMI: Innovative Medicines Initiative
IP: Intellectual property
IPC: International Patent Classification
IPO: Initial Public Offering
KBBE: Knowledge Based Bio-Economy
KTN: Knowledge Transfer Network
LEAP: Leadership Excellence Accelerator Programme
LEIT: Leadership in enabling and industrial technologies
LEP: Local Enterprise Partnership
LQ: Location Quotient
LULUCF: Land use, land-use change and forestry
MGR-Grammar: Massive Reverse Genomics to Decipher Gene Regulatory Grammar
NIBB: Networks in Industrial Biotechnology and Bioenergy. These include:
ADNet: Anaerobic Digestion Network
BIOCATNET: Network in Biocatalyst Discovery, Development and Scale-Up
BioProNET: Bioprocessing Network
C1NET: Chemicals from C1 Gas
CBMNet: Crossing biological membranes
FoodWasteNet: Food Processing Waste and By-Products Utilisation Network
HVCfP: High Value Chemicals from Plants Network
IBCarb: Glycoscience Tools for Biotechnology and Bioenergy
LBNet: Lignocellulosic Biorefinery Network
Metals in Biology: The elements of Biotechnology and Bioenergy
NPRONET: Natural Products Discovery and Bioengineering Network
P2P: A Network of Integrated Technologies: Plants to Products
PHYCONET: unlocking the IB potential of microalgae
NMBP: Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing
NNFCC: National Non-Food Crops Centre
PoC: Proof of concept
PROSEQO: Protein Sequencing Using Optical Single Molecule Real-Time
RECORD-IT: Reservoir Computing with Real-time Data for future Information Technology
SB: Synthetic Biology
SBLC: Synthetic Biology Leadership Council
SBRI: Small Business Research Initiative
SIC: Standard Industrial Classification
SIG: Special Interest Group
sLoLas: BBSRC Strategic Longer and Larger Grants
STAR-COLIBRI: Strategic Targets for 2020 - Collaboration Initiative on Biorefineries
STEM: Science, Technology, Engineering and Mathematics
TRL: Technology Readiness Level
TSB: Technology Strategy Board (Now Innovate UK)
ZWS: Zero Waste Scotland

CONTENTS

EXECUTIVE SUMMARY

In March 2017 RSM was commissioned by a consortium of four NIBB from four UK universities (CBMNet, BIOCATNET, P2P, C1Net) led by the University of Sheffield's 'Crossing Biological Membranes Network (CBMNet)' to produce this report on the UK's Industrial Biotechnology Landscape.

The findings and recommendations provided in this report are based on: an extensive desk based review of relevant strategy and policy documentation; in-depth interviews with 50 strategic industrial biotechnology stakeholders; analysis of secondary datasets including company and investment data; an online survey yielding 160 responses; in-depth case study research; and group consultation with leading academics.

The potential for industrial biotechnology

Industrial biotechnology is the use of biological resources for producing and processing materials, chemicals and energy. The breadth of potential products and markets to which industrial biotechnology can be applied is one of its greatest strengths, but also arguably one of the key reasons why Industrial Biotechnology is not adequately referenced in current UK government policy and / or investment. During the production of this report, a government strategy on the UK Bioeconomy was being prepared and this report and its recommendations are intended to be complementary and supportive of that new Strategy.

Industrial biotechnology will shape the UK's future role and standing in major international industrial markets (currently comprising c.£34bn revenue). More significantly, industrial biotechnology is recognised internationally as the key enabling technology that can help address major societal challenges through new methods of manufacturing consumer products, new materials (such as industrial composites and biodegradable plastics) and sustainable energy in the form of liquid and gaseous biofuels, while simultaneously reducing greenhouse gas emissions and making more effective use of agricultural, food and municipal wastes.

The breadth of IBBE's industrial application, coupled with the UK's excellent scientific research base means that there are fewer industrial areas better placed to deliver against the central thrust of the Industrial Strategy:

> *"Unlike in the past, industrial strategy must be about creating the right conditions for new and growing enterprise to thrive, not protecting the position of incumbents.*
>
> *A modern British industrial strategy must make this country a fertile ground for new businesses and new industries which will challenge and in some cases, displace the companies and industries of today."*

Rt Hon Greg Clark MP, Secretary of State for Business, Energy and Industrial Strategy

Industrial biotechnology's current and future economic contribution

This report updates and enhances previous reports on the contribution of Industrial Biotechnology to the UK economy and shows there are already 1,838 relevant UK biotechnology businesses, employing over 14,000 people, generating £3.7bn in revenue, and contributing £1.2bn in Gross Value Added. Employment growth in industrial biotechnology has significantly outpaced national averages, increasing by over 10% per annum between 2014 and 2016. Median earnings in industrial biotechnology markets are £20,000 above the national average, at c.£48,000.

The UK has particular strength in high growth and emerging industrial biotechnology markets, including in the manufacture of high value, low volume chemicals and the manufacture of recombinant biologics using new technologies from the UK's academic leadership in genomic, systems and synthetic biology, partnered with leading multinational companies and UK-based SMEs.

Addressing barriers to realising industrial biotechnology's potential

However, industrial biotechnology suffers from volatile prices in traditional markets and this has been particularly hard felt in recent years due to a collapse in oil prices and new gas reserves available due to fracking.

Perhaps now more than ever, to keep pace with international competitors, Industrial Biotechnology requires the UK government to have foresight, to trust in the UK's industrial and academic expertise, and to demonstrate its commitment to industrial biotechnology on the global stage.

Recommendations

The industrial biotechnology community cannot make these contributions unless it is adequately supported by the UK government in terms of both specific policy and investment. To that end, this review recommends that:

1. BEIS identifies a long-term plan for Industrial Biotechnology that provides clarity regarding future policy direction and government investment, particularly in light of the decision to leave the EU.
2. The core membership of the Industrial Biotechnology Leadership Forum be expanded to include at least one strong advocate from the academic community.
3. The IB Catalyst be reinstated as a priority, providing at least £20m spend on new research projects, with a call for applications initiated in Q2 2018.
4. Provision is also made for funding a small number of larger scale projects (c.£10 – £50m) via Catapult Centres, by joint government / industry initiatives, or directly by BEIS.
5. BEIS and UKRI explore the potential of modular manufacturing as a method of 'scaling out' industrial biotechnology processes and products on a regional basis.
6. UK Research and Innovation find ways that allow SMEs to be better financially supported to access existing UK scale-up facilities (e.g. at the Centre for Process Innovation).
7. The existing policy and regulatory frameworks are reviewed and simplified where appropriate, without compromising safety and security, and the UK communicates internationally that its approach to regulation and standards is focused on informed risk management.
8. Financial and advisory support be put in place to help businesses, especially start-ups and SMEs, to navigate efficiently regulatory requirements to facilitate innovation.

1.INTRODUCTION

In March 2017 RSM was commissioned by a consortium of four NIBB[1] from four UK universities led by the University of Sheffield's 'Crossing Biological Membranes Network (CBMNet)' to produce this report on the UK's Industrial Biotechnology Landscape.

RSM would like to thank the study Steering Group and Advisory Panel for their advice and guidance throughout.

Name	Organisation
Steering Group	
Dr Jen Vanderhoven	CBMNet Manager, The University of Sheffield
Prof Jeff Green	CBMNet Director, The University of Sheffield
Dr Mark Corbett	BIOCATNET Manager, The University of Manchester
Dr Kirstin Covington	P2P Manager, The University of Bath
Prof Iain Donnison	Aberystwyth University
Prof David Fell	C1Net Co-Director, Oxford Brookes University
Dr Colin Miles	BBRSC (Head of Strategy, Industrial Biotechnology and Bioenergy)
Dr Yvonne Armitage	Knowledge Transfer Network
Prof Rodney Townsend	SusChem and Royal Society of Chemistry
Advisory Panel	
Prof Iain Hunter	University of Strathclyde
Dr Michael Hopkins	University of Sussex
Prof Nilay Shah	Imperial College London
Prof Gary Leeke	Cranfield University

The findings and recommendations provided in this report are based on an extensive desk-based review of relevant strategy and policy documentation; in-depth interviews with 50 strategic industrial biotechnology stakeholders; analysis of secondary datasets including company and investment data; an online survey yielding 160 responses; in-depth case study research; and group consultation with leading academics.

[1] CBMNet (BB/L013703/1), C1Net (BB/L013800/1), BIOCATNET (BB/L013649/1) and P2P (BB/L013819/1)

1.1 Scope of the landscape review

The scope of the landscape review comprised nine components as set out in the individual terms of reference, requiring a combination of primary and secondary qualitative and quantitative research. In some cases, individual components of the review overlap, and the report is therefore structured against the terms of reference as follows:

1. IBBE in the UK to date: a concise, critical synopsis of existing reports on Industrial Biotechnology and Bioenergy (IBBE) in the UK, including identification of any limitations to existing studies;

2. The current UK IBBE landscape: a detailed analysis of the current UK IBBE landscape, including economic contribution, strengths, weaknesses, areas of potential competitive advantage, and emerging technologies and trends;

3. IBBE Investment and Commercialisation: an assessment of commercialisation within IBBE including:

- Analysis of the current IBBE investment landscape;
- A critical evaluation of capacity to commercialise research;
- Identification of good practice in translation of research into commercial application via case studies;
- Identification and assessment of options for a forward looking IBBE translation framework; and

4. International IBBE comparisons: benchmarking of IBBE in the UK against top performing competitor countries;

5. Future direction for IBBE in the UK: an evidence-based road-map and policy recommendations for exploiting the UK's existing IBBE strengths and capacity.

1.2 Methodology

The review methodology uses a mixed method quantitative and qualitative approach, including the following key components:

- Desk based review of existing definitional and economic literature, including review of more than 200 sources;
- In-depth interviews with 50 strategic stakeholders in the UK IBBE sector conducted in April and May 2017, including national policy representatives, industry and academic leaders;
- Analysis of secondary datasets including economic statistics, private sector investment data and intellectual property statistics;
- An online survey of industry representatives conducted in June 2017 yielding 160 responses; and
- Group consultation with the strategic stakeholder group responsible for commissioning the review.

The review has been supported at every stage by a panel of senior academic experts spanning the three core IBBE sub-sectors ('Red', 'Green' and 'White' industrial biotechnology).

1.3 Defining IBBE

There are several definitions of IBBE within existing literature. Following a review of commonly referenced definitions (set out in Table 1.1 below), and based on advice from the academic panel supporting the landscape review, the BBSRC definition has been deemed most appropriate as the basis of the review.

Table 1.1 – Summary of commonly referenced IBBE definitions

Source:	Definitions of IBBE in the UK
Department for Business, Energy and Industrial Strategy (BEIS)	[Bio-transformative activities] which add value through the inclusion of a physically or chemically transformative process that involves either as outputs or as processors, biological resources (the tissues, cells, genes or enzymes of living or formerly living things).
Capital Economics (2015)[2]	Any activity that uses a biotechnological process to produce and process materials, chemicals and energy.
Industrial Biotechnology Innovation Centre (IBioIC)	Industrial biotechnology (IB) is best described as an enabling technology that uses biological substances, systems and processes, to produce materials, chemicals and energy.
OECD	"The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services'".
BBSRC	**Industrial Biotechnology is the use of biological resources for producing and processing materials, chemicals (including pharmaceutical precursors and biopharmaceuticals) and energy. These resources include plants, algae, marine life, fungi and micro-organisms.**

1.3.1 The value and economic state of potential future UK IBBE markets

The breadth of potential products and markets to which industrial biotechnology can be applied is one of its greatest strengths. However, the breadth of its potential is also arguably one of the key reasons why IBBE specifically, is not currently adequately referenced in, or supported by UK government policy, and / or investment.   There is no current, dedicated plan for progressing IBBE in the UK, and related strategies and plans such as the Clean Growth Strategy, the Chemicals Growth Strategy, and the Industrial Strategy do not currently provide detailed policy or investment mechanisms that will help IBBE realise its potential for the future UK economy.

[2] Capital Economics (2015) Biotech Britain: An assessment of the impact of Industrial Biotechnology and Bioenergy on the UK economy, p. 8

- IBBE can provide alternative processes and products that are highly relevant for manufacturing, agriculture and energy production.
- It is an enabling technology that has strategic importance across UK government departments and agencies including (primarily) BEIS, DEFRA, DfT, and HEFCE.
- IBBE can help deliver the next generation of several significant industrial markets including (but not necessarily limited to) personal care, textiles, detergents and animal nutrition, not to mention food and energy.
- Using a conservative estimate, the current value by revenue of UK industrial markets for which IBBE presents a future alternative can be estimated as totalling c.£34bn (excluding pharmaceutical markets).[3]
- Major UK businesses operating in these markets (i.e. those that should eventually seek to diversify into bio-based alternatives) include Unilever, Proctor & Gamble, BOC, Koch Fertiliser, Nufarm UK, Syngenta, and ExxonMobil Chemical Limited and Croda[4] (to name a few).

Figure 1.1 overleaf shows annual revenues by industrial markets. Growth in these established markets is either low, or negative, with the majority exhibiting compound annual growth rates (CAGRs) for the past 5 years of between zero and 2 percent.[5] The maturity of these markets means that future growth is likely to remain low, with an average CAGR of just 0.2% to 2022.

The future of British industry is, as highlighted in the Industrial Strategy, therefore dependent on market disruption via enabling technologies such as IBBE. There is evidence to suggest that bio-based markets are gaining ground, for example the market for bio-surfactants (inputs into soap and detergent, personal care products and industrial and institutional cleaners) grew at a CAGR of 3% between 2008 and 2013[6], and is expected to grow at a rate of 4.4% up to 2023.[7] Robust estimates of the value of the global industrial biotechnology market in 2025 range from £150bn to £360bn.[8]

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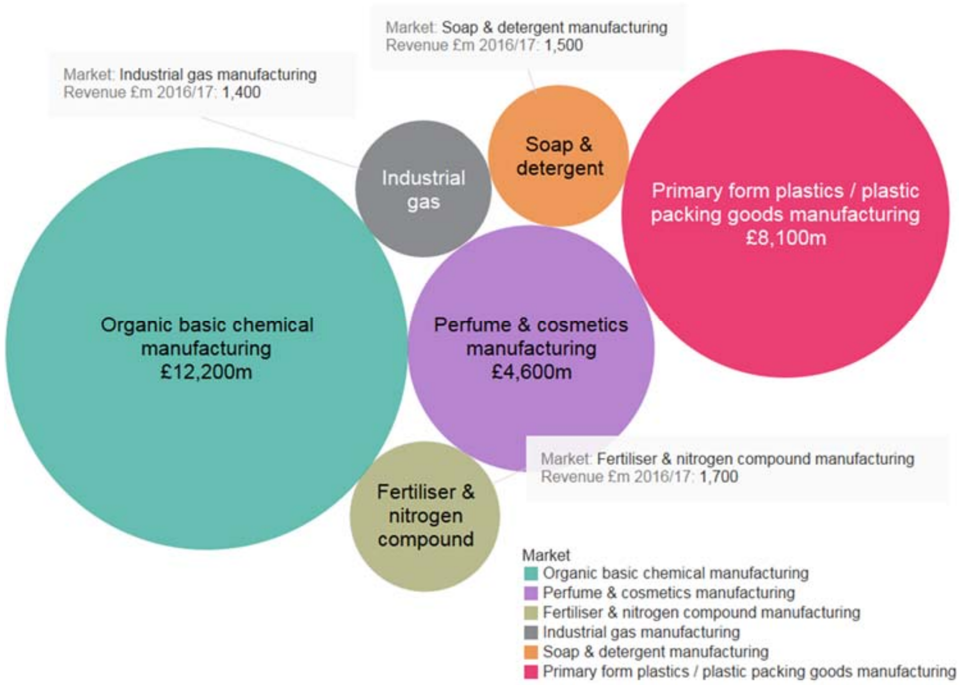
[3] Figure includes estimates of revenue in 2016/17 for: perfume and cosmetics manufacturing, soap and detergent manufacturing, dye & pigment manufacturing, industrial gas manufacturing, organic and inorganic basic chemical manufacturing, fertiliser & nitrogen compound manufacturing, pesticide and other agrochemical manufacturing, and primary form plastics and plastic packing goods manufacturing. Note that Figure 1.1 is for illustrative purposes and does not include all of these standard industrial classification groups.
[4] See https://www.croda.com/en-gb/about-us/corporate-animation
[5] With the exception of inorganic basic chemical manufacturing which has shown stronger growth at 3.6%.
[6] Bio-TIC, Bio-based Surfactants Market Report, http://mig.www.industrialbiotech-europe.eu/new/wp-content/uploads/2014/07/Biosurfactant-Summary_final.pdf
[7] GM Insights, 2016
[8] Life Sciences Scotland and Chemical Sciences Scotland, (2013): *"National Plan for Industrial Biotechnology"*, Scottish Enterprise

Figure 1.1 – Value of current markets for which IBBE presents future supply chain



Source: Industrial Business Intelligence Service (IBISWorld), RSM

1.3.2 Global focus on IBBE

Section 5 of this report looks in detail at IBBE policy, activity and investment in several other countries within and outside the EU. What is clear from the review is that the UK's competitors are investing in IBBE, and that there is therefore a significant risk of the UK losing ground in an area that holds such potential for both the future of UK industry, and major societal challenges.

There are clear examples of other nations investing in, and backing IBBE globally, including key IBBE competitor nations.

Within the UK, the Scottish National Plan for Industrial Biotechnology sets out an expectation to grow the sector almost four-fold to £900m by 2025, IBioIC.

In the Netherlands, there is evidence to suggest that a cluster-based regional approach is successfully supporting IBBE, backed by large anchor firms in the chemicals sector.

In Germany, IBBE is at the core of the national Energiewende (Energy Transition) plan to move towards a low-carbon sustainable energy future.

The Flemish government has recently finalised a roadmap for industrial biotechnology as a Key Enabling Technology. The report lists a series of policy recommendations which will serve as a basis for the establishment of a regional industrial biotechnology strategy.

Beyond the EU, there are also other examples of good practice for the UK to consider. Malaysia is making concerted efforts to attract growth in the IBBE sector through not only indigenous firms, but also through a competitive tax and regulatory environment to attract FDI. Further, whilst nations such as Brazil take a different approach to IBBE (focused on large volume, lower value production), there will be clear scope for international exchange of ideas, collaboration, and commercial opportunities for the UK.

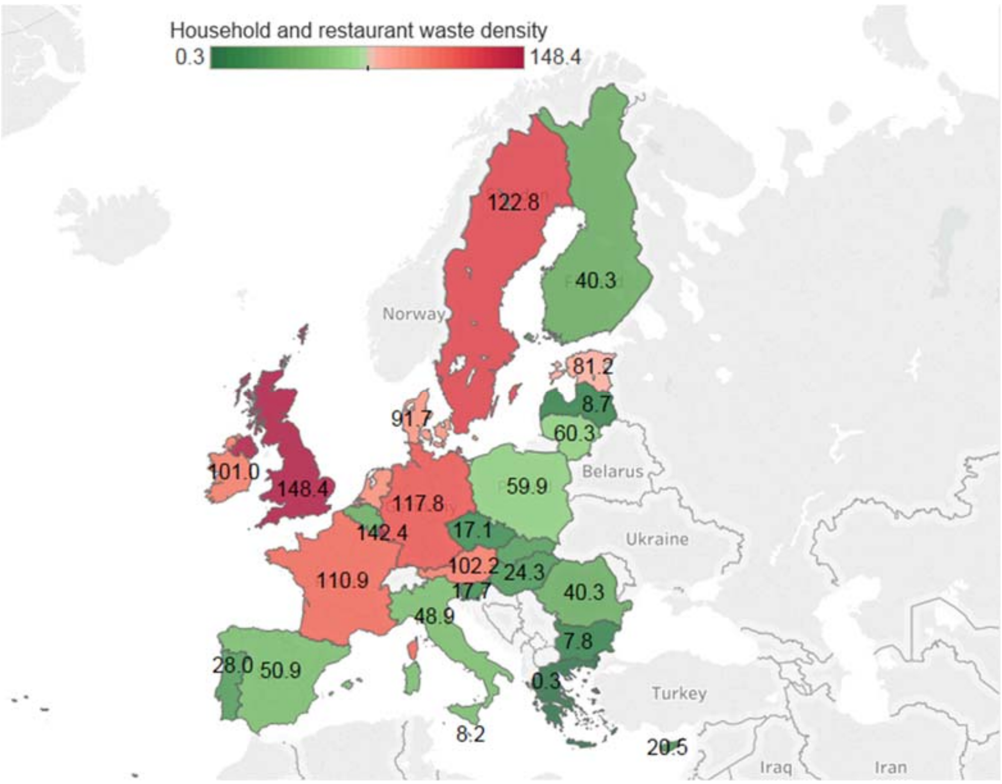
1.3.3 IBBE's role in addressing major societal challenges

So far, this introduction has highlighted the economic potential of IBBE, and shown that competitor nations are investing in specific IBBE policy. Over and above the potential benefits for economic growth and global competition, IBBE will be the source of processes and products that contribute to addressing major societal challenges including addressing food waste, producing sustainable energy, and reducing carbon emissions.

Food waste

The UK produces one of the highest densities of household and restaurant waste in Europe, at just under 150 kilograms per head – considerably higher than the major EU nations, as illustrated in Figure 1.2 below.

Figure 1.2 – Household and restaurant food waste density



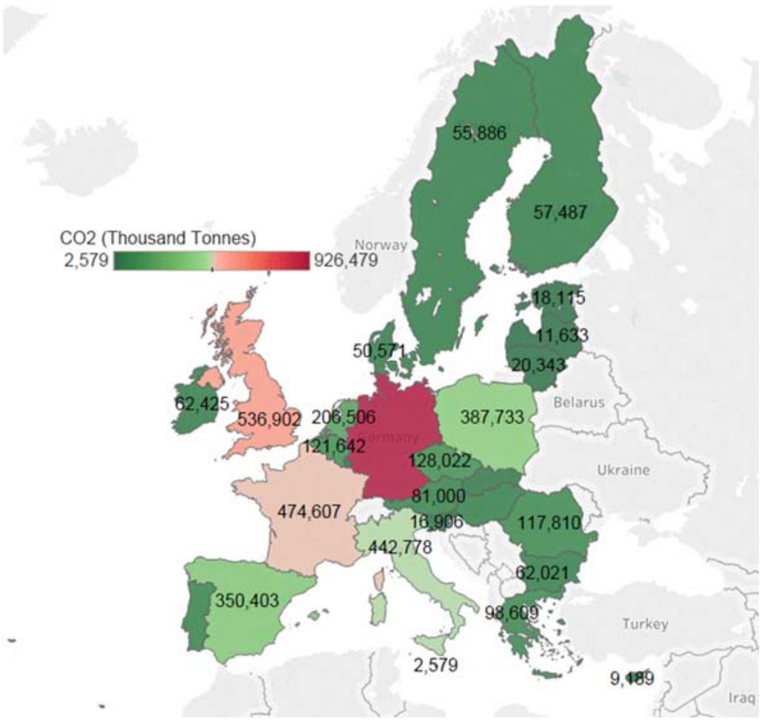
Source: European Commission / Bio-intelligence Service, 2010

IBBE can improve productivity of food waste and by-products by, for example, using it to produce renewable chemicals and bio-based plastics. It also has the potential to reduce food waste by, for example, increasing the shelf-life of perishable products.

Sustainable energy and carbon emissions

The UK is one of 195 countries that signed up to the Paris Agreement on Climate Change (COP21) and is expected to *"vigorously pursue the measures required to deliver on existing UK commitments"* by *"publishing a robust plan to meet the UK carbon budgets, and deliver policies in line with that plan"*.[9] The UK's long-term target is a reduction in greenhouse gas emissions of at least 80% by 2050. In 2015, at over 500 million tonnes, the UK produced the second highest volume of CO_2 of any European country.

Figure 1.3 – CO_2 emissions, thousand tonnes (2015)



Source: Eurostat CO_2 Emissions by Source Sector, 2015

In addition to significant food waste and relatively high CO_2 emissions, since 2004 the UK has become increasingly reliant on foreign energy imports. Industrial biotechnology and bioenergy, together with other renewable sources such as wind and hydro power, will become increasingly important as the UK moves towards targeted reductions in greenhouse gas emissions under the Paris Climate Agreement, and lower dependency on energy imports. Industrial biotechnology represents one of the most significant mechanisms for saving energy and significantly reducing CO_2 emissions by using enzymes and micro-organisms to make biobased plastics and chemical products from renewable resources.[10]

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[9] UK Committee on Climate Change: https://www.theccc.org.uk/wp-content/uploads/2016/10/UK-climate-action-following-the-Paris-Agreement-Committee-on-Climate-Change-October-2016.pdf

[10] OECD Directorate for Science, Technology and Industry (2011), *"Industrial Biotechnology and Climate Change: Challenges and Opportunities"*, OECD.

2 IBBE IN THE UK TO DATE

This chapter provides a synopsis of government publications, academic research, industry analysis and 'grey literature' on IBBE in the United Kingdom produced within the past five years. It summarises findings from an extensive review of existing literature to provide relevant IBBE sector context including relevant European, national and regional policy and funding context, and existing estimates of the size and scale of the UK IBBE sector;

It also highlights, where appropriate, the challenges associated with the existing evidence base and any gaps in the existing evidence. Subsequently, Chapters 3 and 4 provide updated estimates regarding the size and scale of the sector, and investment and commercialisation respectively.

2.1 European, national and regional policy

2.1.1 European policy[11]

European policy on biotechnology was formed in the mid-1970's, leading to the first programme on biotechnology that ran between 1982 and 1986 (the Biomolecular Engineering Programme, BEP). Subsequent programmes saw sustained and increasing investment in biotechnology via the Biotechnology Action Programme (BAP, 1985 - 1990), BRIDGE (1990 – 1993) and the Biotech Programmes (BIOTECH I and II, 1993 – 1998).

The first European Commission Strategy on Biotechnology was produced in 2002 (c.20 years after initial European investment in Biotech programmes). Framework Programme 6 (FP6, 2002 – 2006) was almost exclusively focused on Biotechnology for health, with c.€600m devoted to the area of applied genomics and biotechnology for health, and FP7 (2007 – 2013) has contributed a further €1bn in biotechnology for health via the Innovative Medicines Initiative (IMI). The UK has particularly benefited from IMI, receiving 28% of total IMI funding, €302.8 million, which is the largest amount received by any country.

More recently, biotechnology has been framed in Europe as the core of the knowledge based bioeconomy (KBBE) in which technical scientific biotech expertise and industry leadership are to act together to further innovation. The Europe 2020 Strategy sets out ambitious goals in the areas of employment, innovation, education, poverty reduction and climate / energy, some of which have direct consequences for biotechnology research and innovation. Of specific relevance are the targets:

- to reduce greenhouse gas emissions by 20% of 1990 levels;
- to generate 20% of energy from renewable sources; and
- to deliver a 20% increase in energy efficiency.

The KBBE concept (a synthesis of basic science and industrial application) was initiated in FP7, and was developed further under Horizon 2020 (2014 – 2020) – the financial instrument implementing the Innovation Union.[12]

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[11] Historic content drawn from Aguilar., A. et al "Thirty years of European biotechnology programmes: from biomolecular engineering to the bioeconomy", 2012, Elsevier. Recent policy references drawn from RSM desk review.

[12] The EU strategy to create an innovation-friendly environment – see http://ec.europa.eu/research/innovation-

New EU policy clearly recognises the need for transition to optimal and renewable use of biological resources and sustainable primary production and processing, as well as the importance of biotechnology as a Key Enabling Technology in achieving that transition.

Under Horizon 2020 the knowledge based component of KBBE is addressed under *Part 1: Priority Excellent Science* and the bioeconomy component is addressed under *Part 2: Industrial Leadership.*[13] Biotechnology is also viewed as a Future and Emerging Technology (FET)[14] in addressing the societal challenge of 'Food Security, Sustainable Agriculture and Forestry, Marine Research and the Bioeconomy'.

The specific objectives of biotechnology research and innovation under the industrial leadership component of Horizon 2020 are:

- To develop competitive, sustainable, safe and innovative industrial products and processes; and
- To contribute as an innovation driver in many European sectors including agriculture, forestry, food, energy, chemical and health, as well as the wider bioeconomy.

The 'Excellent Science' component of Horizon 2020 has supported at least eight projects that seek to advance state of the art applications for biotechnology. The focus of these projects, cost, and involvement from UK entities is summarised in Table 2.1 below.

Table 2.1 – H2020 Biotechnology FET Investments

FET Title	Summary Description	Total Public Investment*	UK involvement
AMECRYS	• Revolutionising the manufacture of biopharmaceuticals with innovative membrane crystallization technology.	€3.5m	• Imperial College London • University of Strathclyde • Centre for Process Innovation Ltd. • Fujifilm Diosynth Ltd.
Future-Agriculture	• Efficient metabolic bypass for photorespiration in plants which leads to the loss of CO_2 and consequently to reduced growth yield.	€4.9m	• Imperial College London

union/index_en.cfm for further detail.

[13] European Commission. Proposal for a regulation of the European Parliament and of the Council establishing horizon 2020 – The Framework Programme for Research and Innovation (2014–2020). COM(2011) 809 final. Brussels: European Commission; 2011.

[14] FET actions are expected to initiate radically new lines of technology through unexplored collaborations between advanced multidisciplinary science and cutting-edge engineering.

* Rounded to the nearest €100,000

Human Brain Project	• Cutting-edge ICT-based scientific research infrastructure, that will permit scientific and industrial researchers to advance our knowledge in the fields of neuroscience, computing and brain-related medicine.	€89m	• 17 UK Universities • Medical Research Council
Mara	• Aims to develop cost-effective, autonomous DNA sensors and "DNA origami"-based molecular robots for the detection and destruction of cells.	€4m	• Imperial College London • Apta Biosciences Limited
MGR-Grammar	• Leverage Synthetic Biology with cutting-edge DNA synthesis technologies and high-throughput analysis to generate new types of biological datasets that systematically explore all possible regulatory landscapes rather than just the naturally occurring regulatory sequences.	€4m	• Impsara Limited • Genome Research Limited
PROSEQO	• Novel technologies which will substantially advance protein and DNA sequencing, which eventually hopes to radically transform patient treatment, enabling precise monitoring of disease response to therapeutics at the molecular level.	€2.9m	• No UK involvement
RECORD-IT	• Seeks to develop an intelligent biocompatible sensing device which detects complex behavioural changes in ion concentrations.	€4.2m	• No UK involvement
SYMBIOTIC	• Autonomous electrochemical biosensors hosting synergistically the bio-receptor element inside a passive direct methanol fuel cell (DMFC).	€3.3m	• Imperial College London

Source: EU FET Biotechnology Projects[15]

[15] http://ec.europa.eu/programmes/horizon2020/en/news/h2020-fet-projects-biotechnologies

The 2018 – 2020 work programme is to be adopted and published in late 2017. The 'foresight' work that supported the strategic work planning process identified Synthetic Biology as an important emerging trend, and highlighted biotechnology as the '*next wave of disrupting technologies'* and as one of eight issues *'deserving serious consideration under the programming cycle* [given its] *impact on society in the coming decades'*. The Foresight report specifically describes;

> *"Biotechnology (and preference for certain patterns of diets) will affect industrial processes, biofuels, agriculture and animal breeding, and transform the food chain, waste treatment and environmental remediation. Abounding with radical opportunities, biotechnology is very likely to form the new wave of disruptive technologies."*[16]

The Foresight report highlights transformative opportunities using biotechnology in medicine (e.g. enhancement of human cells / animal breeding for supply of organs to humans); in food (e.g. introduction of entirely new genes to animal feeds, crops and livestock); and in energy (e.g. bio-engineering of bacterial, algal or plant cells to photosynthesize in useful ways). Biotechnology is referenced in various parts of the 2018 – 2020 work programme, including LEIT Nanotechnologies, Advanced Materials, Advanced Manufacturing & Processing, Biotechnology (NMBP)[17] with relevant strategic priorities including: Industrial Solution Revolution; Decarbonising European Industry and Industry in the Circular Economy.

The Bio-Based Industries Public Private Partnership (BBI-PPP) is a further example of European investment. It is a partnership between the EU and the Bio-based Industries Consortium (BIC), operating under Horizon 2020. It is responsible for €3.7bn of investment in bio-based innovation from 2014-2020 comprising €975m of EU Horizon 2020 funds and €2.7bn of private investment. The specific objectives of the partnership are to[18];

- Demonstrate technologies that enable new chemical building blocks, new materials, and new consumer products from European biomass, which replace the need for fossil-based inputs;
- Develop business models that integrate economic actors along the value chain from supply of biomass to biorefinery plants to consumers of bio-based materials, chemicals and fuels, including through creating new cross-sector interconnections and supporting cross-industry clusters; and
- Set-up flagship biorefinery plants that deploy the technologies and business models for bio-based materials, chemicals and fuels and demonstrate cost and performance improvements to levels that are competitive with fossil-based alternatives.

The role and importance of biotechnology in addressing societal challenges and advancing scientific boundaries is very clear in current EU policy. Through Horizon 2020, the UK has played a substantial role in flagship biotechnology FET projects. However, as set out in Chapters 4 and 6, the UK IBBE landscape requires further assurance regarding the level of priority and funding assigned, which will be critical if the UK is to take advantage of the 'transformative opportunities' that will be driven by biotechnology.

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[16] EC "Strategic Foresight: Towards the 3rd Strategic Programme of Horizon 2020", DG Research & Innovation, 2015.
[17] Leadership in Enabling and Industrial Technologies (LEIT)
[18] https://www.bbi-europe.eu/about/objectives

2.1.2 National policy

There is no formal national policy or strategy document dedicated solely to Industrial Biotechnology in the UK. However, there are associated national strategies and policies that have contributed to shaping the IBBE sector and BEIS has been proactive in its call for evidence for the development of a UK Bioeconomy Strategy (December 2016).

There has been some past emphasis on biotechnology from the UK Government. The UK Government founded Celltech in 1980 to begin exploring biotechnology applications. It sold its biologics manufacturing arm to Lonza when it became increasingly focused on drug development. The former Department of Trade and Industry (now BEIS) sponsored efforts such as a protein engineering club in the 1980s. Through its LINK programmes, it supported industrial biotech projects between academia and industry at a consistent but low level from the late 1980s, with programmes in biochemical engineering, cell engineering, biocatalysis, and analytical biotechnology.[19]

Much of the push for IBBE development in the UK has come directly from the sector and its research councils (BBSRC and EPSRC) and Innovate UK (formerly TSB). For example, the Industrial Biotechnology Innovation & Growth Team (IB-IGT)'s '*Maximising UK Opportunities from Industrial Biotechnology in a Low Carbon Economy* report (2009) was a catalyst for action spanning 21 recommendations to Government and helped to establish the Industrial Biotechnology Leadership Forum (IBLF), and support funding for demonstrator infrastructure and skills. The IBLF has strived to drive the case for a strong commercial industrial pull alongside highlighting a corresponding push from the science and technology base since its establishment. BBSRC have heavily supported the IBLF through the provision of funding (together with Innovate UK and EPSRC to a lesser extent).

In 2010, BBSRC confirmed Industrial Biotechnology and Bioenergy as one of its strategic priorities within the '*2010 – 2015 Age of Bioscience Strategic Plan'*. This plan aimed to invest in and develop the UK research base, encourage user interactions and facilitate interactions that meet societal needs. Between 2011-2015, many supporting investments were made within the IBBE sector including: development of the National IB Facility in 2011[20], development of the IB Special Interest Group (IBSIG) and provision of direct support for industrial biotechnology businesses (c.£10m) by Innovate UK (formerly the Technology Strategy Board TSB) between 2010 and 2013. This included the Biorenewables Development Centre at York University[21], BEACON in Wales in 2012[22], and

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[19] Owen, G., and Hopkins, M. (2016): "Science, the State and the City – Britain's struggle for success in biotechnology." Oxford University Press.

[20] Situated at the Centre for Process Innovation the National IB Facility facilitates development, testing, trial and scale up of biotech products and processes.

[21] Originally funded by BIS (£2.5m), the European Regional Development Fund (ERDF) and the University in 2012. The BDC integrates modern genetics with green chemistry and processing techniques to create renewable chemicals and materials. Open-access facilities bridge the gap between the laboratory and industry, providing companies and academia with a way to test, develop and scale up biorefining processes.

[22] Funded (£10.6m) via the European Regional Development Fund Convergence Programme for West Wales and the Valleys. BEACON is led by Aberystwyth University in collaboration with Bangor and Swansea Universities and focusses on research into the production of fuels from energy crops (Aberystwyth), research into new materials and chemicals from plants (Bangor) and use of bacteria and fungi to digest, or ferment plant matter within the biorefining process.

IBioIC in Scotland in 2014[23], in addition to the development of the NIBB[24]. In February 2014 EPSRC, BBSRC and Innovate UK (TSB) launched the IB Catalyst as a mechanism for investing £45m (originally) into major industrial biotechnology research and development projects through government-industry co-investment. The IB Catalyst is viewed by key stakeholders in the sector as a key driver behind an integrated, collaborative approach to growing IB in the UK.

More recently, the drive from within the sector has continued via the BBSRC Delivery Plan 2016-2020, which sets out the delivery priorities for bioscience and growing IBBE in the UK. The BBSRC was set up in 1994, in part to focus upon biotechnology. Policy directives and funding opportunities derived from BBSRC policy are highlighted in the table below, together with other programmes that support R&D in IBBE.

Table 2.2 – Overview of IBBE related R&D programmes (current and recent) in the United Kingdom

Programme	Description
Industrial Biotechnology Leadership Forum (IBLF)	The IBLF was established by BEIS (formerly BIS) to implement the recommendations arising from the IB IGT's 2009 "IB 2025 Maximising UK Opportunities from Industrial Biotechnology in a Low Carbon Economy" report.
BBSRC Strategy for UK IBBE	There are three core components to the BBSRC Strategy for IBBE in the UK: • Building a Strong Community (through investment in NIBB, per below); • Pump Priming Activities (BBSRC provides £11.4m across the networks to support activities through PoC/BIV funding); and • Supporting translation and early scale-up (focuses on production/enhanced efficiency in IB activities, formerly through the IB Catalyst)
Networks in Industrial Biotechnology and Bioenergy (BBSRC NIBB)	The BBSRC NIBB form the central part of the BBSRC's strategy to support the development of Industrial Biotechnology and Bioenergy (IBBE) as a key component of the UK bioeconomy. The NIBB currently have over 7,000 members across the UK and internationally, with almost 2000 industrial memberships and 900 companies. A list of the 13 NIBB are available in Appendix 1.
Industrial Biotechnology Catalyst	The IB Catalyst supported businesses & researchers in IBBE until 2016, with £76m allocated for 82 projects across the following five challenges: • Production of specialty chemicals • Production of commodity, platform and intermediate chemicals and materials • Production of liquid and gaseous biofuels • Production of peptides and proteins

[23] Originally funded by the Scottish Funding Council, Scottish Enterprise and Highlands and Islands Enterprise in 2012. IBioIC is a specialist centre focussed on Industrial Biotechnology, tasked with connecting industry, academia and government to grow the sector in Scotland to £900m by 2025.
[24] In 2014 BBSRC, with support from EPSRC, committed £18M to fund 13 unique, collaborative "Networks in Industrial Biotechnology and Bioenergy".

	• Novel or improved upstream or downstream processes to reduce costs or improve efficiency in IB applications
BBSRC Integrated Biorefining Research and Technology Club	The IBTI is a £6m, 5-year programme aimed at developing biological processes and feedstocks to replace fossil fuels as input.
BBSRC Bioprocessing Research Industry Club	BRIC focuses on industry-academia collaboration to support innovative bioprocess-related research, providing £23m in 48 projects until 2015. The IBTI and BRIC also have industry-academia collaboration as a key focus, which is a particular strength within the UK.
Agri-Tech Catalyst	The Agri-Tech Catalyst co-funds new agricultural technologies to bridge the gap between the laboratory and the market place, including biomass and challenges in downstream food processing.
BBSRC Strategic Longer and Larger Grants	The sLoLas grant programme, currently closed, provided £15.8m to support integrated research projects with long timescales requiring extensive resources and multidisciplinary approaches
BBSRC Responsive Mode Priorities	BBSRC has identified 'new strategic approaches to IB', 'bioenergy: generating new replacement fuels for a greener, sustainable future', 'reducing waste in the food chain', and synthetic biology (among others) as key responsive mode priorities, and will support projects and research proposals aligned to these on a responsive mode basis.
BBSRC Sustainable Bioenergy Centre	The BSBEC is a £19m investment joining up six research programmes from 12 universities that is supported by a further £4m from industry.
Newton Bhabha UK-India Industrial Waste Challenge 2017	As part of the Newton Bhabha Fund Innovate UK, BBSRC and EPSRC and the Government of India's Department of Biotechnology are investing up to £8 million in projects that use cutting-edge solutions to reduce industrial waste in India. The competition aims to encourage partnerships between the UK and India and funds projects addressing the reduction of industrial waste and pollution and improve value recovery from waste using Biotechnology.
ERA CoBioTech - ERA-Net Cofund on Biotechnologies	BBSRC in 2017 co-funded the ERA CoBioTech funding round that UK firms could access. The funding call aimed to attract proposals focused on biotechnology as a key enabling technology (KET), in the context of the bio-based economy and to tackle 21st century societal challenges such as decarbonisation of the economy and reduction of the reliance on fossil feedstocks.

2.1.3 National Bioeconomy strategy and policy

The UK Government's 'Building a High Value Bioeconomy' (2015)[25] report sets out that the UK's vision is to "*see the bioeconomy sector in the UK continuing to grow* [with the UK] *becoming a global leader in producing high value resource efficient materials, chemicals, and energy,* [and ultimately a] *major exporter of process technologies and business models, exploiting intellectual property abroad and retaining value for the UK while offering solutions globally and delivering against environmental targets*."[26]

The UK Government launched a consultation process from December 2016 to January 2017 seeking further views on identifying the opportunities, challenges, barriers and enablers for the UK Bioeconomy. This consultation is expected to feed into an updated UK Bioeconomy strategy, which is expected to be published soon and will look to encourage a world leading bioeconomy, appropriate to the UK's industrial structure and availability of natural resources. The strategy will involve many different sectors across the economy and will need to take account of other objectives such as: decarbonisation, sustainability and food security.

The UK chemical industry provides a clear example of high-value, high productivity economic activity in the UK. It is a global leader, with sales of over £60bn per annum, annual exports of almost £50bn per annum, and supports £15bn in UK GVA. It also drives £4bn per annum in capital and R&D investment, and employs over 150,000 people in the UK directly who earn 30% more than the average UK manufacturing employee.[27] Once again, UK industry organised itself following the Chemistry Growth Strategy via the Chemistry Growth Partnership (CGP). The CGP vision is that:

> *"By 2030, the UK chemical industry will have further reinforced its position as the country's leading manufacturing exporter and enabled the chemistry-using industries to increase their GVA contribution to the UK economy by 50%, from £195 billion to £300 billion. Secure and competitive energy and feedstock, accelerated innovation and strengthened supply chains will be critical in realising this vision."*

To deliver this vision, the CGP has set out a range of actions under the following priorities:

- Securing competitive energy and feedstocks;
- Accelerating innovation;
- Rebuilding UK chemistry supply chains;
- Contributing to climate change solutions;
- Growing UK exports via trade agreements and reducing tax on chemical shipments; and
- Investing in skills from school age through university and into professional accreditation.

CGP is an important stakeholder in IBBE for chemicals manufacturing, but it will likely have little direct impact in research terms as the academic sector is little mentioned in the CGP strategy. There

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[25] HM Government (2015) 'Building a High Value Bioeconomy: Opportunities from Waste' Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/408940/BIS-15-146_Bioeconomy_report_-_opportunities_from_waste.pdf
[26] ibid
[27] Sourced from UK Chemical Industries Association

is clear potential for IBBE to support the CGP but this needs to be incorporated as part of a coherent overall national strategy for UK IBBE. This further highlights the need for a joined-up UK national IBBE strategy.

Showcase Events such as the Industrial Biotechnology Showcase 2015 and the Chemistry and Industrial Biotechnology Showcase 2017 also demonstrate a continued desire amongst government and industry bodies to engage and build links both across the UK and internationally.

2.1.4 National bioenergy strategy and policy

In 2012, the UK Government published its first Bioenergy Strategy for the UK.[28] It rightly recognized that bioenergy can make a significant contribution to the UK's wider carbon reduction planning, and support decarbonisation. The Strategy also recognised the complexity of bioenergy policy given the opportunity cost of the resources available i.e. whilst it is a renewable source which can be used across energy sectors (transport, heat and electricity), it also has competing value regarding food, natural habitats, and use of feedstock resources for industrial biotechnology.

The UK's Bioenergy Strategy sets out several key principles for bioenergy policy:

- Policies that support bioenergy should deliver genuine carbon reductions that help meet UK carbon emissions objectives to 2050 and beyond.
- Support for bioenergy should make a cost-effective contribution to UK carbon emission objectives in the context of overall energy goals.
- Support for bioenergy should aim to maximise the overall benefits and minimise costs (quantifiable and non-quantifiable) across the economy.
- At regular time intervals and when policies promote significant additional demand for bioenergy in the UK, beyond that envisaged by current use, policy makers should assess and respond to the impacts of this increased deployment on other areas, such as food security and biodiversity

It also sets out a number of assumptions regarding the trajectory for bioenergy development in the UK in coming years:

- The use of wood and energy crops for bioenergy is a good carbon reduction option compared to alternative uses of the resource;
- The potential scale of bioenergy deployment: although highly uncertain, analysis indicates that sustainably-sourced bioenergy[29] could contribute by 2020 around 8-11% to the UK's total primary energy demand and around 12% by 2050 (within a wide range of 8%-21%).
- Non-energy sectors will be impacted by the growth of bioenergy in the UK.
- The potential impact on food and food production: Bioenergy development can impact on food production and prices, biodiversity and other environmental objectives;

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[28] HM Government (2012) 'UK Bioenergy Strategy' Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/48337/5142-bioenergy-strategy-.pdf

[29] Sustainably sourced biomass refers to biomass feedstocks that have not been sourced from high carbon stock land (e.g. peat land or virgin forest) or land that is required for competing uses (e.g. food).

- The strategy also identifies the development of biosynthetic gas, hydrogen and advanced biofuels as the key bioenergy hedging options against these inherent long-term uncertainties.

Overall, the strategy shows a commitment to supporting bioenergy in the UK, particularly with its reference that the exclusion of biomass from the UK's energy mix would come at a high cost; it is estimated that without biomass the cost of decarbonising the UK's energy system would reach £44bn.[30]

However, since 2012, the focus on how the UK can source and utilise alternative forms of energy to fossil fuels has arguably diminished. This is in no small part due to the relative collapse in oil prices in the past five years. Despite this, the US Energy Information Administration (EIA) projects that global demand for crude oil will drive the price of a barrel to $136 by 2040 (in 2015 prices).[31] Therefore, demand may be volatile in the coming years; however, the underlying pressures for UK energy security (price volatility, geopolitics, and the need to consider domestic fuels) will mean that bioenergy and biofuels will remain on the agenda.

The subsections below bring the policy context up to date, by discussing changes enacted by the incumbent government, and some possible implications of the UK leaving the European Union that have already surfaced in official literature.

2.1.5 EU Referendum and the Industrial Strategy

Following the EU Referendum, the resultant government and cabinet has a markedly different approach to industrial and environmental policy compared to recent years. The new Industrial Strategy will have a substantial effect on IB in the UK and its continued development. The Brexit dimension cannot be separated from these developments, and could have a profound effect if transposed legislation (e.g. the Renewable Energy Directive) is repealed.

The Industrial Strategy seeks to build on existing strength, and tackle low productivity. The core tenets of the strategy, and implications for UK IBBE are set out below.

- The Green Paper published in January 2017 sets out ten pillars that Industrial Strategy will be built on, the first of these being *science, research and innovation*. This is to encompass all new policies HM's Government will implement to increase innovation throughout the economy and improve the commercialisation of world-class UK research activities. The seventh pillar of the strategy, *delivering affordable energy and clean growth*, also directly relates to IB as the government will seek to capture the benefits of transitioning to a post-fossil economy. The final two pillars of the strategy, *cultivating world-leading sectors* and *driving growth across the whole country* are also relevant for IBBE insofar as they should support important IBBE sub-sectors such as synthetic biology, and should seek to further opportunities for industrial biotechnology outside of the 'golden triangle'.
- As part of the Industrial Strategy the government will provide an additional £4.7bn in funding to R&D by 2020-2021, which is designed to be invested into basic research and support for commercialisation. The government is also seeking to support new technologies in biotechnology and synthetic biology and/or quantum technologies through the Industrial Strategy

[30] Energy Technologies Institute, ESME modelling
[31] US Energy Information Administration (2015) https://www.eia.gov/outlooks/aeo/data/browser/

Challenge Fund, as these are listed as one of the 'Eight Great Technologies'. NIBB recently received £1.3m from the fund as 'IB seeding awards'. This fund is also intended to support growth across the country, as its resources will be used to stimulate nascent or active industries in economically underprivileged areas. The fund is the part of the industrial strategy which most benefits IB and most directly targets it.

- By increasing funding in R&D and strengthening the UK's strategic capability in research, the government aims to keep improving its efforts at supporting commercialisation, capitalising on local strengths and delivering sector-specific funding to support business investment. The government will also continue to support further Science & Innovation Audits (SIAs) to build an evidence base highlighting local strengths and capacity.
- Simultaneous to these activities supporting science, research & innovation, the government will produce a roadmap in 2017 to reduce energy costs and review opportunities for growth from the energy sector. As part of this pillar the government aims to accelerate the transition to ultra-low emission vehicles and achieve decarbonisation goals. The Committee on Climate Change's report to Parliament in June 2017 called for urgent action on decarbonisation policy, including a package of measures on power, buildings, industry, transport, agriculture, LULUCF, waste and F-gases that are often underpinned by IBBE.[32]

2.1.6 UK General Election and the Conservative Manifesto

The result of the recent UK General Election, and installation of a minority Conservative Government is nonetheless expected to result in the implementation of the most recent 2017 Conservative Party Manifesto, including the following policy initiatives over the next Parliament:

Conservative Manifesto Initiatives
• Establishing new institutes of technology "in every major city of England" (degree level and above).
• National Productivity Investment Fund £23bn.
• Future Britain Funds (pension fund implications including within IBBE).
• Sustained payments to farmers until 2022 and development of a 'new agri-environment system'.
• 25-year post EU Environment Plan.

It is somewhat concerning, given the preceding analysis of EU policy and prioritisation of biotechnology, that the manifesto makes no mention of 'bio' or of 'green', particularly as there is no evidence in the Industrial Strategy Green Paper or other policy documents as to what IBBE is or does. It is imperative that central government adds weight to the strong industry drive, making its support for IBBE (in terms of both policy direction and funding) abundantly clear nationally, and globally.

The summary of prior and current national policy is testament to the breadth and complexity of the IBBE sector in the UK, but also provides evidence of a recent focus on developing the sector (including its various specialist strands), supported by BEIS, and driven largely from within the sector by key actors including the IBLF, Innovate UK, BBSRC and EPSRC.

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[32] Committee on Climate Change (2017) "Meeting Carbon Budgets: Closing the Policy Gap – 2017 Report to Parliament", June 2017.

However, at the time of writing, specific government policy to exploit the significant economic and societal potential of IBBE does not exist. While there are mechanisms through which specific IBBE policy can be instated (via the UK Bioeconomy Strategy), if the UK is to keep pace with international competitor nations, and exploit the future economic potential of IBBE, it is imperative that a detailed IBBE plan is developed and backed by the UK government.

2.1.7 Regional policy

Regional policy often plays a vital role in supporting knowledge exchange and commercialisation[33]. There are examples of good practice in regional IBBE policy across the UK, including in Yorkshire & the Humber where IB represents a clear priority for the Local Enterprise Partnership (LEP). IBBE is part of Priority 2 of its Strategic Economic Plan: *become a global leader in agri-food & the bioeconomy*.[34] Activities outlined in the plan include:

- Facilitating connections between agri-food / biorenewables and supporting supply chain interventions;
- Enabling businesses to access new IP, technology and processes to drive commercial value;
- Attracting investment to Yorkshire, including new businesses and businesses already active in the IBBE sector;
- Develop new and existing markets; and
- Develop the pipeline of skills required by bio businesses.

These LEP activities are consistent with the BioVale strategy for a bioeconomy innovation cluster, which was developed in March 2015[35]. This strategy represents a multi-level attempt to coordinate bio-economy innovation in a region, as its activities are funded by the EU (ERDF), UK (HEFCE third stream funding) and implemented with support from local (higher) education institutes (Askham Bryan College, York), private research divisions (Biorenewables Development Centre, Centre for Novel Agricultural Products) and councils (Leeds, York).

There are 3 Enterprise Zones in England which have a specific focus on Industrial Biotechnology, recognising the potential of the sector, and the importance of regional policy and infrastructure:

- **Alconbury Enterprise Campus**: located in the Greater Cambridge and Peterborough LEP area, home to Enval[36] with links to Cambridge Cleantech[37];

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[33] Involving collaboration between government, industry and research institutions also referred to as 'Triple Helix' developments.

[34] LEP York, North Yorkshire, East Riding (2016) *Strategic Economic Plan, Update 2016*

[35] BioVale: A strategy for a bioeconomy innovation cluster across Yorkshire and Humber (2015), BioVale.

[36] The company has developed a process for the recycling of laminated plastic and aluminium packaging which separates the packaging into its constituent components, producing clean aluminium and hydrocarbons that can be used as fuel or chemical feedstock. The process offers a much more beneficial outcome for waste that would otherwise be sent to landfill or incinerated.

[37] A members' organisation founded by the University of Cambridge and partners to support the growth of cleantech (environmental goods and services) companies in the Greater Cambridge area.

- **Discovery Park:** located in the South East LEP area, home to numerous biotech businesses but with a specific focus on medical application;
- **Nottingham Enterprise Zone**[38]: located in the D2N2 LEP area, home to the Energy Technologies Research Institute which specialises in Carbon Capture and Storage, Renewable Energy, Bioenergy and Low Energy Buildings. BioCity Nottingham, one of Europe's largest bioscience business incubator facilities is also located within the zone.

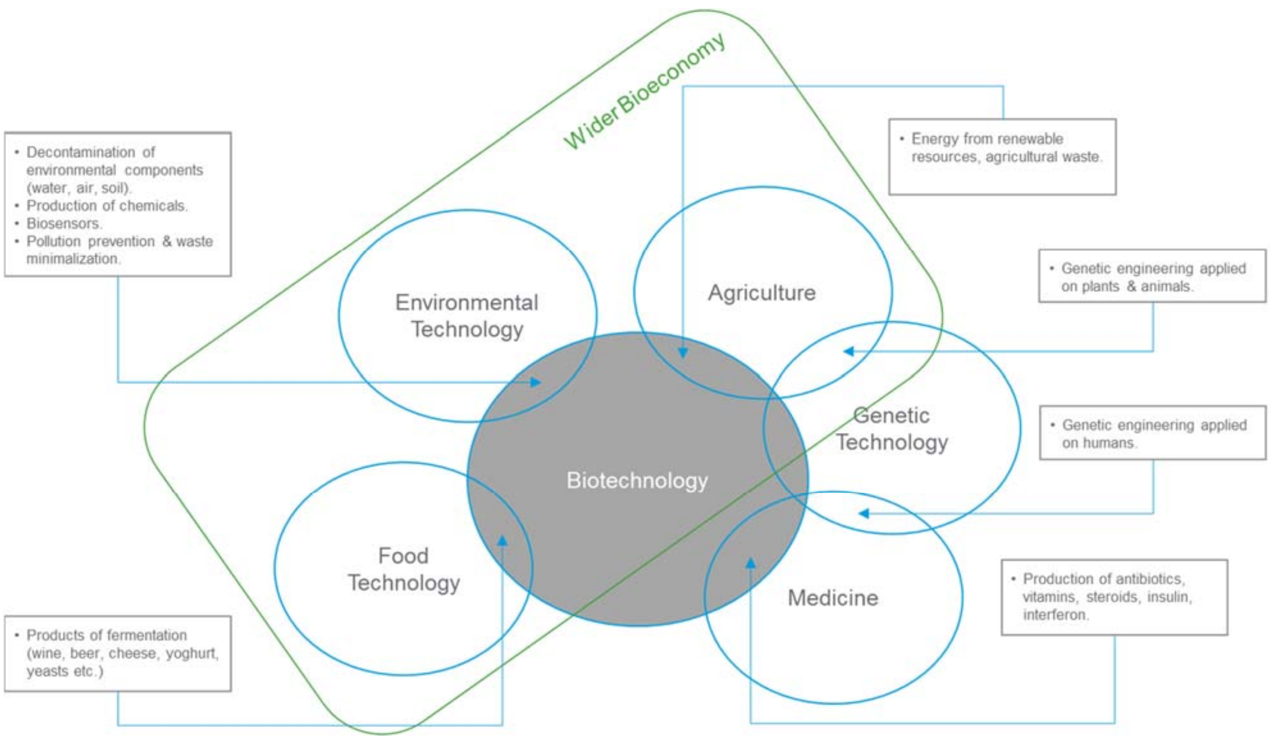
Other clusters with IBBE activity to differing degrees include the European Centre for Marine Biotechnology in Scotland, the North East of England Process Industry Cluster, One Nucleus, Oxfordshire Bioscience Network, and Norwich Research Park. Scotland also has its own '*National Plan for Industrial Biotechnology 2015-2025'* which sets out to 'transform the competitiveness and sustainability of multiple industries in Scotland, to grow industrial biotechnology-relayed turnover to £900m by 2025 (from £230m in 2015), and to grow from 50+ companies in the IBBE sector to 200 by 2025. The Scottish Funding Council and partners have invested considerably in IBBE, including the £10m investment in IBioIC, and a further £2.8m in open access centres. Study contributors expressed a view that IBBE in Scotland is better co-ordinated than the sector in the rest of the UK.

2.2 Existing estimates of the size and scale of IBBE

As discussed in Section 2.1, biotechnology is widely recognised as a key enabling technology in both European and national literature. However, the intersections between biotechnology and various fields of science and industry are multiple and complex. Figure 2.1 overleaf provides a visualisation of biotechnology as an enabling technology, with various intersections to science and industry, and the relationship between biotechnology and the wider bioeconomy.

[38] Available at: https://www.localinvestuk.com/enterprise-zone/nottingham-enterprise-zone

Figure 2.1 – Visualising the role of biotechnology



Source: Gavrilescu (2010). Environmental Biotechnology: Achievements, Opportunities & Challenges

There have been several reports in recent years which have sought to provide a 'market overview' of the size and activities of both IBBE, and the wider bioeconomy. Key findings from two prominent recent reports are summarised below.

In 2015, a **Capital Economics** report entitled **Biotech Britain** provided a snapshot of UK IBBE economic activities at that time. The report estimated IBBE economic contributions including:

- 225 active IBBE companies in the UK;
- 8,800 direct employees, adding just under £1bn per annum in GVA to the UK economy;
- Additional expenditure of approximately £1.8bn on supplies of equipment, feedstocks and services, supporting a further 16,000 jobs and an additional £780m in GVA.

In 2016, BBSRC commissioned an independent study into the economic contribution of the wider bioeconomy (of which IBBE, together with Synthetic Biology, forms an integral but as yet comparatively small part). **BBSRC's (2016) 'Evidencing the Bioeconomy Report'** provides a broader SIC code analysis that suggests a notably larger economic contribution, including: 6,500 firms, 78,200 employees, and turnover and GVA more than £17bn and £7bn respectively. Table 2.1 overleaf summarises the SIC code analysis produced in the BBSRC report.

Table 2.1 – BBSRC Estimate of UK Bioeconomy Activity

Activity	Employment	Number of Firms	GVA (£bn)	Turnover (£bn)
Research and development (72.110)	25,300		0.8	3.2
Engineering, construction, design and technical support	16,100		2.5	5.4
Bio-plastics	11,300		0.2	0.6
Bio-chemicals	9,100		1.9	5.2
Health, personal care and household products	4,000		0.4	0.3
Bio-electronics	3,900		0.4	0.6
Other	2,600		0.4	0.3
Rubber products	2,200		0.1	0.3
Bio-pharmaceuticals and bio-processed pharmaceuticals	2,000		0.4	0.8
Leather products	1,100		0	0.2
Agri-chemicals	600		0	0.1
Total	**78,200**	**6,505**	**7.2**	**17.2**

Source: BBSRC Evidencing the Bioeconomy

The 2016 Bioeconomy report provides a broad but interesting analysis of employment and GVA by industry sub-sectors. However, the difference between the estimates reflects a common challenge associated with estimating the economic contribution in many emerging sectors. A narrower definition, such as that used in Biotech Britain, risks underestimating the sector's contribution, whereas a broader definition and SIC code analysis of the wider Bioeconomy is not granular enough to establish the underlying activity of businesses, and therefore accurately attribute lower level economic contributions. In addition, the impact and role of IBBE as an enabler of other sectors is also difficult to include in estimates and forecasts of GVA or employments relating to IBBE.

Notwithstanding definitional and methodological differences between the two reports, Biotech Britain suggests that the narrower IBBE sector contributes 29% of the GVA, 32% of the employment, and 3% of the businesses that make up the wider bioeconomy.

Chapter 3 of this report provides an updated assessment of the economic contribution of IBBE to the UK economy. The analysis uses the BBSRC definition of IBBE, following a review of various definitions found within existing literature, as explained in more detail below.

3 THE CURRENT UK IBBE LANDSCAPE

This Chapter provides a detailed analysis of the current UK IBBE landscape. It sets out an updated assessment of the economic contribution of IBBE, before combining findings from the desk based review and in-depth interviews with strategic stakeholders to set out IBBE strengths, weaknesses, areas of potential competitive advantage, and emerging technologies and trends.

3.1 Size and scale of IBBE: an update

Using the agreed definition, this study updates and builds on the 2015 Biotech Britain report. The definitional working paper used to agree the IBBE definition for the purposes of this study, which includes caveats and limitations to the analysis, is available at Appendix 2. RSM has examined SIC2007 code 72110 (R&D in Biotechnology) in further detail using RSM's in-house Tracker system.[39] A summary of approach and headline findings from the analysis are presented in Table 3.1 below.

Table 3.1 – IBBE headline findings

Approach	Output
Active UK companies reporting SIC2007 Primary, Secondary, or Tertiary activity as 72110 (R&D in Biotechnology)	• 1,838 companies[40]
Filtering where company data yields both: total sales and total employment (within 2015/16 FY).	• 14,113 FTEs (based on 168 companies for which data was available) • £3.7bn sales and c.£1.2bn value added (based on 220 companies for which data was available

Source: ONS, Orbis, RSM Tracker

Using the same method as the Biotech Britain report, these findings suggest that within the past three years, employment and GVA from IB activities have shown a *consistent increase of approximately 8% per annum*. The sub-section overleaf presents the number and location of UK companies based on the agreed definition.

3.1.1 Profile of UK IBBE businesses

It is important to identify the size of firms (i.e. staff number, annual turnover, balance sheet totals) aligned to IBBE in the UK. This will allow policies and support to be developed and tailored that recognises the size of the firm, e.g. an SME with annual revenues of £1m may be more receptive of funding support of up to £100k than a non-SME with revenues of £100m. The EU definition (2003/261) of an SME is based on staff headcount and turnover or balance sheet totals, as set out in Table 3.2 overleaf.

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[39] Tracker is an in-house database of UK businesses that can be used to research individual companies, or companies with specific profiles.

[40] Please note an outlier (AstraZeneca) was identified and removed from the sample to avoid undue skewing of results given its proportionally large revenue c. £25bn per annum.

Table 3.2 – EU SME Definition

Company category	Staff headcount	Turnover	Balance sheet total
Medium-sized	< 250	≤ € 50 m	≤ € 43 m
Small	< 50	≤ € 10 m	≤ € 10 m
Micro	< 10	≤ € 2 m	≤ € 2 m

Source: European Commission SME Definition

Employment data is available for approximately 10% of IBBE firms[41], providing an estimated total of over 14,000 employees (average of 84 employees per IBBE firm). Approximately two thirds of businesses are categorised as micro or small firms (approximately equal split) with a quarter of businesses categorised as medium sized and c.7% categorised as large firms.

Table 3.3 – IBBE business size by employment

Company category	Staff headcount	Number of Companies	%
Large	250+	11	7%
Medium-sized	< 250	40	24%
Small	< 50	55	33%
Micro	< 10	61	36%
		168	

Source: RSM Tacker

Revenue data is available for approximately 12% of firms[42]. By measure of revenue, more than half of IBBE businesses are categorised as 'micro' firms, one fifth are categorised as 'small' firms and approximately one fifth are categorised as either medium or large firms. It is likely that the firms which we lack data on are smaller firms and that therefore many more smaller firms are not represented in the table above.

Table 3.4 – IBBE business size by employment

Company category	Revenue	Number of Companies	%
Large	> €50 m	9	5%
Medium-sized	≤ € 50 m	30	17%
Small	≤ € 10 m	37	21%
Micro	≤ € 2 m	101	57%
		177	

Source: RSM Tracker

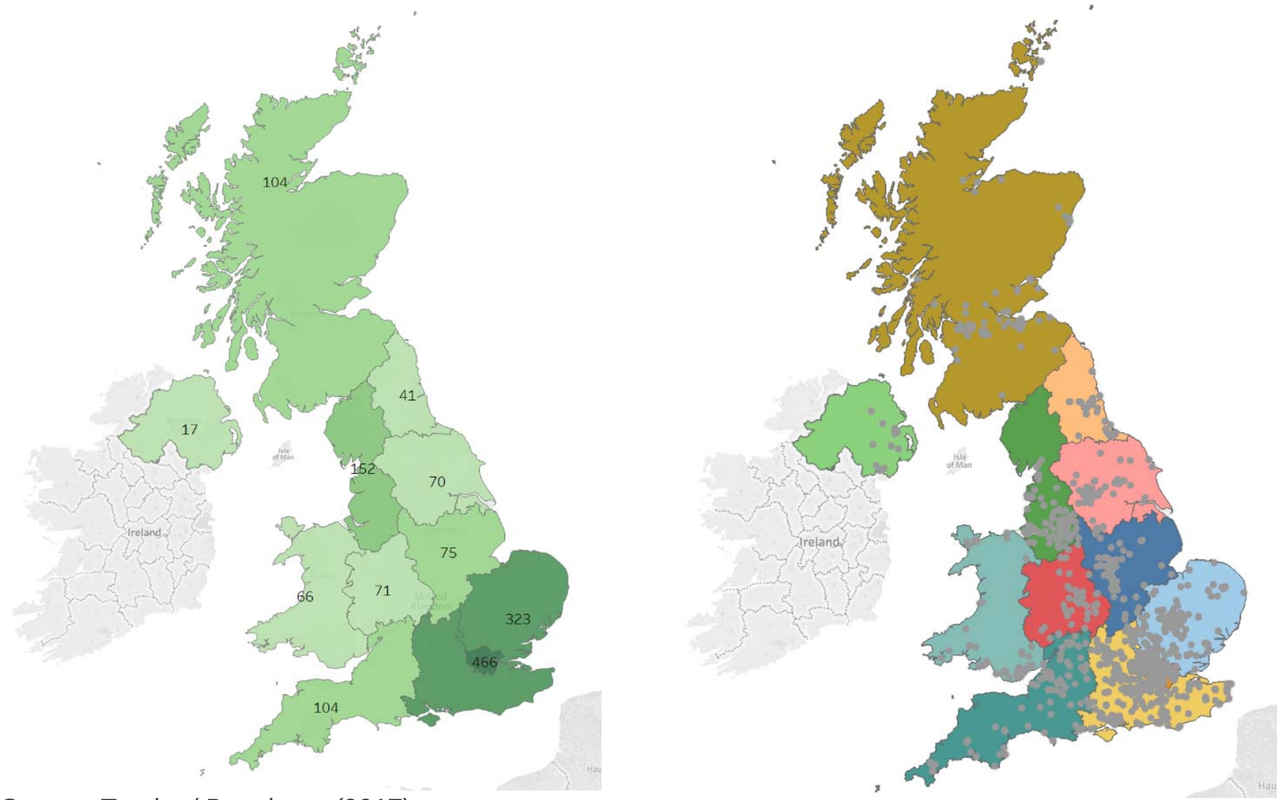
Overall, a minimum of 95% of firms in the IBBE sector are estimated to be SMEs, however this figure is likely to be higher (at c.99%).

[41] 168 of c.1,800
[42] 220 of c.1,800

3.1.2 Location of UK IBBE businesses

A regional summary of the number (left hand chart) and location (right hand chart) of IBBE businesses is presented in Figure 3.1 below.[43] The mapping suggests that company activity is concentrated in the South East, as expected given the strength of the 'Golden Triangle' in biopharma. However, beyond the South East, the North West and Scotland have the largest clusters of activity.

Figure 3.1 – Number (left) and location (right) of IBBE businesses



Source: Tracker/ Beauhurst (2017)

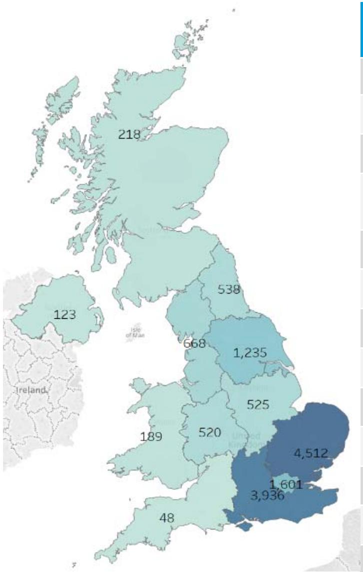
The analysis signals that whilst there are notable IB clusters, business activity is still dispersed across the UK resulting in the need for a regional and national approach to supporting IB. In-depth consultation with strategic stakeholders noted the delineation in industry focus by geography, highlighting that the so-called 'Golden Triangle' of Cambridge / Oxford / London is home to a concentration of biopharma businesses, whereas IBBE businesses more broadly are present across the UK. The analysis adds weight to the regional policy analysis presented in Section 2.1.3; and to the industry perspective that IBBE is highly regional. This therefore very much supports the 'place' component of the UK Industrial Strategy. The analysis also shows the existence of an IBBE cluster in Northern Ireland which may be particularly affected by Brexit, should any form of 'hard border' between Northern Ireland and the Republic of Ireland be introduced.

[43] For transparency, RSM has utilised the company 'trade address' rather than registered address to better depict where the business activities are undertaken.

3.1.3 Employment in IBBE

The economic analysis indicates that there are at least 14,100 full-time jobs in the sector. Figure 3.2 overleaf highlights the number of IBBE FTEs across UK regions, and assesses the relative concentration (and importance) of IBBE sector (72110) employment regionally using a Location Quotient analysis. The analysis highlights the comparatively high concentration of employment in IBBE in the East and South East of England (LQs of 3.36 and 1.96 respectively). IBBE in the North East, Yorkshire and the Humber is clearly also an important contributor to regional employment (with LQs at or marginally above 1). The concentration of IBBE employment in some regions is lower than might be anticipated (particularly regions with strong existing IB infrastructure such as Scotland, Wales and the North West) suggesting scope for expanding employment in those regions.

Figure 3.2 – Regional FTE Employment



Regional (Dec 2016 estimates)	Employment	% UK	IBBE Employment.	% IBBE	LQ
United Kingdom	**31,841,000**	**100%**	**14,113**	**100%**	**1.00**
North East	1,209,000	3.8%	538	3.8%	1.00
North West	3,429,000	10.8%	668	4.7%	0.44
Yorkshire and The Humber	2,577,000	8.1%	1,235	8.8%	1.08
East Midlands	2,273,000	7.1%	525	3.7%	0.52
West Midlands	2,655,000	8.3%	520	3.7%	0.44
East	3,029,000	9.5%	4,512	32.0%	3.36
London	4,500,000	14.1%	1,601	11.3%	0.80
South East	4,541,000	14.3%	3,936	27.9%	1.96
South West	2,758,000	8.7%	48	0.3%	0.04
Wales	1,446,000	4.5%	189	1.3%	0.29
Scotland	2,596,000	8.2%	218	1.5%	0.19
Northern Ireland	828,000	2.6%	123	0.9%	0.34

Source: ONS Regional Labour Force Survey Summary (April 2017). LQ analysis undertaken by RSM.

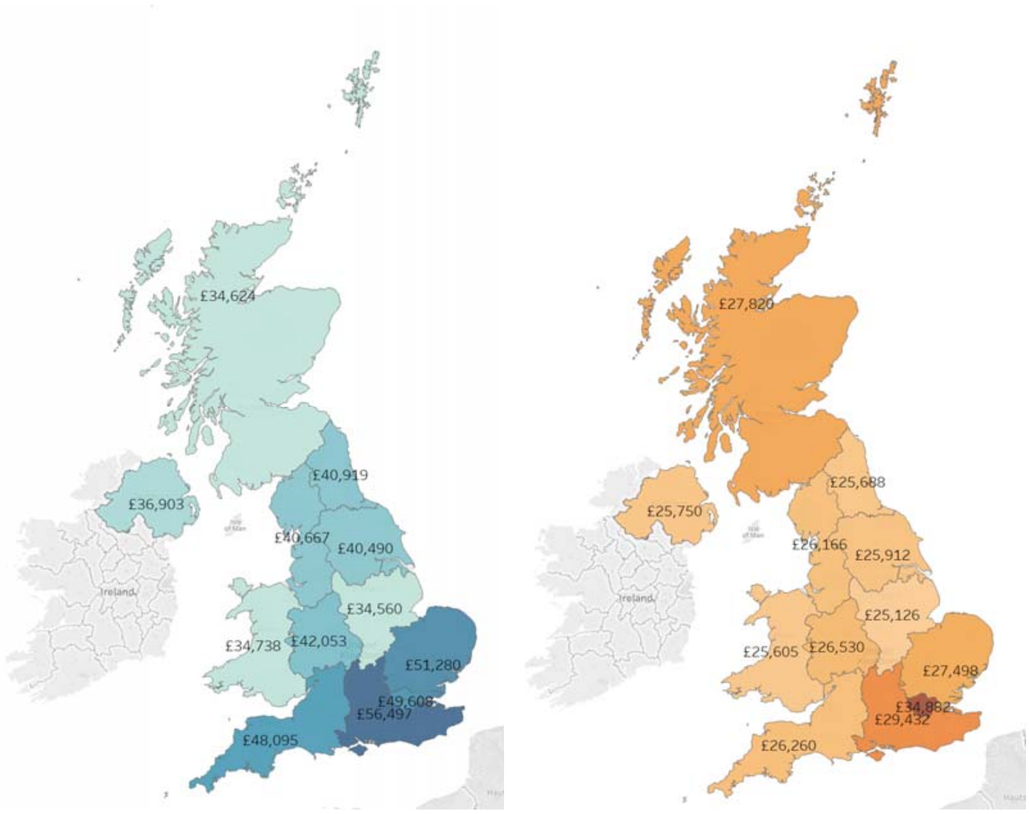
The analysis also indicates that employment growth in IBBE is outstripping that of the national economy. In 2014, IBBE sector employment (SIC72110) was 11,339. It grew to 12,865 in 2015 (+13%) and 14,113 in 2016 (+10% from 2015 and +24% from the 2014 base). Accepting the sector's lower base numbers, IBBE has been exhibiting strong employment growth compared to national year-on-year FTE employment growth of approximately 1.4% in 2015, and 1.9% in 2016.

3.1.4 IBBE wages & salaries

Employee remuneration data was available for 165 of the companies within the dataset. Within the 2015/16 financial year, employee remuneration (salary and bonuses) totalled to £715m for 14,017 FTE staff, equating to a median remuneration package of £47,187.

Figure 3.3 below demonstrates median salary (for those within firms with SIC code 72210) by region and how this contrasts to national median earnings (Source, ASHE, December 2016). As expected, given the skills required, IB is a high-wage, high-value sector. Further, it offers an encouraging dynamic regarding the promotion of regional growth beyond London and the South East, with the earnings premium in the North (NE, NW and Yorkshire and the Humber) outpacing the regional median by over 60% (i.e. £40,000s vs £26,000).

Figure 3.3 Regional Median Earnings (Annual)



Median UK: £47,187 (Source: RSM Tracker) *Median UK: £28,011 (Source: ONS, ASHE[44])*

These findings are broadly consistent with the Biotech Britain report, which suggested that the average wage for sector employees was £48k. The difference between average UK earnings and sector earnings is more pronounced in this study, with sector earnings at c.70% above the national average, compared to a 40% differential reported in Biotech Britain. It is worth noting the methodological difference between the two reports. Biotech Britain used primary research (an industry survey) to gather wage data, whereas this study uses RSM's in-house company database.[45]

3.2 Strengths, weaknesses, opportunities and threats

This section combines findings from the desk based review and in-depth interviews with strategic stakeholders to identify IBBE strengths, weaknesses, opportunities and threats. The matrix overleaf provides a long list of issues spanning policy, infrastructure, networks, investment, competition, skills and resources.

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[44] Figures presented here from ASHE are Median Weekly Earnings for Full-time workers multiplied by 52 to give annual values.

[45] 'Tracker' is RSM's in-house company database which includes company profiles, employment and financial information.

Figure 3.4 – IBBE Strengths, Weaknesses, Opportunities & Threats

Strengths	Opportunities
Policy & strategy • Continued move from horizontal to vertical industrial policies for key technologies. • Best practice examples of IBBE policy development e.g. via the *National Industrial Symbiosis Programme*.[46] • Government committed to supporting biotech research, promoting 'Triple Helix' collaboration & creating R&D tax incentives. • Biofuels supported through fuel mandates. *Research & infrastructure* • World class academic research e.g. on plants, microbes, algae, biochemistry / biotech. • High quality fit for purpose space for early stage biotech businesses (science parks and enterprise zones regionally). • High quality research infrastructure within Higher Education Institutions. • Purpose oriented facilities including CPI and UK based bio-refineries (e.g. Vivergo). *Networks* • Strong networks for promoting entrepreneurial activities and firms in new industries. • Connected and collaborative IBBE community via BBSRC, NIBB, Innovate UK SIG, KTNs and Catapults. *Investment & financing*	*Policy & strategy* • Policy interventions being implemented through the EU, national governments and devolved administrations. • Contribution of IBBE to Industrial Strategy, including regional / place based component. • New trade agreements. • Reduced greenhouse emissions to combat and pre-empt climate change, and opportunity to cement emerging 'circular economy' policies. *Research & infrastructure* • Synthetic biology widely recognised as rapidly growing sector and UK research well positioned internationally. • Emergence of green chemisty and industrial biotechnology is increasing the need and demand for new biorefineries.[47] • Rapid advances in biotechnology are enabling several economic sectors to use more biomass. OECD predicts that by 2030 the bio-economy could contribute 2.7% of GDP across OECD countries. • Larger scale demonstration site to show biorefineries plant works. *Networks* • Continuation of strong issue based networks and increased co-ordination with regional policy-making. • Encourage engineers and life scientists to work more closely together in considering manufacturability and scalability of emerging processes.

[46] Hodgson et al (2015)
[47] Source: Biofuels, Bioproducts and Biorefining (2017)

- IB, HVM & Biomedical catalysts have incorporated best practice (project-oriented financing, peer-review, co-investment).
- Favourable tax regulation (Seed & Enterprise Investment Scheme, patent box).

Competition & geo-politics

- Wider economy competitive vis-à-vis similar sized European economies, with a globally competitive strong science research base.
- UK research respected internationally, particularly in hotspots such as biochemicals.

Skills & resources

- High-skilled workforce with sector-relevant skills and sizeable number of biotech training programs.
- Comparatively high priority given to importance of skills.

Investment & financing

- Provides opportunities for small scale businesses which are prominent in the UK.

Competition & geo-politics

- Brexit may enable UK to adopt idiosyncratic industrial policy (e.g. cessation of state aid regulation, reinstate patent box fully).
- Global political and industrial consensus regarding bioeconomy being key components of sustainable economic growth in coming decades.
- Reduced energy prices and increase security (reduce dependence on fossil fuels from volatile import sources).
- More productive and innovative use of food and solid waste e.g. production of new sterile fibres for biorefining[48], conversion of food waste into antibiotics.[49]

Skills & resources

- Further increase in high-skill & well-paid private sector jobs.

Weaknesses

Policy & strategy

- Lack of a national policy framework leads to coordination failure and duplication in efforts.
- Lack of direction for making more productive use of significant food and municipal waste.

Research & infrastructure

- Access to demonstration facilities in the UK not as streamlined as it could be.

Threats

Policy & strategy

- Loss of priority for biotech as an enabling technology – subsumed into narrower sector deal.
- Dilution of strength of advocacy from within sector if breadth of existing networks is eroded via Industrial Strategy.
- Transformative potential of biotech not understood by central government / not effectively communicated.

Research & infrastructure

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[48] Wilson Bio-Chemical has developed a process using steam and high pressure to convert the biological portion (mainly food waste, garden waste, paper, and cardboard) into a sterile fiber (Wilson Fibre).

[49] GSK, Veolia, and the Biorenewables Development Centre (BDC) have already proven at pilot-scale the potential for converting potato-processing and sandwich-manufacturing by-products into antibiotics, and have now started a new project funded by Scottish Enterprise to take the technology closer to commercialization.

- Focus on ‘science park innovation’ leads to large number of financially unviable firms.
- Large gap between operational delivery of biorefining and research knowledge.
- Universities perceive technology transfer as fund-generating activity without considering wider benefits.
- Lack of awareness among academics and innovative businesses regarding key infrastructure e.g. the CPI.

Networks

- Scope remains to improve connection between central / national and regional IC networks.

Investment & financing

- Withdrawal of IB Catalyst
- Enterprise Investment Scheme too low for firms to grow substantially and compete effectively on global market.
- Limited availability of scale-up investment.
- Lack of a large anchor company in IB.

Competition & geo-politics

- UK variety of capitalism unconducive to patient capital & incremental innovation.
- Brexit may remove access to important sources of research funding and collaborative networks, perhaps restrict access to EU market for UK IBBE.

Skills & resources

- Lack of scale in biorefining and question-marks on the sufficiency of UK biomass to make large scale biorefining feasible.

- Large institutions (especially Big Pharma) too rigid to enable true innovation, hence such projects led by inexperienced new ventures.

Networks

- Distrust regarding IP ownership prevents effective knowledge exchange between business and academia.

Investment & financing

- Long time scale from scientific breakthrough to developing market-ready product.
- Unclear what research will result in and who will benefit from it.
- Foreign investment leads to loss of IP.

Competition & geo-politics

- Commercialisation of UK inventions abroad.

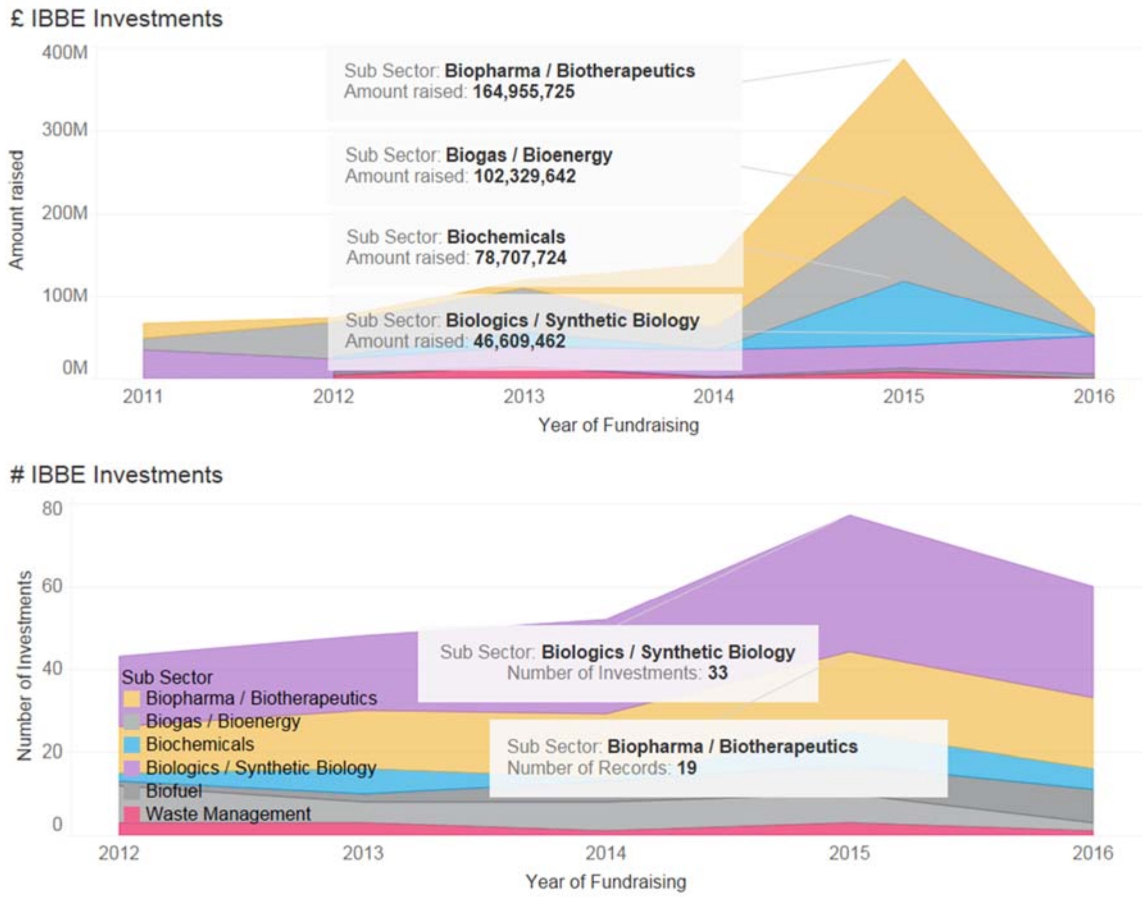
Skills & resources

- Political and economic uncertainty re Brexit, particularly regarding potential labour constraints and possible supply chain issues.
- Technology transfer constrained by lack of IP management in research institutions.

3.3 Emerging trends & UK strengths

The assessment of strengths and weaknesses presented above, and findings from in-depth interviews with strategic stakeholders have consistently pointed to certain sub-fields within IBBE as emerging trends. Analysis of private investment data (see Figure 3.5 below) reinforces stakeholder assertions that the sub-fields of biologics, synthetic biology and chemicals from biological processes are exhibiting growth potential.

Figure 3.5 – Investment in IBBE Sub-Fields, 2012 - 2016



Source: Beauhurst, RSM

By measure of total investment value, more established markets including biopharma, biogas and bioenergy are the largest sub-fields, receiving investments of over £150m and £100m in 2015 respectively. Total investment in biochemicals saw a spike in 2015, while investment in biologics and synthetic biology has shown a steady increase, at lower value.

However, by measure of total number of investments (arguably a better indicator of market development), the sub-fields of biologics and synthetic biology have shown significant and increasing levels of investment activity since 2012, with a peak of 33 investments in 2015; approximately 75% more investments than biopharma and biotherapeutics. The sub-sections below examine growth potential and UK strength in the sub-fields of chemicals from biological processes, biologics, marine biotechnology, and synthetic biology in more detail.

3.3.1 Chemicals from biological processes

IB-IGT previously set out growth projections of up to 11% and up to £12bn by 2025, based on a 'thriving biochemical industry' scenario in which IB would generate both low and high value biochemical products. Globally, the IB biochemicals market has been estimated to grow by 15% to an upper bound of £360bn by 2025.[50]

Comparatively low crude oil prices have supressed investment in, and production of low value, high volume chemicals derived through direct production. In contrast, direct production processes such as fermentation and biocatalysis applied to produce high-value, low-volume chemicals have continued to develop, and were seen by study contributors as representing an area of potential UK competitive advantage on the basis that it exploits the UK's strong academic and technology base. IB-IGT concluded that: *UK industry could take a strong position in this area based on its capabilities in nature-derived chemicals and chemical formulation, and a strong customer base for such products*.

Investment data presented previously (Figure 3.5) suggests that commercial appetite for the biochemicals market now exists, and case study research suggests that companies such as Green Biologics are now providing a solid industry base. In 2016, Green Biologics' employed c.100 staff in the UK and generated turnover of c.£37m. A detailed case study, provided in Appendix 3, charts the growth of Green Biologics, documenting the role that both the private and public sectors have played to date. It illustrates how the UK's innovation ecosystem can effectively support innovative bio-businesses. Key points from the case study research, as they relate to strength in the UK's biochemical sub-field and future growth, include:

Green Biologics – UK growth in chemicals from biological processes

- Green Biologics is a renewable chemicals company focused on developing and delivering new green alternatives for everyday products. It aims to provide sustainable and high value products using petroleum-based alternatives for the global chemicals market.
- The company has expertise in advanced Clostridium microbial fermentation, using a technology platform that converts a wide range of sustainable feedstocks into high value green chemicals including n-butanol, acetone and, through chemical synthesis, derivatives for downstream formulations.
- Green Biologics is a global leader in Clostridium microbial technology whose leadership team has more than 175 years combined experience in Industrial Biotechnology, chemicals and process industries.
- Over the last 14 years the company has grown significantly. In 2012 it merged with one of its main competitors, Butylfuel™ Inc. and expanded into the US market, which led to the acquisition of Central MN Ethanol Co-op LLC in 2014. This brought with it a 21 million gallon per year ethanol plant which has now been repurposed by Green Biologics to produce bio-based normal butanol and acetone.

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[50] IB-IGT, *"IB 2025 – Maximising UK Opportunities from Industrial Biotechnology in a Low Carbon Economy"*, 2009.

- Green Biologics headquarters are still located in Abingdon, UK but the company has executive offices and facilities in the US, as well as satellite offices in China, Brazil and India.
- Since its conception Green Biologics Ltd has raised over $40 million in equity financing from investors and venture capital firms. Initially, substantial support from UK investors, particularly angel investors in the sector, and further support from UK based investors such as Oxford Capital Partners, the Rockley Fund and the founders of Oxford Instruments.
- Within the past decade (since 2006), Green Biologics has been awarded 18 projects by Innovate UK, with a combined investment of £2.8m covering several sectors, with seven in Health and Life Sciences, nine in Manufacturing and Materials and one in Infrastructure Systems.
- Green Biologics has received investment and support from other UK initiatives including Infrastructure UK grants (now a part of the Infrastructure and Projects Authority), Patent Box the IB Catalyst, and KTP awards.
- At scale, Green Biologics now relies on investors from outside the UK to maintain and expand its business model (France, Belgium and Hong Kong).
- The European Union has provided funding in the past that has greatly benefited Green Biologics, such as through the ERANET and Horizon 2020 Project funding programme. There is uncertainty about the relationship between European and UK researchers over the coming years and it is desirable for Green Biologics that the UK models Switzerland's or Norway's relationship models which allow them to be part of research partnerships through associate status.
- In the foreseeable future, Research and Development arms of Green Biologics will primarily remain in the UK. However, manufacturing in the UK seems to have limited prospect since the UK is not a large-scale producer of necessary feedstocks and cost of production will consequently be higher than in certain other locations. For this reason, Green Biologics currently operates in Minnesota as these resources are readily and cheaply available and in the future, will likely explore the Northern US states, Brazil or Malaysia.
- The UK is insufficient in size to meet the scale of demands for readily available raw materials in this manner. Despite these limited operational opportunities, the UK will remain as the head-quarter and intellectual hub due to the aforementioned benefits.

3.3.2 Biologics

Biologic medicines were a second field commonly cited by industry, academic and government stakeholders as a high growth emerging sector. BBSRC's June 2017 'Bioscience Facts & Figures' highlights:

- Biologic medicines are projected to make up 15% of New Active Substances to become available between 1996 and 2020.
- Monoclonal Antibodies (MABs) and human insulin underpin much of the growth in biologics, with four out of the world's top five biologics in 2012 being MABs.
- Biologics are expected to improve the treatment of various autoimmune diseases, with spending in this area expected to reach $75-90BN by 2021.

A 2017 white paper by Quintiles IMS[51] evidences biologics as a growth market globally, with a c.70% increase in revenue between 2011 and 2016 to $232bn.[52] Growth in biologics has increased more significantly than the small molecules market, despite several small molecules 'blockbusters' in the areas of hepatitis and oncology. According to the White Paper, within the next five to ten years the biologics market will go through a period of rapid maturation and transformation including five key market trends:

- Biologics entering non-traditional biologic disease areas. Biologics are entering therapy areas where they have not been present historically, such as asthma, dyslipidaemia, and allergy. They will expand treatment options for patients in these indications, many of which are underserved. Collectively these are important areas for future biologic growth, but will also present challenges of market creation.
- Disruptive drugs and technologies. The number of novel biologic molecules approved by the EMA and FDA has surged since 2013. In 2016 50% of FDA new chemical entity approvals were for biologics. This period of high biologic innovation output will bring drugs that will compete with and expand the current biologic market.
- Biologic asset revaluation. The biologic model, both in pre-commercialisation and commercialisation, is now well understood and proven effective. Confidence in the growing role biologics are playing in the pharmaceutical market is impacting acquisition trends.
- Biosimilars. Soon the largest biologics will face biosimilar competition in all major markets which will put downward pressure on prices and make markets more competitive on one hand, and expand the overall size of the biologics market on the other.
- Competition and market environment. While previously many new biologics were first-in-class, now many biologics are entering the market competing with the same mechanisms of action, increasing the ferocity of competition. As payers find they have increasing choice in many areas, such as autoimmune, competitive dynamics for biologics increasingly resemble those of mature small molecule areas and payers place pressure on prices.

By 2025, the global biologics market is expected to grow to $400bn. While biologics is clearly exhibiting a growth trend, there is less certainty about the UK's potential competitive advantage. A new £38m National Biologics Manufacturing Centre was opened in Darlington in 2015 to help boost the commercial potential of UK Biologics. The Cell and Gene Therapy Catapult also looks to support researchers and industry in turning early stage ideas into commercially viable projects.

There are sizeable biologics businesses within the UK industry base, including Fujifilm Diosynth Biotechnologies and Amgen. In 2016 Fujifilm Diosynth employed c.500 staff and generated turnover of c.£55m in the UK.

[51] Quintiles IMS, 2017 White Paper "Disruption and maturity: the next phase of biologics", Quintiles IMS
[52] QI MIDAS MAT Q2 2016; LCUS$ used for growth figures.

3.3.3 Marine biotechnology

Advances in science and technology are providing new insights into the diversity of life in the oceans, and contributing to an improved understanding of marine bio-resources. As knowledge of these resources increases, it is becoming clear that the biodiversity of the ocean offers manifold possibilities for development and exploitation. Marine biotechnology may also deliver innovative food production systems, new sources of renewable energy, and products for health and wellbeing. Marine biotechnology has applications in sectors such as energy (algal biofuels), pharmaceuticals (novel antibacterials) food (e.g. genomics of major fish food species) and chemical industries. As a result, marine biotechnology is now being integrated into national bioeconomy and innovation strategies internationally. The IB-IGT 2009 report highlighted that marine biotechnology, and particularly marine-derived resources should have a critical role to play in driving a bio-based economy. Yet, as is the case with IBBE more generally, the specifics of UK policy to develop the field of marine bio-technology has not materialised.

3.3.4 Synthetic Biology

In-depth interviews with representatives from both academia and industry highlighted significant potential for the UK to be a global leader in synthetic biology.[53] Several stakeholders agreed that synthetic biology as a sub-field has moved *"very quickly over the past few years, to the extent that the question that is already being asked is how quickly we can commercialise, rather than 'what is synbio'?"*.

Synthetic biology has been identified by BEIS as one of the 'eight great technologies'. RCUK's SynBio Roadmap sets out the UK's vision, and recognises that *"the UK is in an excellent place to progress synthetic biology"*, not least due to the strength of the academic base, a strong and internationally networked industrial base in synthetic biology applications, and proportionate and robust regulatory frameworks.[54] In July 2017 Synbicite – the UK's national centre for the commercialisation of synthetic biology based at Imperial College London – published research which suggests that synthetic biology *"has reached a critical mass of companies"* with comparatively low business death rates (c.76% of the start-ups founded in the 2000 – 2016 period are still active).

As has been the case more broadly within IBBE, the synthetic biology community has been self-perpetuating. However, potentially the biggest differentiating factor in the prospect for synthetic biology vis-a-vis other sub-fields of IBBE is the interest that some of the UK's leading innovation entrepreneurs are taking in synthetic biology. The list includes ARM founder Hermann Hauser, who is co-founder of synbiobeta – 'the leading community of entrepreneurs, investors, policy makers and enthusiasts devoted to the responsible growth of the synthetic biology field.[55]

Similarly, SynbiCITE believes that, *"with the right support, the UK synthetic biology ecosystem will be able to model itself on the self-sustaining clusters found in the US in Silicon Valley, CA and*

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[53] Synthetic biology is defined by the Royal Academy of Engineering as the design and engineering of biologically based parts, novel devices and systems as well as the redesign of existing, natural biological systems. - UK Synthetic Biology Roadmap Co-ordination Group (2012) "A Synthetic Biology Roadmap for the UK", Research Councils UK

[54] UK Synthetic Biology Roadmap Co-ordination Group (2012) *"A Synthetic Biology Roadmap for the UK"*, Research Councils UK

[55] See https://synbiobeta.com/person/hermann-hauser/ for more information.

Cambridge, MA.”[56] Consistent with prior discussion regarding the regional nature of IBBE, emergence of synthetic biology appears to be taking a similar form, as illustrated in Figure 3.6.

Figure 3.6 – Synthetic Biology Start-Ups by Region

Source: SynbiCITE, UK Synthetic Biology Start-Up Survey 2017

In-depth interviews suggested that, given the pace at which the synthetic biology field is moving, the most effective areas for UK government support concern i) sustainability of strong existing industry networks, ii) certainty regarding sustainability of academic skills, and iii) maintenance of a pragmatic and appropriate regulatory environment.

The current strength of the UK industry base in synthetic biology is not as easy to quantify, given the nascent nature of the sub-field, and limited data available on the relatively small businesses within it. Nevertheless, desk research presented above suggests notable business activity, among firms such as Synthace, and Shell.

3.3.5 Conclusion

- The UK has particular strength in high growth and emerging Industrial Biotechnology markets, including in the manufacture of high value chemicals, and the manufacture of recombinant biologics using new technologies from the UK’s academic leadership in genomic, systems and synthetic biology, partnered with leading multinational companies and UK-based SMEs. Therefore, the UK can be most successful where it aligns activities in IB to feedstock availability and targets high value products.

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[56] See http://www.synbicite.com/news-events/2017/jul/21/vibrant-synthetic-biology-ecosystem-has-developed-/

- Businesses producing chemicals from biological processes in the UK have shown how public and private sector support can work together to build an emerging market, and this puts the UK in a strong position to capitalise on the expanding global market for chemicals from biological processes.
- When it comes to future growth potential, the most striking opportunities are in synthetic biology and biologics, which have seen numbers of private investments trend above investments in biopharma and biotherapeutics.

4 INVESTMENT & COMMERCIALISATION

Industrial biotechnology and bioenergy is recognised as an area with considerable growth potential for the UK regarding revenue, employment, exports and GVA. The UK Government's investments have acted as a catalyst for further research and business opportunities, and this is evidenced through the expansion in UK IB revenue and GVA over the past five years.

However, encouraging public investment and support is only one part of the jigsaw for growing IBBE in the UK. With a maturing R&D landscape, it is imperative that private investment can be encouraged, supported, sustained and grown in future years; and that the UK is viewed as 'a key destination for investment in IB'. As one strategic stakeholder put it:

> *"Firms require investment to take things through from intermediate stage research to near commercial operation – in order to cross the 'valley of death' and enable investors to become more interested in pushing products over the finish line. That's precisely where the money must be provided, and isn't in place at the moment [reference to withdrawal of IB Catalyst funding across TRLs]."*

In turn, increasing the availability of private investment represents just one component of improving the UK's ability to commercialise IBBE products and processes. This Chapter discusses the challenges regarding investment in IBBE in the UK, before providing an overview of UK private sector investment in IBBE, and detailing the broader issues affecting the UK's ability to commercialise IBBE research.

4.1 The UK IBBE investment landscape

IB is increasingly recognised as a promising approach to 'overcoming the consequences of diminishing fossil resources, reducing the energy intensity of industrial processes, and provides the tools and mechanism for the development of new products that cannot be made using traditional chemical processes' (Festel, 2016). For this reason, the expansion and growth of IB in the UK is not a zero-sum game; but rather has the capacity to:

- Provide economic benefits through material cost-reduction, and thereby enhanced national productivity and competitiveness;
- Yield strong returns on investment for investors;
- Improve environmental sustainability;
- Deliver enhanced IB related production, output and thereby increase UK GDP and employment.

The BIA's publication of 'Money, Momentum and Maturity: UK Biotech Financing and Deals in 2015/16' estimates that £489m of venture capital investment was raised in 2015, compared to £323m in 2014 (+51%), and that the UK contributed to over a third of the European total. Further, UK companies accounted for 27% (£178m) of the amount raised by European biotech company IPOs in 2015.[57] The report highlights a marked trend towards 'larger financing rounds of fewer, but better positioned businesses, as investors move towards increased maturity'.

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[57] Available at: http://www.bioindustry.org/document-library/money-momentum-maturity-uk-biotech-financing-deals-in-2015-16/

4.1.1 Challenges for IBBE investment

Private sector investment in IBBE continues to face long-standing challenges, as identified in the SWOT matrix in Section 3.2, and explained in a recent Financial Times investment article:

> "*…the vast majority of investors wouldn't touch biotech firms with a ten-foot bargepole; following such high-profile flops as British Biotech, Scotia and Phytopharm…. the sector has two characteristics which formal investment analysis dislikes: incredibly specialised intellectual property and little or no cash flow. Biotechs just don't sit easily in an Excel spreadsheet.*[58]

A 2011 report by Nesta provides insight into the bespoke challenges when it comes to IBBE investment. In 'Financing Industrial Biotechnology in the UK' Nesta found that:

- The UK lacks indigenous large companies to support its SMEs with investments, partnering, training and credibility – the 'tall trees' of a healthy industrial ecosystem;
- IBBE is different from other technology investments because of the need for investment in heavy plant equipment. IB products cost much less per kilogram than IT or healthcare biotech[59], and therefore commercialisation is an expensive process (large plants can cost >£100m, and a sub-scale industrial biotechnology plant can cost c. £20m). These metrics are not conducive to venture capital investment.
- Banks are failing to meet the gap required in financing, as they are not willing to lend to early-stage IB companies (even if they are profitable) given the risk of failure to commercialise and grow;
- Commercial outcomes need to be emphasised within the relationships between academia and industry, to improve economic activity and outcomes; and
- A sustainable platform for grant availability for start-ups is essential: grant funding and R&D tax credits are needed for the growth of early-stage companies.

Six years have passed since this review, and several of the policy recommendations made by the NESTA report have been taken on board and implemented including the development of BBSRC NIBB, IB Catalyst funding (though it was later cut), and leadership of the IBLF.

However, there remain financial challenges and barriers to growth for IBBE firms in the UK, including within high growth / emerging fields like synthetic biology. The Synthetic Biology Leadership Council (2016)[60] states that financing is a large barrier for small, growing businesses. The NNFCC (2016)[61] support this argument and evidence through consultation responses from SMEs, for instance, UK Venture Capital are hesitant when it comes to investing in early phase projects as the returns are low, due to high risk and costs. SBLC (2016) report that Venture Capital is a powerful tool for synthetic biology start-ups in the US, which are backed by loan guarantee and tax relief schemes. If the same approach was taken in the UK, there could be potential for greater investment. The House

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[58] FT (2015) 'Can biotech cure investment lethargy?' Available at: https://www.ft.com/content/0bc54034-84ed-11e2-891d-00144feabdc0

[59] Nesta specifically exclude healthcare from their definition of IBBE.

[60] Biodesign for the Bioeconomy: UK Synthetic Biology Strategic Plan 2016

[61] Bio-based UK: A review of barriers and interventions needed to stimulate growth of the bio-based economy and improve UK competitiveness

of Lords (2014) also perceive limited access to finance for innovative SMEs to be a key barrier. The Venture Capital relationship to the sector is not well established, therefore it is not as beneficial for the UK compared to countries like the US or Germany. (Capital Economics 2016).

A survey of IBBE businesses completed as part of this landscape study asked whether respondents had received finance from a range of sources within the past three years. Table 4.1 below shows the responses of funding received by 46 businesses within the sector.

Table 4.1 – RSM IBBE Survey Responses – Access to Finance

Funding Type	Number of Responses	Percentage
Not received any funding (in relation to IBBE)	16	35%
Private Equity	9	20%
Venture Capital	4	9%
Seed Capital	2	4%
P2P Lending	2	4%
Corporate Venture Capital	1	2%
IPO/Public	1	2%
Angel Finance	1	2%
Asset-based Finance	1	2%
Growth Finance	0	0%
Loans/Bonds		
Trade/Export Finance		
Inward Investment		
Equity Crowdfunding		
Other (please specify)		
Innovate UK	4	9%
BBSRC	2	4%
Research Council / BEACON / EBRI	2	4%
Retained Profit	1	2%
TOTAL	**46**	**100%**

Source: RSM Online Survey (May/June 2017)

Over a third (35%) of respondents had not received any funding, either public or private in relation to IBBE activities. Twenty percent had utilised private equity and just nine percent had availed of Venture Capital investment. Respondents also recorded support from Innovate UK (9%) and BBSRC and other research councils (8%).

Whilst this is a small sample size, the results lend weight to the market view that whilst private finance has improved in recent years, there are limitations to financial investment, and the approach to funding IBBE in the UK is somewhat fragmented. Also of note is the absence of any Crowdfunding finance – a mechanism that has emerged as a common form of investment raising in other emerging / innovative sectors in recent years. Qualitative data provided in response to survey questions about investment and finance included:

- *“We need more diverse funding sources to be able to commercialise our innovative technologies.”*

- *"Financing is difficult with new technologies. Our input feedstock is municipal solid waste and this is available in the form of commercial and industrial waste but this cannot be contracted. Domestic waste can be contracted but local authorities will not invest in/implement new technologies. Patient capital is hard to secure in the UK. Government state that they would like circular economy industrial solutions, but the cross-sector mechanisms are not in place."*
- *"As a manufacturing start-up, we project to make a loss in the first three years, but there is a growing demand for our sustainable materials. There has been a lack of seed funding for us, and as the entrepreneur taking a product to market which I researched at university I have had no income while I build the business. We have only now begun to access research council funds after 6 months, but these are designed for existing businesses who can contribute match funding, rather than start-ups. If the UK wants innovative businesses to take risks and get to market, they need to be supported early with seed funding and not made to compete with existing businesses for funds."*

One respondent also felt that there were good opportunities in the UK if the ideas can be commercialised, however, the challenge lay in supporting financing further along the TRL process:

- *"There are lots of opportunities that need complete supply chain maturity and product back thinking. Any idea worth its salt will secure financial investment, however if the scale jumps, that will need better support."*

Between the online survey and in-depth interviews, several study contributors also mentioned loan guarantees, suggesting that the UK should have a similar scheme to support new businesses and fund the demonstration scale required for large scale production of chemicals. A call that has been made since the turn of the decade:

> *"The banks are extremely reluctant to lend to early-stage IB companies even if they are trading profitably, thus restricting their growth. Loan guarantees could offer a partial solution to this problem and thereby play a role in unlocking revenue growth. It would be worth exploring a nationally administered scheme tailored specifically for strategically important industrial sectors" (NESTA: 2011).*

There is clearly a need, therefore, to allay investor concerns regarding commercial capacity and to restore trust and confidence in a market which does carry inherent risks but also considerable economic and environmental rewards. Furthermore, this also evidences the need for government support to promote stability and reduce risk to help limit market volatility and over-reaction to failed pilots and trials.

4.1.2 The current state of private investment in IBBE

This study accessed primary investment data to allow for a more granular analysis of the IBBE private investment landscape.[62] The search yielded 506 investments across 171 companies between 2003 and 2017 including, for example, a £96m investment in Agrivert in 2015, a £74m investment in Green Biologics etc. The data has been cleaned and matched against UK Tracker company data to create a profile of investment in UK IBBE firms. Note: the analysis does not rely on SIC codes, but rather activity brackets and search parameters. The search criteria used as the basis of the analysis is available in Appendix 4.

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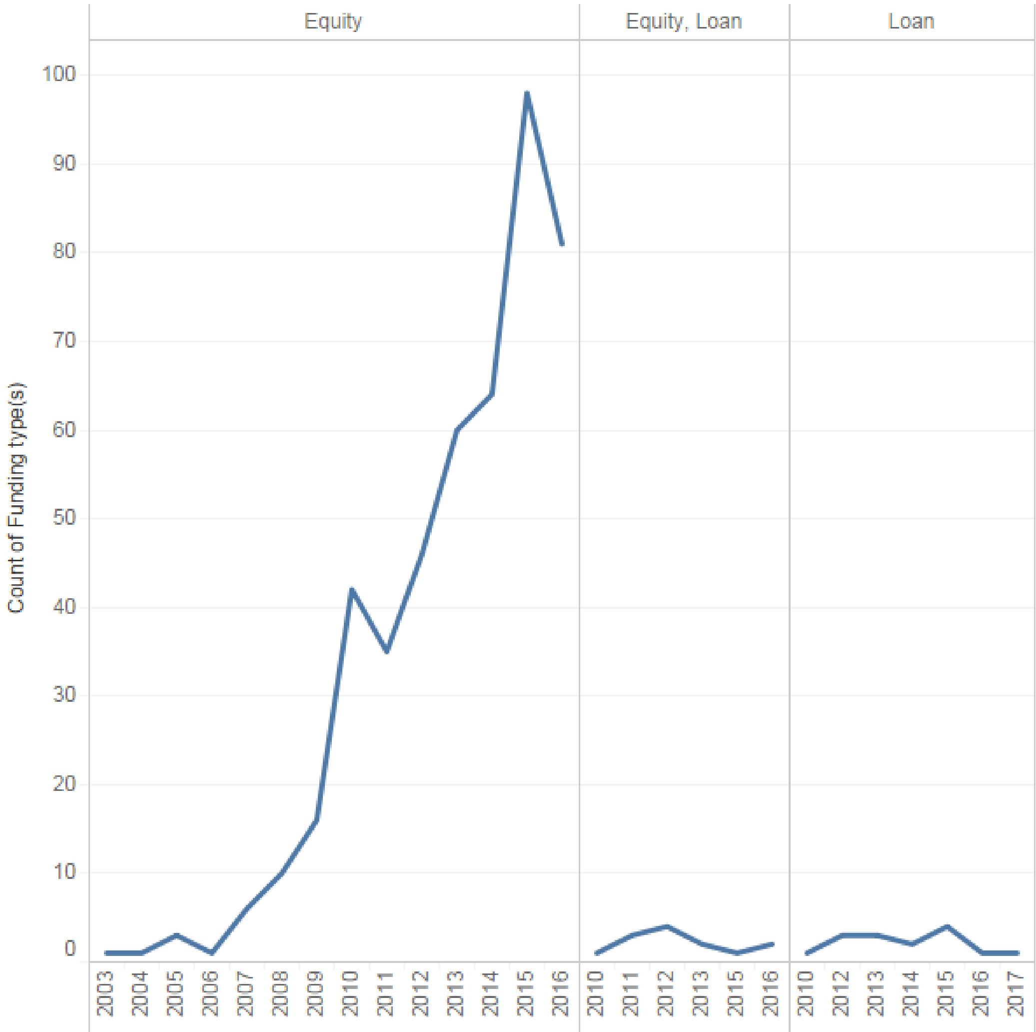
[62] Via Beauhurst, a leading UK investment research platform: http://about.beauhurst.com/

Over time, as the number of IBBE companies and activity has increased, investment has increased, providing both capital for further growth, and serving to generate positive sentiment and further interest from private investors. Figure 4.1 below illustrates the rapid growth in the number of equity investments in the sector over the past decade – more significant when considered in the context of significant economic uncertainty during the period. The data also suggests a heavy reliance on equity investment as the financing mechanism for IBBE.

Figure 4.1: Number and Type of Investments in IB (2003-17)

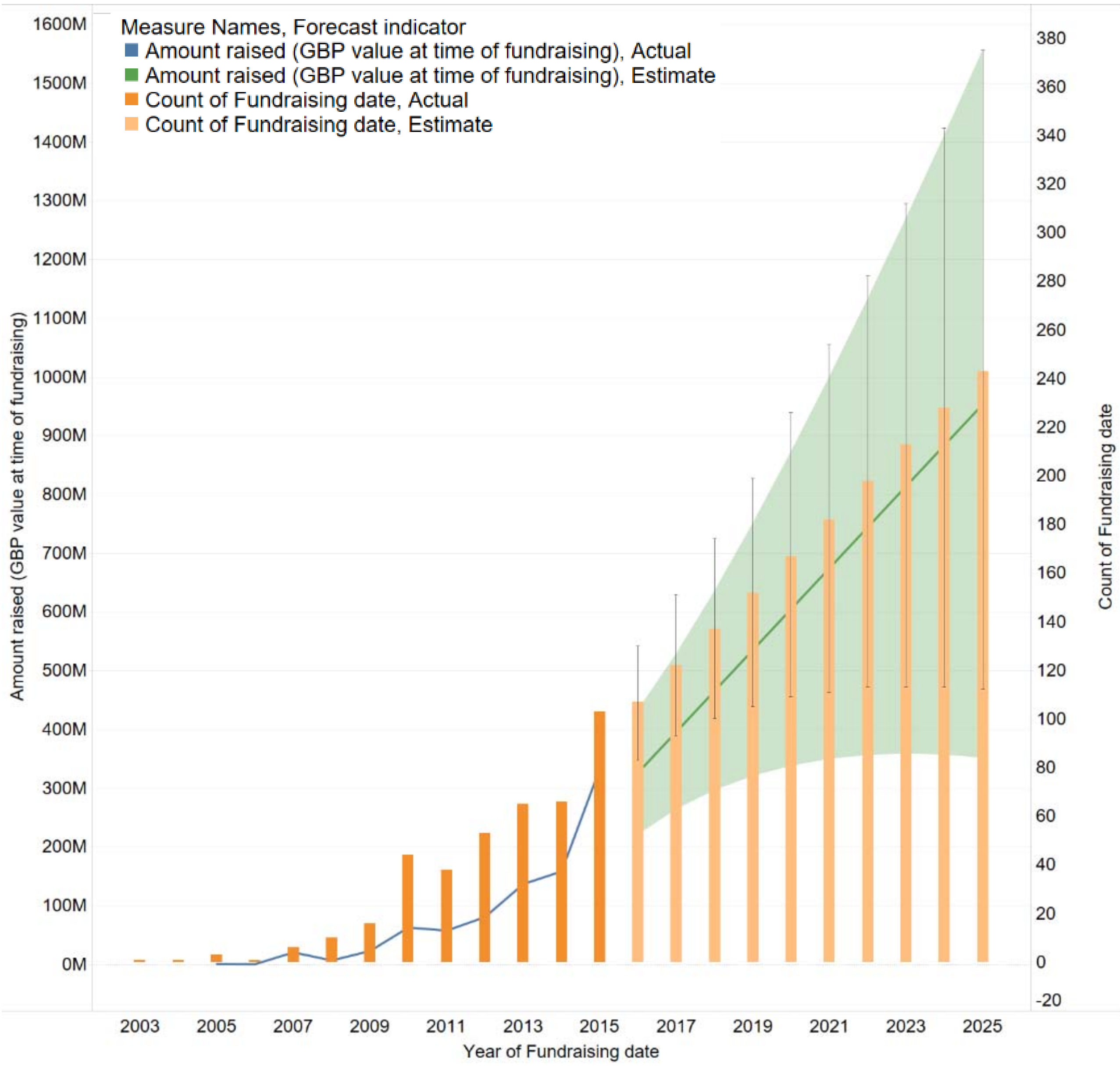


Source: Beauhurst (April 2017)

Given the growth in the number of investments, it follows that there has been considerable growth in the amount raised by IB firms in the UK from fundraising, as shown below in Figure 4.2. The figure includes an estimate trend line for IB investment (assuming comparable proportional growth until 2025 as experienced between 2005 and 2015). This suggests (at 95% confidence, based on the assumption of comparable growth) that investment in UK IBBE could reach in the region of £953m by 2025.[63]

[63] £360m (worst-case) and £1.56bn (best-case)

Figure 4.2 – Amount raised by UK IBBE firms



Source: Beauhurst (April 2017)

Between 2003 and 2017 £1Bn (£1,033,164,285)[64] was raised through fundraising. Of this, £375,266,281 (36%) of total funds raised were from companies dealing primarily in pharmaceuticals, and pharmaceutical research or reagents.

[64] GBP value at date of fundraising

4.2 Commercialisation of IBBE research

The UK is recognised as a world leader in science, technology and engineering. Close attention has been paid to how research is commercialised and innovative SMEs are supported since the early 20th Century, and yet the perception is that the UK's commercialisation report card still reads 'could do better'.[65]

Since then, the UK has undergone a number of initiatives to bring research councils and establishments, universities and wider public and private interests together e.g. through the creation of the RDAs in the 1990s, the Technology Strategy Board (now Innovate UK) with a range of programmes (including accelerators) and the promotion of innovation centres (some seven sector Catapults). Whilst these policies have resulted in some commercial opportunities, the UK is still viewed as poor at commercialising its world class science base.[66] Specific sectors such as universities and their role in commercialisation have become the focus of government research and inquiries along with the work of the Science and Technology Committee.[67]

In recent years, there has been a clearer relationship between industry, academia, and government regarding the promotion and support for industrial biotechnology in the UK, particularly evidenced through the IBLF and the BBSRC NIBB. These actively encourage the development of relationships between business and academia to tackle research problems and enhance commercial activity, supported by government policy, strategy and funding support.

For example, the IBLF offers businesses access to an overview and support in 'Navigating the IB Landscape in the UK'[68], identifying key actors across industry, academia and government, and opportunities for accessing funding, accessing facilities, and opportunities for international collaboration and trade are publicised via a combination of BEIS, BBSRC, EPSRC, Innovate UK, the NIBB and the IBLF.

> *'Strong science and flexible markets is a good combination of polices. But, it is not enough. It misses out crucial stuff in the middle – real decisions on backing key technologies on their way to the marketplace. It is the missing third pillar to any successful high-tech strategy'* (David Willetts, 2013).

Despite the criticism, OECD data suggests that, per capita, the UK performs reasonably well when it comes to commercialising IBBE research. Figures 4.3 and 4.4 overleaf present leading countries' shares of biotechnology patent applications, and biotechnology R&D spending within industry – two key indicators of strength in commercialisation.

The UK ranks sixth (excluding 28 EU country figure) by measure of its overall share of biotechnology patent applications. When considered in almost any other guise e.g. in per capita or per total R&D investment terms, it is highly possible that the UK would rank higher.

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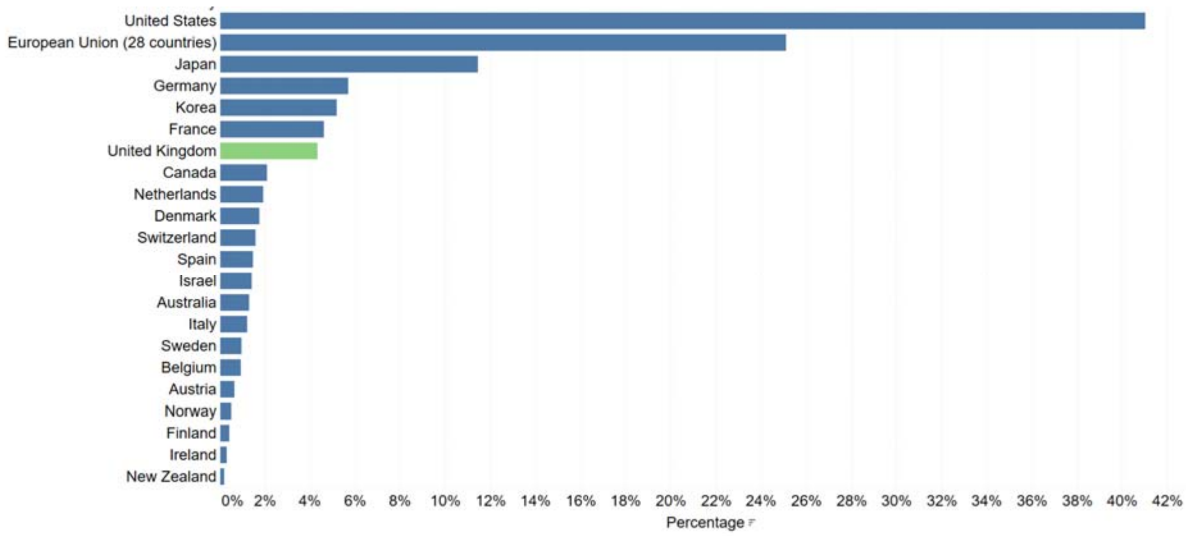
[65] Establishment of the Committee on Finance and Industry in 1929

[66] https://www.publications.parliament.uk/pa/cm201213/cmselect/cmsctech/348/348.pdf

[67] STC. Managing Innovation and Technology Transfer

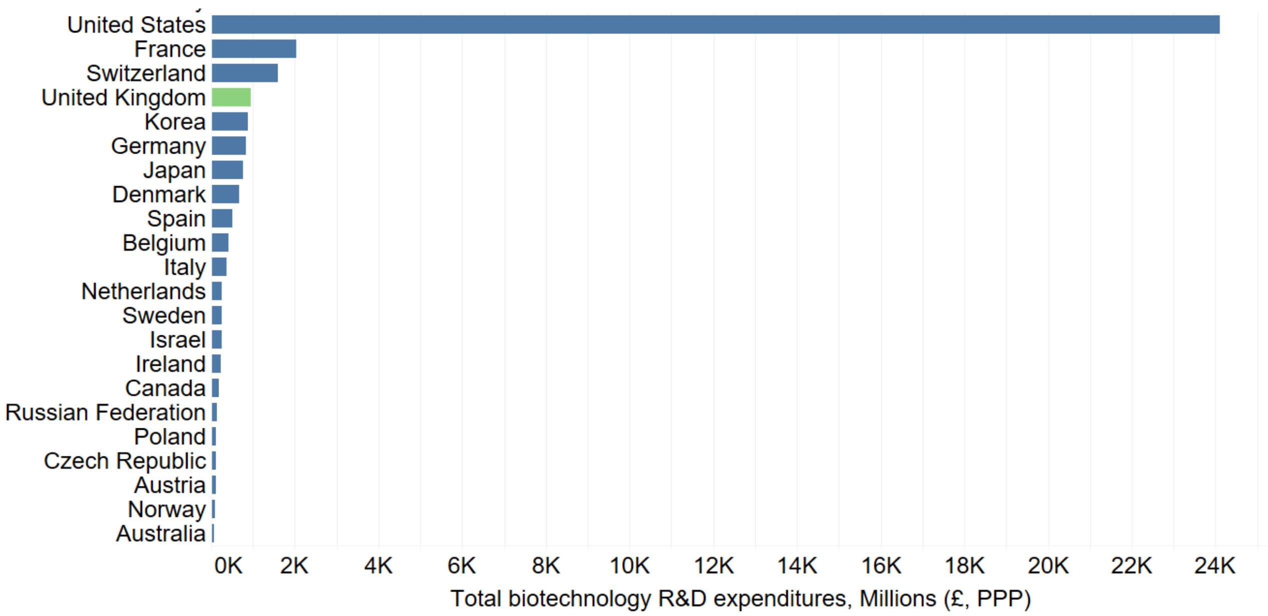
[68] IBLF, 2016: *"Navigating the IB Landscape in the UK: An Introductory Guide to Networking in Industrial Biotechnology"*

Figure 4.3 - Leading countries' shares of total biotechnology patent applications filed under the Patent Cooperation Treaty, 2014 (per cent)



Source: OECD, 2014[69]

Figure 4.4 - Biotechnology research and development expenditures in the business sector, 2014 or latest available year, £ billion



*Source: OECD *UK uses IBBE investment via Capital Economics (2015)*

[69] Biotechnology patents are currently identified using the following codes of the International Patent Classification (IPC): A01H1/00, A01H4/00, A61K38/00, A61K39/00, A61K48/00, C02F3/34, C07G(11/00,13/00,15/00), C07K(4/00,14/00,16/00,17/00,19/00), C12M, **C12N**, C12P, C12Q, C12S, G01N27/327, G01N33/(53*,54*,55*,57*,68,74,76,78,88,92)

4.3 A framework for IBBE commercialisation

This section of the report sets out a framework for how IBBE commercialisation might be best viewed, with regard to the size of firms working within IBBE and their movement along the TRLs. Finally, it will set out how government might further support and encourage commercialisation of IB research in the UK, and provide an overview of what some of the potential benefits and costs of doing so.

To put this chapter in context it is worth noting that the issues faced in the UK are similar to those in Europe and elsewhere. In broad terms the EU and other countries tend to spend a higher percentage of GDP (in nominal terms) on R&D. In the UK, the business R&D investment is just over one percent of GDP, around half that of Germany and well below the OECD average. Other countries (e.g. Germany, Japan, Israel and China) with higher levels of investment spending also focus their infrastructure and expertise on the final stages of R&D where innovation is taken forward. However, the UK has considerably strengthened its own co-innovation system. Businesses incentives through tax incentives and support for universities and public funding programmes are in place to try and address the commercialisation issues across the board. The next chapter sets out some international benchmarking on key indicators.

4.3.1 The State of Commercialisation in the UK

> *"Policy makers in several countries* ***believe that firms in their country lag behind the United States in their ability to commercialise national biotechnology research efforts****. The result has been the development of a variety of policies to encourage commercialisation. Several countries (including the United Kingdom) provide subsidies or grants to increase seed and start-up capital for small biotechnology firms, including university spin-offs and start-ups. Relevant indicators include patents and other technical know-how (TKH), venture capital investment, alliances, sales and employment."*
>
> OECD: Commercialising Biotechnology Research (2013) & Arundel (2003)

The commercialisation of research in the UK is well-recognised as a field embedded into multiple strands of national policy-making. There has been a strong emphasis on how best to support the commercialisation of academic research and promote technology transfer, given the potential for economic, social and competitiveness benefit.[70]

There are good practice examples of IBBE commercialisation in the UK, including the case of Green Biologics which can be found in full in Appendix 3.

In 2017, the recent Industrial Strategy Green Paper has set out the Government's aim to 'do more to commercialise our world leading science base', with the promise of additional funding for 'incentivising university collaboration in technology transfer' (£120m over four years) and developing a separate Industrial Strategy Challenge Fund (£23bn) to address 'historic weakness in commercialisation' building on the work of Innovate UK's IB SIG[71] .

[70] HoC Science and Technology Committee (2016-17) 'Managing Intellectual Property and Technology Transfer' Available at: https://www.publications.parliament.uk/pa/cm201617/cmselect/cmsctech/755/755.pdf

[71] https://connect.innovateuk.org/web/industrial-biotechnology/articles

Beyond funding, the Government has set an 'open door' challenge to industry to come to Government with 'Sector Deals' setting out the steps and support needed to help them promote competitiveness, innovation, address regulatory barriers and enable the commercialisation of research.

The Industrial Strategy Green Paper sets out that the UK now produces 'a similar number of spin-off companies as US universities, and more than Japan per unit of research funding; however, we fund far fewer patents'[72] (a proxy measure for the state of commercialisation) and despite the world-leading science base in the UK (at an aggregate level), the UK does not have any universities within the 'Top 10' global Innovation and Commercialisation institutions.

However, there is notable potential for better commercialisation of research in the UK, particularly considering that the UK has 1% of the global population, but 3% of global research funding, 8% of papers published, and 16% of global citations. It is a high-quality, well-respected research community. HEFCE (2015)[73] has also set out that the UK HE 'knowledge exchange' market is worth £4.2bn per annum to the UK economy, and has clear potential for growth where activities can be aligned well to a sector deal or for use by an industrial sector/interest group.

Within the past decade, there have been several interventions to address weak commercialisation in the UK; for example, the development of the Higher Education Innovation Fund (HEIF) in the university sector (especially in England), and in the field of IB, the development of the NIBB and associated Proof of Concept funds and alignment to Research Council accelerator funding has been beneficial. However, there is a risk that commercialisation in the UK focuses too much on the supply of research (i.e. funds to higher education institutions), rather than the demand for research by industry and society. As set out by the House of Commons Science and Technology Committee, without an industrial demand for R&D activities, the capacity for commercializing research is limited.

> *"Some academic research is working towards technologies that, while academically interesting, are far too expensive to fit into a standard IBBE R&D pipeline. This means IBBE funds are being spent on curiosity rather than practically useful outputs. This is not a comment on funding blue skies research, which is necessary, but on the use of funds that could be used to make viable IBBE R&D into a set of routine tasks. In effect, the only true marker of academic success in this regard is if the technology moves into the mainstream and is no longer a university exercise."*

In the past ten years, this is evidenced in the internationally weak private R&D investment in the UK, which has continually remained below 2% of GDP, as illustrated in Figure 4.5 below.

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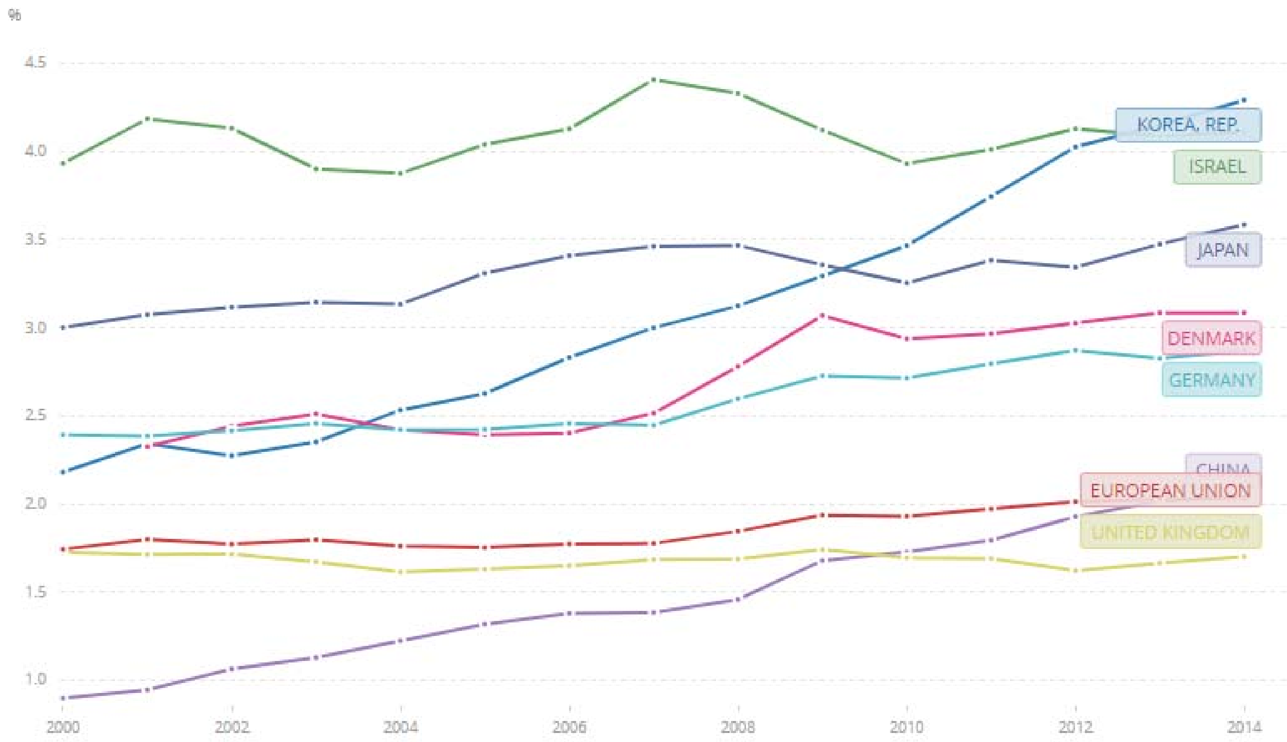
[72] Measured using: OECD (2016) Main Science and Technology Indicators
[73] HEFCE (2015) HE Knowledge Exchange Statistics (2014-15)

Figure 4.5 – R&D Expenditure as a % of GDP



Source: OECD

Therefore, commercialisation of research in the UK cannot focus solely on the activities of the HE sector, or even the extent to which universities and business collaborate, as important as that is. Rather, the success of commercialising IBBE will be reliant on the extent to which industrial partners can demand further university research that can be commercialised and that there are appropriate mechanisms to allow this to happen.

An effective framework for commercialisation will need to focus on the size and scale of IBBE firms, their capacity and appetite to absorb or mitigate risk, and an enabling public funding environment to help support the private sector (through grants, incentives, co-investment funds, R&D tax credits, tax relief on investment through SEIs, EIs and VAT, and SBRI support recognising that research can be borne through industry and not solely academia).

However, there have been improvements in the commercialisation landscape. Some of the legacy issues with commercialisation in the UK e.g. HEIs demanding large stakes in university spin-outs (up to 50% in the UK, compared to 10% in the US[74]) given the heavy lifting required in initial funding and support, are being addressed. For example, Oxford University's technology commercialisation unit established a £500m fund (Oxford Sciences Innovation) in 2015 to develop and commercialise research in the life sciences and other fields. The establishment of exploitation companies through Imperial College, University College London and the universities of Cambridge and Edinburgh have also taken place in parallel. HEFCE's funding for HEIF has also enabled c. £150m for knowledge exchange leading to commercialisation projects such as SETSquared Centres in the south

[74] New Electronics (2017) http://www.newelectronics.co.uk/article-images/150045/P18-19.pdf

east/west, which in the past ten years has supported approximately 1000 companies to commercialise their IP and raise over £1bn in funding.

To help develop the innovation eco-system and bring partners together the government has launched Science and Innovation Audits (SIAs) in key areas as part of a national initiative.

The commercialisation landscape is moving in the right direction in the UK; government is seeking to utilise the Industrial Strategy Challenge Fund to support the industrial and commercial development of key enabling technologies to improve long-term UK productivity.

IBBE is recognised as being at the heart of this approach as the UK has proven scientific strength and capacity for global influence, as well as offering considerable economic potential. It is also in a strong position with the recent development of the NIBB and their c.7,000 members, connected to help bridge the gap between research supply and demand.

However, **how funding is channelled through the Industrial Challenge Strategy Fund will be crucial for supporting the commercialisation of IBBE** along each stage of the TRLs. In consultations, the IB Catalyst funding was commended for the capacity to support IBBE research and commercialisation by reducing financial uncertainty for businesses moving up the TRL scale. However, the IB Catalyst funding scheme only lasted for 4 rounds (an announced 5th round was postponed and then abandoned) in contrast to the continued success of the Biomedical Catalyst funding scheme.

Finally, as argued by the STC and HEFCE, the *"vast majority of innovations do not begin as discoveries in academic research and the Government must be alert to, and address the needs of, the UK's broader innovation landscape."*[75]

> *"The vast majority of new technologies in the world that become commercially adopted will be devised and developed in the business world, by entrepreneurs, technology consultants, large and small businesses and in supply chains (albeit, we believe, infused and informed by university ideas and human capital development) […] we estimate that only 19% of patent application filings from [the] UK [originate in] universities."*

4.3.2 Investment in UK IB over time

Figure 4.6 details the change in number of companies receiving fundraising, as well as the type of business over time. In 2009 (pictured left) there were a total of 28 companies receiving investment. This has increased to 176 in 2016, which is six times larger than the 2009 value. It is also worth noting that BBSRC NIBB investment was made during this period of growth in investment in IB. [76]

For the companies that received fundraising; Twenty-one (12%) of these companies were growth, 72 were seed (41%), and 58 were venture (33%). Just 14% are now either dead or have exited (14%).

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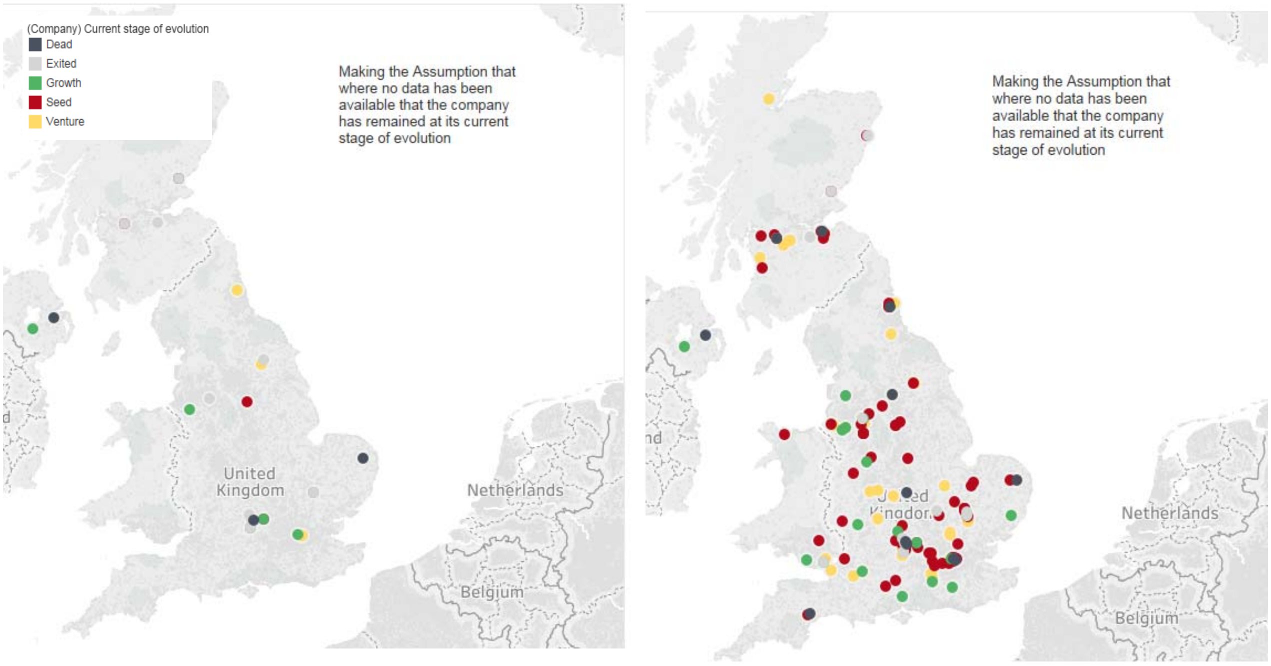
[75] Ibid, Reference 69

[76] As outlined in the BBSRC Vision and Strategy for IBBE (2012/13)

Figure 4.6 – IBBE fundraising comparison (2009 vs 2016)



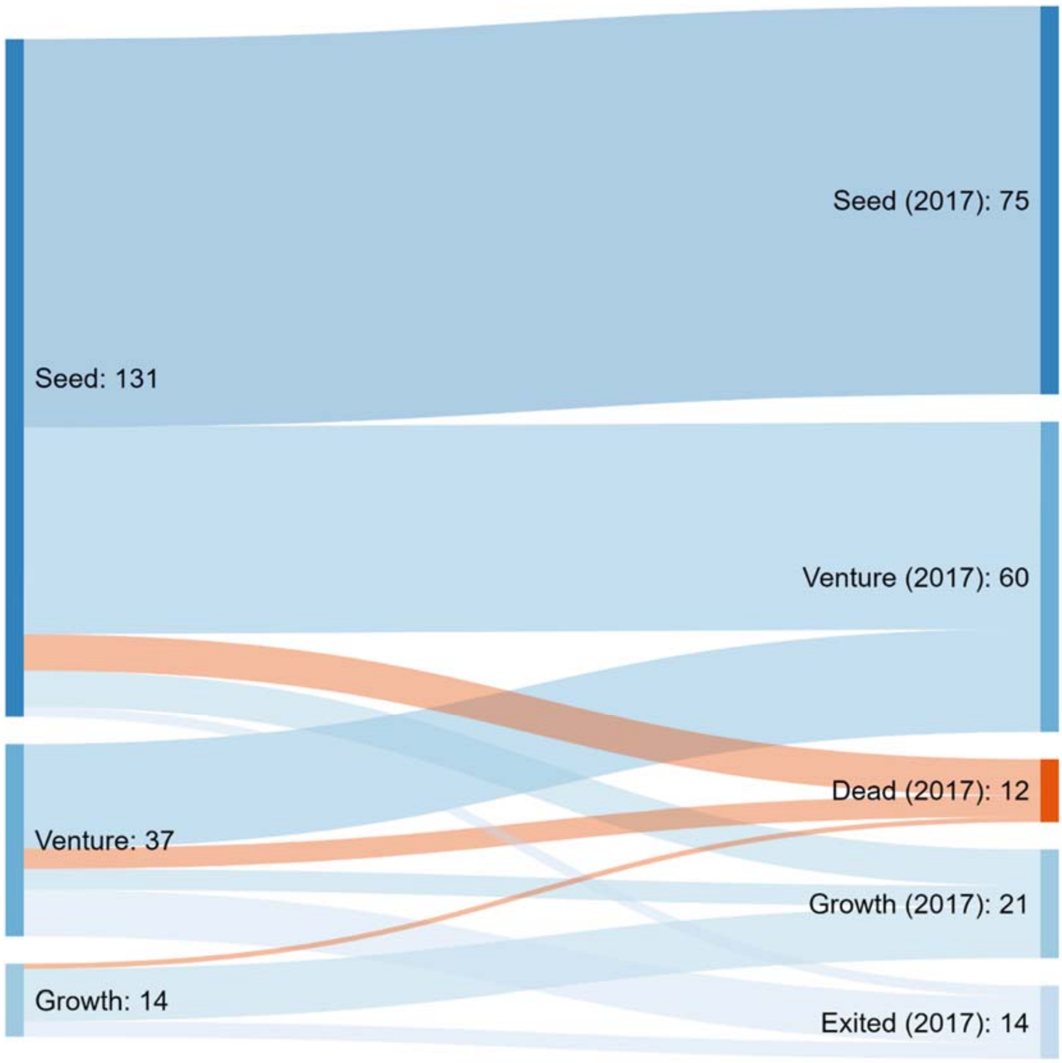
Source: Beauhurst (April 2017)

Figure 4.6 above indicates the stage of business evolution for all companies at each instance of fundraising. The graph shows that consecutively between 2009 and 2017 the most common stage of business evolution is “seed” i.e. firms seeking funding to get their businesses started, typically via angel investors. Overall this accounts for 50% of all instances of fundraising, with an average investment of £900,000.

The second largest stage of evolution is “venture” (smaller businesses seeking funding to upscale their businesses), which accounts for 37% of all fundraising records, with an average investment of £2.6m.

The remaining instances of fundraising have all been for “growth” companies. Instances of growth companies receiving funding has increased consecutively between 2009 and 2017 from 1 to 27 instances with an average investment of £7.7m. There exists both challenge and opportunity for the UK in how it best ensures these companies can maintain and sustain continued growth, employment and best exploit commercial opportunities.

Figure 4.7 – Stage of evolution



Source: Beauhurst (April 2017)

Whilst "growth" investments have increased considerably in the last three years, this also sits against a backdrop in which seed capital investments have also risen, indicating an increased demand within the UK for investment in new IBBE firms. This offers a big opportunity for the UK: how does it best encourage enhanced private seed, venture and growth investment; and how can these investments be best allocated towards moving IBBE firms along in evolving, and promoting commercialisation and export growth?

> *"We have some world-class science in the UK, and it probably won't take much in the way of positive progress to change the market's perception of this sector. I believe we are on the cusp of some extraordinary breakthroughs in the UK and I am very excited about the long-term value opportunity."* (Neil Woodford, Woodford Investment Management)[77]

[77] Woodford, N (2014): Quoted in Telegraph - http://www.telegraph.co.uk/finance/personalfinance/investing/funds/11109260/10000-into-31000-in-three-years-Can-the-

4.3.3 UK exploitation of IP

There is little readily available data on the extent to which IP (in its different forms) and know-how that is generated in the UK is exploited overall and in specific sectors, including IBBE. There is a general view that much IP is not fully exploited directly through platforms, products, processes and services. Hence public expenditure is spread across the different stages of R&D and IP development (as potentially reflected in TRLs). However, the take up of R&D tax credits, and other incentives amongst start-ups and smaller businesses in particular is relatively low.

According to the Wellcome Trust (2014)[78], UK academics are 'half as likely to patent' as their US counterparts, with a third stating their patent decision is due to 'driving their grant or career' rather than seeking a commercial outcome. There is clearly therefore a gap between how the UK seeks to commercialise its research in areas such as IBBE, and its traditional performance.

Government policy is to increase investment in R&D significantly by 2020-21 (by 20 percent) with a focus on key technologies (such as energy, bioscience and biotechnology) and on Challenge and accelerator funds (through Innovate UK, research councils and universities) and the Catapult programmes. In universities, there has been an increase in spin-outs and licensing in the sectors above with links to medicine, health and engineering.

The above trends recognise issues faced and seek to address, in part, some of the key IP issues related to financing and research exploitation processes, particularly at later TRLs. Specifically, increased funding by the public sector combined with private sector incentives will increase the overall R&D in different stages. The steps to accelerate exploitation will help underpin all stages from POC/POM to validation prototyping and market readiness.

The increase in funding and its focus should help to stimulate collaborative research initiatives and put greater emphasis on partnership arrangements to help secure public and private venture funds. For example, there is already significant development in collaborative and contract research between businesses and universities and the engagement of investors in growing university spin-out activity.

4.3.4 Contributor perspectives on commercialisation

Ranga and Etzkowitz (2013)[79] set out that the Triple Helix system offers the best way of examining the relationship between how universities, industry and government interact and contribute to national innovation and economic development. The Triple Helix system composes i) components (institutional assets of university, industry and government including actors ii) relationship between these components (e.g. networks and leadership), and iii) functions (processes including knowledge, innovation and consensus spaces).

The Triple Helix provides a useful framework for assessing commercialisation of IBBE in the UK. There has been a clear appetite within the sector for an inclusive and communicative approach between these three components. RSM asked study contributors which component they were most closely aligned to, and their thoughts on how industry, universities and government could work better together to improve the performance of the IB sector.

Biotech-Growth-trust-keep-rising.html

[78] Wellcome Trust (2014) 'The UK's innovation ecosystem'

[79] https://triplehelix.stanford.edu/images/Triple_Helix_Systems.pdf

Data was collected from over forty strategic stakeholders via in-depth telephone interviews and online survey responses to test the hypothesis that the UK underperforms when it comes to commercialising IBBE research, and to identify practical measures across the Triple Helix that could be taken to improve IBBE commercialisation. We asked:

- *How effective do you think the UK is at commercialising its research in IBBE? Why do you think this is the case?*
- *What should the UK be doing differently to develop a more effective IBBE commercialisation framework in the UK? What practical steps could in your view be taken (and by whom) to improve commercialisation?*
- *What future financing and collaboration mechanisms could be tested to improve commercialisation, provide longer-term commitment by partners and / or de-risk investment?*
- *What lessons, if any, do you think the UK could benefit from other countries/regions regarding commercialising research in IBBE?*

This section sets out key findings, and some of the underpinning rationale from representatives in industry and academia.

4.3.5 Scope for more effective IBBE commercialisation

Sixty-five percent of respondents (n=46) believe that the UK is not effective in commercialising IBBE research. The paragraphs below categorise the qualitative responses that provide the rationale underpinning this perception.

Policy and strategy

- *"Declining incentives, increasingly stringent regulation and costs associated with that, misplaced perception that it is a 'mature' technology which limits investment and also may not provide accurate risk profiles."*

Commercial culture and emphasis on research supply

- *"There seems to be little incentive for commercialisation of fundamental research in universities."*
- *"There is a sense of excessive reliance upon government funding, as growth plans seem dominated by securing grants rather than commercialisation."*
- *"There is insufficient IBBE expertise in Knowledge Transfer and commercialisation."*

Lead time from research to commercialisation

- *"The time and funding to convert university research to a scaled IB process is almost insurmountable meaning that great research remains as research and never gets translated into businesses."*

Access to finance at latter TRLs

- *"Small companies struggle with the costs of patenting, and will often prefer to keep their IP a trade secret that they use in house to facilitate industry-backed projects, rather than to patent their tech and commercialise a sellable product."*

- *“Examples of promising companies going to the Boston cluster because they get investment much more easily there; It seems that we lack genuine / organic innovation 'hubs' such as San Diego, San Francisco, Boston etc. and hence lack the pool of people who have raised funds, started companies and developed ideas to the market.”*

- *“The IBBE system is still too fragmented in the UK. The funding bridges between academia and industry are insufficient, and gap between UK academia and industry is highlighted through a risk-averse research base, as evidenced by many recent IB developments occurring overseas despite UK research leadership.”*

- *“One of our biggest problems is following up on positive research that is commercially viable. We need to have larger funds available to start-up companies, and not rely on universities and research bodies to do this.”*

Economics of IBBE

- *“At present, a low oil price makes most bio-based processes uneconomic. These volatile prices make it hard to invest.”*

- *“The future for innovation is in SMEs, and these are run by people who have no spare time. Reducing the administrative load for innovation support and investment, and focusing on the scalability of technology, would both help.”*

Regulation

- *“We can do the job that needs doing (recycling urban wastes to farm land) and do so safely and to all-round benefit including financially to all parties BUT we are seriously inhibited, not by regulation (which is necessary and we approve of) but by non-science-based, over-regulation in a tick-box system.”*

4.3.6 Building a more effective IBBE commercialisation framework

When asked about the practical steps that the UK should be taking to develop a more effective IBBE commercialisation framework, study contributors made wide ranging suggestions, categorised in the paragraphs below. It should be noted that a considerable majority of responses referred to increasing the scale and timeframe of financing (>3 yrs.) – an issue discussed previously in the report and therefore not repeated here.

Encouraging a commercial culture and incentivising research exploitation

- *“Include umbrella risk to help nurture entrepreneurial skills in IBBE.”*

- *“Incentivise university researchers to invent / own rather than publish / disclose. An example of this is the money coming into academia from seedcorn. Panel reviews for the end of projects to seek out potential in industry.”*

- *“Second emerging academic talent to industry projects in the start-up phase where there are lots of problems that need solving but which are smaller than academia is used to and need to be solved faster than academia is used to.”*

Regional Focus

- *“Build on the regional strength of IBBE by including IBBE in regional business plans and move investment away from London into places where IBBE takes place.”*

Disseminate limited commercialisation knowledge

- *“Ensure that the few people in the UK with practical experience of innovation / company creation share their knowledge (sit on multiple boards). Recruit experienced innovators from US (with funding connections) to sit on multiple UK boards.”*

Allow greater flexibility on collaboration

- *"Reduce the number of partners required in collaborations. Typically, these require 3 partners, which is an extremely challenging prospect when IP is developing and the exact route to market is unclear.”*

- *“Increased support for Open Innovation approaches and new business models. The CATAPULT model can work, although perhaps needs resetting in this field as it's not as broadly successful as it could be.”*

Leveraging private sector capital and IBBE facilities

- *“Identify industrial partners with whom technology fits and provide them with attractive terms to take the technology forward. While start-ups and spin-outs are excellent showcases and should be encouraged, when they fail (which is the majority of time), the IP is often wasted when it could be offered up.”*

- *“Provide loan guarantees to build production units using first to market technology.”*

- *“More closely connected interactions between companies, large and small, with researchers to enable award winning research to be translated into returns. A UK based scale-up facility that can be used to assess processes and products to prove to sceptical businesses that it is worth the risk to branch out with the research.”*

- *“Incubation labs exist throughout the country (such as CIP). These have enormous facilities and equipment, but are very expensive to use. To encourage use these costs need to be reduced, otherwise you're just going to be targeting APIs not IB.”*

In addition, the limitations regarding access to finance set out in Section 4.1 have a knock-on effect for commercialisation. Empirical analysis of 1,541 product development projects in the US reliant on biotechnological processes has revealed that R&D projects only succeed when executives stick to their respective market niche and do not diversify too soon.[80] Such research provides two crucial insights about the biotech industry:

- Career expertise of top executives is key to successful product development
- Long lead times to commercial viability cause companies to diversify outside of their core business too soon.

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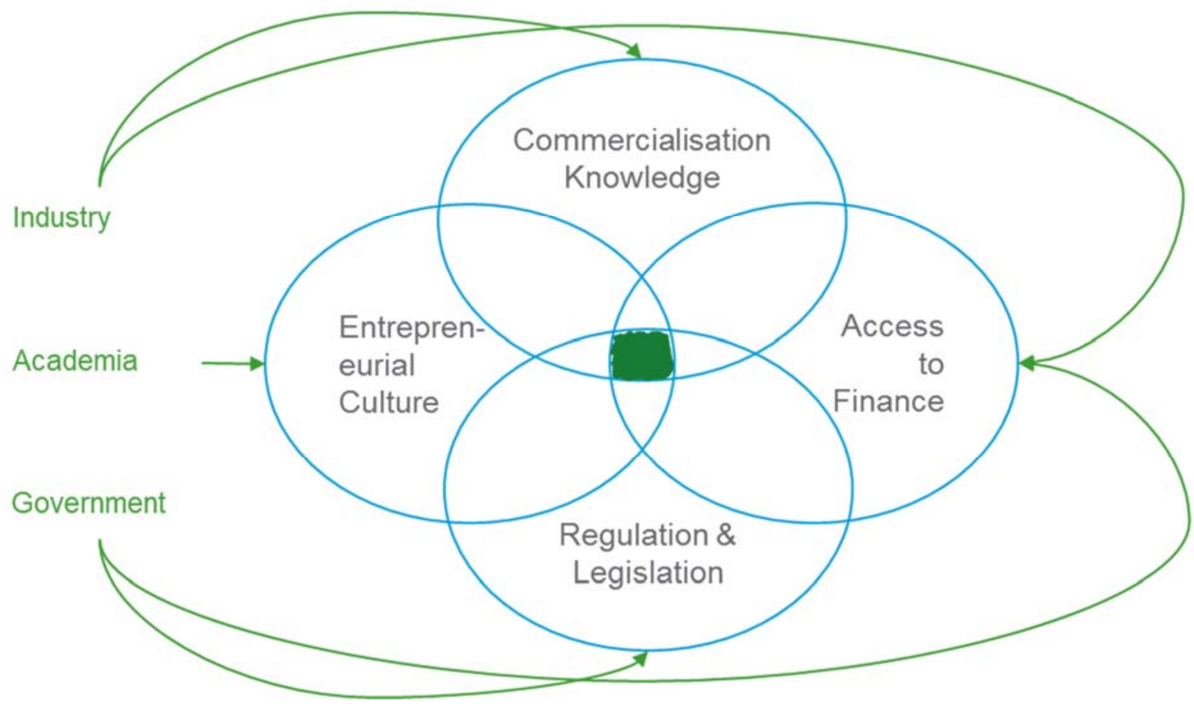
[80] Pisano, B. (2006) Science Business: The Promise, The Reality & The Future of Biotech Business

4.3.7 Alignment with existing frameworks

The issues raised by study contributors can be broadly categorised into four key areas, or priorities, namely: i) commercialisation knowledge (finance & IP); ii) Entrepreneurial Culture; iii) Access to Finance and iv) Regulation & Legislation. While nothing regarding knowledge exchange and commercialisation can be black and white, leadership, or primary responsibility for each of these priorities tends to gravitate towards a single actor from within the Triple Helix, as illustrated in Figure 4.8 below. It is also clear that the government strategy for innovation is crucial and that it needs to be coherent, consistent and continual, reflecting the long timeframe it takes for new technological capabilities to grow.

Figure 4.8 – IBBE commercialisation priorities and actors



Source: RSM IBBE Landscape Review Research

Secondary research on commercialisation suggests that the issues raised by contributors to this study are common internationally. For example, an Australian framework for the commercialisation of university scientific research identifies that Australia *"faces a greater task than most economies in developing a system and culture that encourages and promotes* [economic value] *from a system and culture in which these have not been a significant factor."*[81] The Australian framework sets out the following requirements for more effective commercialisation:

- Substantial revision to the fiscal and taxation regime that encourages research out of university and into industry;

[81] Collier, A., (2009) *"Australian Framework for the Commercialisation of University Scientific Research"*, Australian Institute for Commercialisation, 2009.

- More capital available at the earlier stages of the innovation cycle so that they progress from proof of concept through early stage development;
- A cohesive intellectual property regime that can be easily understood by researchers, capital and industry; and
- The need to develop university missions and policies that focus on commercialisation, including the recognition that commercialisation is a criterion for academic progression.

4.3.8 Good practice internationally in commercialisation of IBBE research

This study sought to identify good practice in commercialisation of IBBE research. In 2016 Johns Hopkins University was recognised by Times Higher Education as the fourth most successful university in attracting industry investment[82], and ranks 28th in the world in biological sciences[83]. The paragraphs below discuss the model used at Johns Hopkins for commercialising research.[84]

Johns Hopkins Technology Ventures (JHTV) is the intellectual property administration centre of the university. It acts as the licensing, patent and technology commercialisation office for university researchers and inventors. JHTV also supports the growth of start-up companies and works with third parties who are interested in making use of university research for academic or corporate purposes.

In its 2016 Annual Report[85] JHTV noted the following impacts it had made in the last 12 months;

- 501 invention disclosures received
- $58m in licensing revenue
- 162 licenses and options
- 153 new US patents granted in FY 2016 (an 8% increase over FY 2015) for a total of 2,454 active patents
- 22 new start-up companies
- $434m in follow up funding received by JHTV start-ups to date

JHTV has made significant investments in on-site facilities to provide entrepreneurs with the necessary space and collaborative environment to innovate, these are known as the ‘FastForward’ innovation hubs. ‘FastForward East’ hub is a 6,000-square-foot facility that offers educational events geared to start-ups; provides one-on-one mentorship; facilitates meetings with key figures, including venture capitalists; and encourages collaborations between entrepreneurs and researchers. ‘FastForward Homewood’ is another 12,000-square-foot hub that has operated at capacity since opening in 2013. The university is also investing in a new hub with 8,000 square feet of office and co-working space and 15,000 square feet of wet lab space and is also looking to relocate ‘FastForward Homewood’ to a new space designed specifically for start-ups.

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[82] Available at: https://www.timeshighereducation.com/world-university-rankings/funding-for-innovation-ranking-2016
[83] Available at: https://www.topuniversities.com/university-rankings/university-subject-rankings/2016/biological-sciences
[84] Note that JHU has a total undergraduate enrolment of 6,117, which is comparatively small compared to leading UK universities such as Oxford and Cambridge.
[85] Available at: https://ventures.jhu.edu/year-in-brief-fy-2016/#impact

In addition to providing facilities, JHTV also provides a range of services with the aim of helping start-ups to work through the stages to commercialisation. These services include:

- A Social Innovation Lab - 8 start-ups completed the seven-month program in 2016 where they received training in turning ideas into thriving ventures through funding, mentorship, space and training.
- Mentors-in-Residence - 15 experienced entrepreneurs, industry leaders and venture capitalists participated as mentors in 2016 helping to guide university staff and start-ups along the commercialisation path.
- National Science Foundation's I-Corps Program –supporting scientists and engineers to think outside of the lab and develop business plans.
- University Technology Showcase – 2-day event which attracted nearly 200 entrepreneurs, faculty members, venture capitalists and corporate executives who discussed emerging opportunities and trends within health care facilitating open dialogue and long-term relationships.
- Commercialization Academy – a program to guide students through commercialisation.
- Pro bono support from law firms to help start-ups through the legal complexities of a start-up.
- University Bootcamp for Technology Entrepreneurs - featured 16 mentors and 16 guest speakers who showed an audience representing diverse disciplines how to move ideas from laboratory to market.
- FastForward Educational Series – a series of events hosted by JHTV with 1,200 entrepreneurs in attendance with a series of events focusing on advice and hot topics within the start-up community.

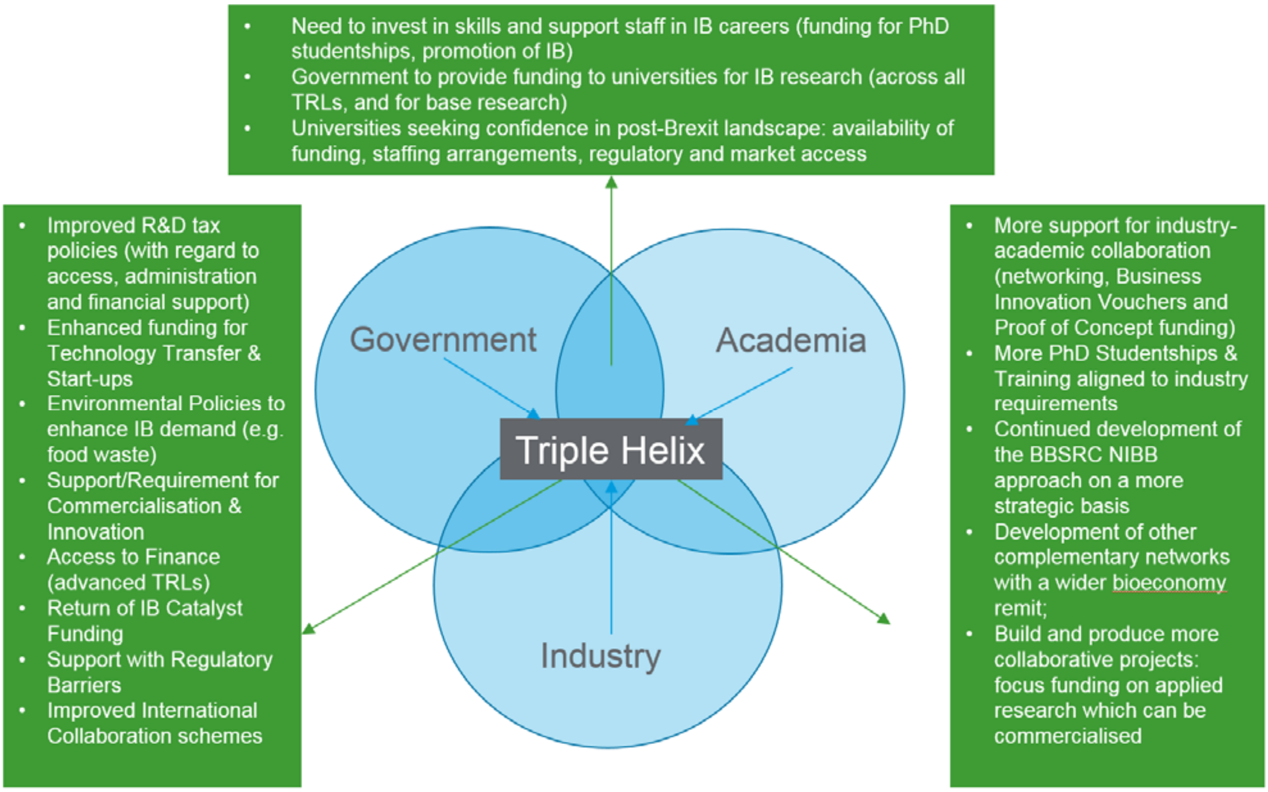
4.3.9 In summary

- The current framework for UK IBBE commercialisation is viewed by stakeholders to focus on 'higher risk, low probability' projects and, as a consequence, commercialisation of projects generated through universities can be limited given wider challenges in scale up and product development.
- One of the key reasons that UK commercialisation may be held back is that, while the current firms are well positioned to grow, the lack of a large anchor firm may inhibit overall market activity, including commercialisation of research. As one stakeholder noted: *"We don't typically attract large scale manufacturing, so we need to focus on R&D as initial step until people become prepared to do long-term investment."*
- Stakeholders welcomed (at an early stage) the work being undertaken on the Industrial Strategy, and felt that the mapping of the bioeconomy and associated assets can be useful in improving commercial outcomes through focusing minds, strategy and funding:
  - "*Our future is in the ideas. High scale production is unlikely to happen in the UK as anchor firms will a) go where the market is b) go to feedstocks (not in the UK) c) chase incentives (available in Canada, US, China etc.) and go to where costs are low. However – if we can develop technology in UK, or licencing out, at least the UK can be seen as a go to place, policy as a 'friendly place' to do business.*"

- *"UK is really strong in high value chemicals e.g. personal care, pharmaceuticals and synthetic biology."*

- Contributors to this study have put forward a range of measures that they believe can improve the effectiveness of IBBE research commercialisation. It is critical that these suggestions a) are owned and driven forward by a distinct IBBE commercialisation stakeholder group and b) that the group tasked with taking the commercialisation framework forward is fully embedded within the UK's existing knowledge exchange / technology transfer agenda.
- When asked to pose suggestions for improving commercialisation of IBBE research, study contributors identified a range of measures as set out in Figure 4.9 below.

Figure 4.9 – Measures to improve commercialisation of IBBE research



Source: RSM in-depth interviews and online survey

5 INTERNATIONAL IBBE COMPARISONS

As set out in Section 4.2, there are variations in how industrial biotechnology is defined and measured internationally, and therefore the overall size of the global industrial biotechnology market is estimated. As set out in Biotech Britain (2015)[86], there have been a number of estimates regarding **revenue**:

- In 2009, Arthur D. Little estimated global IB sales of between £35-53bn, with the UK having a 3.4% to 5.1% market share (therefore estimating UK industry revenue share from between £1.2bn - £2.7bn;[87]
- In 2011, the OECD estimated the global revenues produced using industrial biotechnology as between €50-60bn;[88]
- In 2014, EY estimated that the wider biotechnology sector had revenues of $99bn globally, of which the UK had 5.8% of the global total[89] (c. £3.5bn revenue[90]); and
- RSM (2017) analysis estimates UK IB revenues (in 2016) at £3.7bn, with GVA of £1.2bn.[91]

Given the growth of IBBE globally, governments across the world have identified that this offers capacity to grow national economies, as well as tackle increased demand for energy, food and materials in a sustainable way. However, there is variation in how different countries support and have grown their IBBE sector given the mix in resources involved e.g. finance structures, availability of land and feedstocks, national skill sets and public acceptance of IBBE. It is argued that these can be best segmented into three categories, as set out in Table 5.1 below.

Table 5.1 – Focus of IBBE supports internationally

Bioeconomy Focus	Examples
Countries rich in biomass focussed on adding value in primary industries.	Brazil, Malaysia, Argentina, Finland, Mauritius, Norway, Thailand, Indonesia, New Zealand
High prominence of energy and security issues with aim of becoming more self-sufficient.	Paraguay, Uganda, Kenya, Tanzania, Mozambique
Focus on development of high-tech industries and supporting emerging technology.	Netherlands, China, India, Australia, France, Germany, UK, South Korea

Source: Capital Economics (2016) analysis of German Bioeconomy Council[92]

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[86] http://www.bbsrc.ac.uk/documents/capital-economics-biotech-britain-july-2015/
[87] Arthur D. Little, Quantitative modelling of industrial biotechnology and renewable chemicals (Arthur D. Little, Cambridge) May 2009, p. 7
[88] Organisation for Economic Co-operation and Development, Future prospects for industrial biotechnology (Organisation for Economic Co-operation and Development, Paris), 2011, p. 10.
[89] Ernst & Young (2014) Beyond borders - Biotechnology Industry Report 2014 Unlocking value (Ernst & Young, London), 2014, pp. 37-49
[90] $5.7bn (assuming £1 = $1.60 in 2014)
[91] Analysis of 220 company returns.
[92] The German Bioeconomy Council, *The German Bioeconomy Council - Recommendations and activities on the way to the biobased economy* (The German Bioeconomy Council, Berlin), October 2013

Furthermore, strategies and polices have developed in different ways across countries. In Germany, Japan and the United States, a 'national strategy for the bioeconomy' is in place, whereas in countries such as Canada, regional devolution means this is not the case.

The UK's policy approach to date has been 'industry-based and bottom-up, similar to that of France and Italy'. (Capital Economics: 2016).[93] However, within the UK, BEIS recently launched a call for evidence for a UK Bioeconomy Strategy, indicating that the facilitation of more co-ordinated and focused policy across relevant departments, agencies and research councils is underway on a formal basis.

Many of the policy supports and strategies, particularly for nations focusing on the development of emerging development, focus on grant funding across all stages of technology readiness. For example:

- In France, €1.5bn has been committed (2015-2025) to fund the Health and Biotechnologies Programme to support infrastructure, research and training in biotechnology, and a further €1.35bn has been made available for demonstration and testing facilities for bioenergy.[94] The French government has also changed its public procurement approach to encourage contractors to utilise ecological and bio-based products in construction activities.
- In Germany, the National Policy Strategy for the Bioeconomy (2013) brings together six government ministries aligned to the bioeconomy alongside €2.4bn of dedicated funds for renewable energy, and biotechnology research.
- In the United States, in 2012 a national Bioeconomy Blueprint was published setting out five key strategic imperatives for Federal agencies to support including:
  - 1. Support R&D investments that will provide the foundation for the future bioeconomy.
  - 2. Facilitate the transition of bioinventions from research lab to market, including an increased focus on translational and regulatory sciences.
  - 3. Develop and reform regulations to reduce barriers, increase the speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health.
  - 4. Update training programs and align academic institution incentives with student training for national workforce needs.
  - 5. Identify and support opportunities for the development of public-private partnerships and precompetitive collaborations—where competitors pool resources, knowledge, and expertise to learn from successes and failures.
- One of the major industry supports has been through the USDA's Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program, which 'assists in the development, construction, and retrofitting of new and emerging technologies for the development of Advanced Biofuels, Renewable Chemicals, and Biobased Product Manufacturing by providing

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[93] Report by Capital Economics, TBR and E4Tech for BBSRC (2016) 'Evidencing the Bioeconomy'. Available at: http://www.bbsrc.ac.uk/documents/1607-evidencing-the-bioeconomy-report/

[94] Ambassade de France à Londres, Investments for the Future Programme (Ambassade de France à Londres, London), September 2015

loan guarantees for up to $250 million'[95]. Whilst the former US administration signalled formal support for the bioeconomy, there has been little to suggest that the Trump administration has similar support, and it is therefore possible R&D and federal funding may reduce in the next few years.

- The European Union has also played a significant role in the development of UK (and EU27) emerging IBBE sector, with financial support (H2020, ERDF, and ERA-NET programmes) and research and strategy development.

It is clear, therefore that with over 40 countries developing their own bioeconomy strategies and funding streams, that the UK must understand its strengths and opportunities, and put policies in place which enable its growth and competitiveness globally. This includes funding, but also setting in place an environment in which those who wish to develop a successful and vibrant IBBE sector are enabled to do so. This is perhaps best reflected in the recently elected French President Macron's statement that he wishes to *"make the planet great again"* and encourage the world's scientists to live, work and research in France. The next few years mark a significant opportunity for the UK to show a similar commitment. IBBE and the wider bioeconomy present a significant opportunity to deliver on the pledge to *"move beyond short-term thinking to focus on the big decisions that will deliver long-term, sustainable success."*

5.1 International benchmarking: selected countries

This section sets out a benchmark assessment of the UK IBBE industry compared to that of top performing and emerging competitors. We have selected the following countries to highlight where the UK performs well, and where it can draw lessons from other nations: USA, Denmark, Netherlands, Germany, Canada, Brazil, Malaysia, and South Korea.

5.1.1 Country: USA

Overview of IBBE sector

Large investment in production capacity, innovation research and development, and employment training mean that the US is likely to lead the growth in the industrial biotech industry (Between 2010 - 2015 investors pumped $9.2bn into industrial biotechnology – primarily in renewable chemicals and biobased polymers. Fifty-seven percent of this investment came in the form of venture capital).

Half of the states have one or more publicly supported seed or venture fund that can invest in bioscience related companies, with 5 states having funds exclusively for this purpose. Thirty-five states have at least one IBBE networking or trade association, reinforcing the assertion that IBBE is a truly regional sector.[96]

Several US States have adjusted tax policy, including R&D tax credits, investment tax credits, capital gains cuts, net operating loss provisions, and tax credit transferability.[4]

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[95] Available at: https://www.rd.usda.gov/programs-services/biorefinery-renewable-chemical-and-biobased-product-manufacturing

[96] Bagchi-Sen, S. Lawton Smith, H., and Hall, L (2004) The US biotechnology industry: industry dynamics and policy, section 2.3: The regional infrastructure for the biotechnology industry

Key lessons for the UK

The US is clearly somewhere the UK could learn from as the Industrial Biotechnology market has been, and is set to continue, growing rapidly. A significant factor is suggested to come from the encouragement of networking schemes to put investors and people within the industry together, as well as the government support.

5.1.2 Country: Malaysia

Overview of IBBE sector

In 2005, Malaysia established its National Biotechnology Policy (NBP) aiming to turn biotechnology into a key economic driver, aimed for 5% of GDP by 2020.[97] It is Malaysia's ambition to be a 'world leader in biotechnology'.

However, by 2009 there were no notable IBBE firms in Malaysia, despite the government previously outlining successes in the industry to occur by 2005 these did not materialise. However, in recent years, the sector has started to emerge, and by 2014 has encouraged several global biotechnology firms such as US based 'Glycos Biotechnology' to locate in the country, across a number of new bioparks.[98]

The more recent success in Malaysia is viewed as being the result of a commitment to a long-term strategic plan for the sector. Having built capacity in a first stage (2005-2010), the strategy then focussed on taking science to business i.e. commercialisation (2011 – 2015).

At a practical level, the state's investment in several 'plug-and-play' concept bioparks (including purpose built office space, auditoriums, shared laboratory space and centralised facilities).

Perhaps more significantly, Malaysia has established a strong IP protection regime (one of few countries in the region that has set up specialist courts to address intellectual property matters), in addition to low operating costs.[99]

Key lessons for the UK

A key lesson to take from Malaysia is that a long-term strategy needs to be taken to build the business over time. By building the infrastructure that the business needs, and provided a guided outline, these policies produce the motivation needed for innovative behaviour in R&D individuals.

Sahrom et al (2016)[100] find that in the Malaysian case, the effects of tax breaks on the production of biotechnology to be insignificant, suggesting that the long-term planning and implementation of building infrastructure and businesses is more important. They also note that the centralisation of the process of fund provision in Malaysia allows for coordination of large scale investments. However, as noted in the section on the US, this can be counterproductive to innovation, where

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[97] Malaysia Annouces "New" National Biotechnology policy (http://www.ita.doc.gov/td/health/malaysia_biotech05.pdf)
[98] Natalie Heng (2014) Malaysia's biotech landscape finally starting to emerge (http://www.thestar.com.my/lifestyle/features/2014/11/13/malaysias-biotech-landscape-finally-starting-to-emerge/)
[99] Sahrom, N.S., Tan, C.L., and Yahya, S. (2016). Regulation, incentives and government policy: How does it stimulates R&D engineers' innovative behaviour in Malaysia biotechnology SMEs? Asian Academy of Management Journal, 21(Supp. 1), 49–73. http://dx.doi.org/10.21315/aamj2016.21.supp.1.3
[100] ibid

firms can benefit from being investable rather than continue to drive product development on a sustainable basis.[101]

5.1.3 Country: Germany

In Germany, Federal Government Support is strong, and central government has set out a clear growth plan ("Germany to host the economically dominant bio-based products of industrial biotechnology, with the greatest long-term growth rates, include biotechnologically manufactured fine and special chemicals, in addition to antibiotics for the pharmaceutical industry, with an estimated market value of €20bn".)

Overview of IBBE sector

Like the UK, Germany is well recognised as having considerable expertise in biotechnological research, with a workforce (when compared to other countries) that is highly educated in this sector. However, also similar to the UK, there is untapped potential in terms of the application of research expertise for economic benefit. It is estimated there are 600 dedicated biotech companies in Germany, which means this industry is still relatively small and SME dominated. In 2015, national revenue was estimated at EUR 3.4bn (similar to the UK's £2.9bn) with investment of EUR 1bn[102]. Germany is ranked number one within the European Union for KETs enabled employment and enabled level of production in industrial biotechnology[103]. Additionally, these companies normally act as suppliers, rather than 'to-market providers', and it is argued that this produces lower risk but does offer fewer export opportunities[13].

The Federal Government has dedicated EUR 100 million for projects which foster innovative industrial biotechnology processes and products, and have outlined a clear path for growth in this industry.[16]

Key lessons for the UK

Having an educated workforce, and good regulatory standards are not enough to produce a larger market as funding chains are needed. For example, in Germany it is difficult to raise the venture capital needed for these projects, due to the tax regulation that discriminates against equity finance in comparison to debt.[104] In fact, the secondary research suggests that Germany is experiencing the same challenges as the UK. However, the UK should continue to follow the example that Germany has displayed by dedicating funds specifically toward IBBE, as in this area specifically they have shown great progress.

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[101] As discussed in Bagchi-Sen, S, Lawton Smith, H. Hall, L (2004) The US biotechnology industry: industry dynamics and policy, section 2.3: The regional infrastructure for the biotechnology industry

[102] Acatech Impulse (2016) Innovation Potential of Biotechnology. Note that this does not necessarily convert directly to the industrial biotechnology sector (given definitional constraints). (http://www.acatech.de/fileadmin/user_upload/Baumstruktur_nach_Website/Acatech/root/de/Publikationen/Stellungnahmen/IMPULS_Biotechnologie_EN_KF_final.pdf)

[103] European Commission (2015) Key Enabling Technologies (KETs) Observatory

[104] Ibid, reference 101

5.1.4 Country: Denmark

Overview of IBBE sector

The EC's Key Enabling Technologies (KET) Observatory ranks Denmark as top in Europe for all three dimensions in industrial biotechnology: production, trade and technology.[105]

One of Denmark's strengths is the long-term commitment to industrial biotechnology with regard to policy and funding, which helps to build confidence in the domestic markets. Additionally, the government have recognised the need for a solid infrastructure and supported the building of such infrastructure.[106] Historically Denmark has also led the way in terms of local and sustainable integration of companies, local authorities, and residential facilities with the Kalundborg, industrial zone near Copenhagen an example of this.

The Danish Government is actively taking measures to prepare Denmark for the pull towards biofuels, and ensuring that Denmark is the leading provider of research, technology, and know-how by supporting the testing and market maturation of biobased products – also promoting schemes to reduce the cost of producing biomass.[107]

Interestingly the government does not have a specific biotechnology strategy, rather, they include this within the broader policies of growth, innovation, and environment. Denmark has wide inter-ministerial cooperation in tackling these topics and some panels do make specific statements and recommendations surrounding biotechnology.[108]

Key lessons for the UK

Developing a long-term plan to make growth in the industry possible is key, in Denmark companies expect the price of taking biofuels to market to reduce, and feel they will have support from the government in continuing development. Clearly this provides the framework for producing a large industry (as Denmark has for industrial biotechnology).

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[105] European Commission (2015) Key Enabling Technologies (KETs) Observatory (https://ec.europa.eu/growth/tools-databases/kets-tools/sites/default/files/deployment_data/composite_indicator/kets_composite_indicator_industrial_biotechnology.pdf)

[106] Nordic Council of Ministers (2016) State of Play: Bioeconomy strategies and policies in the Baltic Sea Region countries

[107] The Danish Government (2013) Denmark at Work: Plan for Growth for Water, Bio & Environmental solutions (https://biobs.jrc.ec.europa.eu/sites/default/files/generated/files/policy/Denmark%20Plan%20for%20Growth.pdf)

[108] Ibid, reference 105

5.1.5 Country: South Korea

Overview of IBBE sector

South Korea is recognised as world leader in R&D expenditure (c. 4-5% of GDP) and innovation. The South Korean President has pledged to support the launch of 100 globally competitive biotech start-ups by dedicating a fund that allocates KRW80 billion (USD$67.62 million) to supporting them.

South Korea has also implemented the creation of an R&D centre tailored to early-stage companies, financial incentives, and programs to support exports and international expansion. Further, this is supported by a strong system to protect IP and the recognition of the importance of a close working relationship between universities and business early on – encouraging commercialisation[109].

A large comparative advantage for South Korea is its early adoption of a strong system to protect intellectual property, thus making it a logical hub for businesses trying to operate in Asia. Additionally, South Korea also recognised at an early stage the importance of nurturing close working relationships between universities and the business sector to encourage commercialisation.

Key lessons for the UK

Subject to EU negotiations, there may be scope to tailor the level of IP protection to encourage businesses to see the UK as a European base.

5.1.6 Country: Brazil

Overview of IBBE sector

Brazil implemented the world's largest biomass-to-energy program in 1975 as a reaction to 1973 oil crisis – promoting the production of ethanol from sugarcane.

There is a concentration of biotech activity in the south-east of Brazil, with 22.5% of companies in agri-biotech, 21.1% in materials, 18.3% in animal health, 16.9% in human health, 14.1% in environment, and 4.1% in bioenergy[110]

Key lessons for the UK

Forming these "hubs", or technology parks, allows the smaller companies to grow both through the support, as well as the collaborative nature, that they provide. With SMEs being a significant part of what builds up the industrial biotech industry it's clear that the UK could follow suit and provide central hubs of biotechnology.

Learning from the weaknesses in Brazil's policy, the UK should ensure that there is a good level of cooperation in both the micro (inter-ministerial) sense, as well as the macro (global) sense, to ensure that the outcomes of the policies are maximised.

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[109] Pugatch consilium (2016) Building the Bioeconomy in 2016 Annex: Enabling Factors and Economy Case Studies, pg. 42

[110] OECD, Brazil's biotech initiatives (https://www.oecd.org/sti/biotech/46381658.pdf)

5.1.7 Country: Netherlands

Overview of IBBE sector

Port of Rotterdam is the main actor in worldwide distribution, logistics and storage of biomass[24]. The Netherlands has strength in the chemicals sector. It is a location for 19 out of top 25 global chemical companies, including BASF), and its cluster approach to supporting IB has delivered strong employment (c. 5,000 jobs) and 18 biorefineries and plants.

The responsibility of the biotechnology sector is shared by several ministries, and all new applications of biotechnology must be assessed and approved by the government (however they do say that the only reason they wouldn't approve it is if it caused damage to humans, animals, or the environment).[111]

Strengths/Areas of Comparative Advantage

World class knowledge of the field due to the expertise of Delft University of Technology and BE-BASIC's high level of research on industrial biotechnology. They have several shared pilot facilities to allow for testing upscaling abilities etc. without the financial burden of setting up a whole lab. Further, they have an established and strong chemical sector[112] (although there are some questions about the future of this due to the increased competition coming from South East Asia) and the country is seen as a leader of responsible, sustainable biotechnology within Europe.

Policies in place to support IB

Recognised industrial biotechnology as one of the top nine sectors which have the potential to stimulate the Dutch economy. There are several networks in place to help build the industry. Additionally, they have funding that comes mainly from a combination of public and private funding through top sectors frameworks (e.g. BE BASIC has EUR45 million, EUR8 million coming from Dutch govt.)[113]

The government provides many types of support to R&D, e.g. they invested EUR120 million in 2013 for biomaterials.[114]

Although their policy is not significantly different to other countries there does seem to be a tendency for them to implement it ahead of others, however it is possible that the industry is held back by unexpected policy changes and a lack of strong public support.[29]

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[111] The Netherlands Ministry of Housing, Spatial Planning and the Environment (Undated) VROM policy and granting of permits (https://webcache.googleusercontent.com/search?q=cache:Bj3DvgqmKYMJ:https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/brochures/2010/11/25/biotechnology/11fs2007g317-200761-174047.pdf+&cd=5&hl=en&ct=clnk&gl=uk)

[112] 10 Reasons Why West Holland is the Hotspot for Biobased Industry (http://www.visiekrimpenerwaard.nl/wp-content/uploads/2016/12/InnovationQuarter-Infographic-Biobased-Industry-042016-ENG-4-pages.pdf)

[113] BIO-TIC (http://www.industrialbiotech-europe.eu/map/the-netherlands/)

[114] Biomass Research and Food & Biobased Research (2016) Netherlands and the Biobased Economy (http://www.innovatielink.nl/app/uploads/2017/02/Netherlands-position-biobased-economy_FBR-Biomass-Research-2016_0.pdf)

Key lessons for the UK

A key part of what has made the Netherlands successful is that they have played to their strengths, by building biotech on their already well established chemicals sector. The academic expertise in industrial biotechnology has obviously helped this. The UK has a similarly strong existing chemicals industry base and UK government should invest in IBBE so that it can continue to compete.

The UK should also learn from some of the difficulties faced by the Dutch by ensuring that the UK recognises the difficulties that can arise from lack of public support, and as was the case in Denmark, ensure there are strong routes to and demand from the market.

5.1.8 Country: Canada

Overview of IBBE sector

The Canadian government has a specific biotechnology strategy, rather than the broader approach adopted in Denmark. The Canadian government also set up an External Advisory Committee on Smart Regulation in 2003 that tries to seek out the best ways to redesign policy in order to maintain a competitive advantage in Canada (which applies to Biotechnology).[115] However, a 2006 review found a lack of public understanding of IBBE issues and applications, and determining that federal government should increase its role in support of longer-term funding for research and stronger regulation.[116]

Policies in place to support IB

BIOTECanada – the national industry association for the biotechnology sector – with over 200 members (a significant network given the number of biotech companies in Canada).[117]

Some of the aggressive, multi-layered, approaches to attracting businesses adopted in the US are not available in all areas of Canada – e.g. Ontario cannot lend funds or other property, sell any property below the fair market price, or give exemptions of levies, charges or fees – however they can work with national government to help provide these. Wider government incentives play a key role in the Canadian system, such as tax rates, green job incentives, zoning, rural development, and/or skills training. Lower levels of corporation tax attract companies who are looking for long term incentives, rather than deals on the initial cost that can be negotiated in the US.[118]

Key lessons for the UK

Short-term tax breaks to tempt businesses to invest in the country are not the be all and end all – especially in IBBE, given the need for long term stability. Also, the importance of a strong network (such as BIOTECanada, and a recognised strength in the UK) is key to allow cooperation. Setting up an independent review of policy is a good idea in theory, but there isn't much detail on how well this has worked in Canada.

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[115] Canada's Biotechnology Strategy, Government of Canada (https://www.canada.ca/en/health-canada/services/science-research/emerging-technology/biotechnology/role/canada-biotechnology-strategy.html)
[116] Decima Research (2006) Public Engagement on the Future Government of Canada Role in Biotechnology
[117] http://www.biotech.ca/about/home/
[118] David Sparling and Erin Cheney, (2016), Food and Industrial Biotechnology, Lawrence National Centre for Policy and Management IVEY Business School at Western University

5.1.9 Summary

The focus of IBBE policies and industry organisation internationally is driven by the strength of inputs into the sector – biomass supply, energy security challenges, or the production of excellent science. Benchmarking the UK with these selected comparators has highlighted that many of those economies face similar challenges to the UK. It has served to reinforce the importance of some of the UK's existing IBBE strengths – for example the comparatively connected and collaborative sector networks.

However, it has also identified several commonly occurring themes in countries deemed to have successful IBBE sectors. Of most note are:

- the specific IBBE focus of policy and strategy;
- the notable role of federal (regional) policy and practical sector supports; and
- the importance of bringing industry expertise in commercialisation to the science base – a factor that is perhaps most blatantly obvious in the case of Johns Hopkins' JHTV example provided in Chapter 4.

It is also clear that, among comparators with similar IBBE drivers and economic contexts, the UK with the right package of measures, is well placed to remain at the forefront of IBBE globally. However, this will only be achieved through implementation of a coherent, long-term strategy which provides the right package of supporting measures.

6 FUTURE DIRECTION FOR IBBE IN THE UK

IBBE has significant potential to deliver sustainable alternatives to products that drive major existing markets including agriculture, energy, plastics and petro-chemicals.

The breadth of IBBE's industrial application, coupled with the UK's excellent biological science base, means that there are fewer industrial areas better placed to deliver against the central thrust of the Industrial Strategy:

> *"Unlike in the past, industrial strategy must be about creating the right conditions for new and growing enterprise to thrive, not protecting the position of incumbents.*
>
> *A modern British industrial strategy must make this country a fertile ground for new businesses and new industries which will challenge and in some cases displace the companies and industries of today."*

Rt Hon Greg Clark MP, Secretary of State for Business, Energy and Industrial Strategy

Beyond its role in delivering on the central tenet of the Industrial Strategy, IBBE also has significant potential to address major societal challenges, including those of real concern to the UK – sustainable energy, greenhouse gas emissions, and food waste.

IBBE cannot make these contributions unless it is adequately supported by the UK government in terms of both specific policy and investment. This section puts forward recommendations that will allow the UK to remain globally competitive, and help IBBE realise its significant potential.

A review of previous policy recommendations highlights that many of the issues raised by contributors to this study are long-standing. Swift and decisive action is required to address these issues if the UK is to harness the potential of its excellent IBBE research base, and avoid losing its competitive edge at a time when other nations are realising the disruptive potential of industrial biotechnology. ([119] [120] [121] [122])

6.1 IBBE strategy and leadership

Development of the Industrial Strategy and associated sector deals presents a unique, but time limited opportunity to maximise the potential of industrial biotechnology in the UK. However, the Industrial Strategy Green Paper provides no inclusion of what IBBE is or does, or its potential contribution to wider economy and society. This review highlighted a strongly held opinion that IBBE is at significant risk of losing ground to its international competitors if a) specific IBBE policy is not developed, b) sector leadership is not heard when it comes to Industrial Biotechnology specifically, and c) if the future industry base for markets in bio-energy, high value chemicals from biological processes, biologics and synthetic biology are not pro-actively cultivated.

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[119] Hodgson et al (2015) Horizon scanning the European bio-based economy: a novel approach to the identification of barriers and key policy interventions from stakeholders in multiple sectors and regions
[120] European Commission (2011) Priority recommendations of the Lead Market Initiative Ad-Hoc Advisory Group for Bio-based products
[121] BIO-TIC (2015) The Bioeconomy Enabled: A roadmap to a thriving industrial biotechnology sector
[122] STAR-Colibri (2011) Joint European Biorefinery Vision for 2030

6.1.1 Recommendations on IBBE strategy and leadership

- BEIS should identify a specific long-term IBBE strategy and action plan that provides clarity regarding future policy direction and government investment in IBBE. This should include further study of the potential extent to which bio-based processes could replace and enhance existing processes within UK firms and analysis of the potential costs and benefits to the UK more broadly.
- The core membership of the IBLF should be expanded to include at least one strong IBBE advocate from the academic community. Further, an IBBE working group that reports to the IBLF comprising NIBB membership should also be established.
- The IBLF, NIBB and Bio-Based and Biodegradable Industries Association (BBIA) should work closely together to pool knowledge, resource and membership, to strengthen IBBE advocacy.
- Limited UK expertise in commercialising IBBE research should be harnessed in e.g. an IBLF panel of commercialisation advisors, retained on a framework to provide advice to IBLF / NIBB members.
- UK businesses that represent, and are invested in, generating future bio-based markets (such as Croda and Green Biologics) should be identified and engaged in strategic IBBE decision-making.

6.2 Access to finance

The IB Catalyst was a valuable and effective source of funding. It provided for the sharing of risk in commercialising technology, supporting the development and the demonstration of technology, products and processes. Its cessation has exacerbated what is already a highly challenging funding landscape given lead times to commercialisation, and is disadvantaging the IBBE sector vis a vis international competition and other innovative UK sectors.

6.2.1 Recommendations on IBBE finance

- The IB Catalyst be reinstated as a priority, providing at least £20m spend on new research projects, with a call for applications initiated in Q2 2018. Provision should also be made for funding a small number of larger scale projects (c.£10 – £50m) via Catapult Centres, by joint government / industry initiatives, or directly by BEIS.
- The IBLF and NIBB should be supported to procure a feasibility study that assesses the implications of WTO subsidy limits, and the likely future parameters of UK industry / academia funding.
- The IBLF and NIBB should also play a co-ordinating role in responding to the current BEIS Patient Capital Review.[123]

[123] HM Government (2017) Terms of Reference for the Patient Capital Review ‘ Available at: https://www.gov.uk/government/publications/patient-capital-review/terms-of-reference-for-the-patient-capital-review

6.3 Infrastructure

Study contributors suggested that UK IBBE infrastructure is relatively strong, but that there is a need for greater access to existing infrastructure by small business, and that the regional nature of IBBE calls for less capital intensive, relatively lower cost 'scale-out' infrastructure.

6.3.1 Recommendation on IBBE infrastructure

Currently it is not economically feasible for existing infrastructure (e.g. the CPI) to finance access by smaller scale projects / SMEs. This is due to funding rules that require Innovate UK to broker access via a maximum cost contribution of 20%. There is currently no mechanism for funding transfer between the Research Councils and Innovate UK.

- The coming together of Innovate UK and the UK Research Councils under UKRI should allow rules regarding funding transfer or pooling of funds to be changed so that SMEs can be better supported financially to access existing facilities.
- BEIS and UKRI should explore the potential of modular manufacturing (similar to the Flexible, Fast and Future (F3) Factory project tested recently in Leverkusen) as a method of 'scaling out' industrial biotechnology processes and products on a regional basis.[124]

6.4 Regulation and standards

While many study contributors felt that the UK regulatory environment remains pragmatic, a significant minority held the view that UK regulation was becoming increasingly prescriptive, and more costly to navigate. In addition, several study contributors pointed to inconsistency in applying regulatory standards and the consequent uncertainties placed on the financial viability of IBBE innovation at TRLs 3 – 5, in particular because of increased investment uncertainty.

EU and international regulation and standards are likely to still apply to UK IBBE post-Brexit for the free flow of trade. Nevertheless, the UK could enhance its competitive advantages in the burgeoning IBBE sector post-Brexit by putting in place specific UK support structures that speed up responsiveness to the needs of IBBE businesses, and offer ongoing financial and advisory support to SMEs. This should be coupled with a regulatory support system that keeps pace better with the rapidly moving research by working alongside researchers, thus speeding up required yet safe modifications to regulations and standards which operate in parallel with new understanding and discoveries.

6.4.1 Recommendations on regulation and standards

IBBE provides an indispensable set of tools that will be required to deliver the UK's industrial strategy objectives of a sustainable, productive economy that is supportive of, and driven by innovative businesses. An up-to-date, pragmatic regulatory framework will be critical if the UK is to remain at the forefront of commercialising IBBE research. Government should therefore:

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[124] See http://www.f3factory.com/scripts/pages/en/newsevents/F3_Factory_final_report_to_EC.pdf for the Final EC report which identifies notable reductions in capital and operating expenditures due to intensified manufacturing processes.

- Review the existing regulatory frameworks and simplify these where appropriate without compromising safety and security;
- Design monitoring processes that work in an ongoing mode with innovators to update regulatory principles as new discoveries and innovations take place;
- Examine where it is safe and responsible to move in favour of informed risk management rather than applying a “knee jerk” precautionary approach to emerging technology opportunities;
- Communicate the pragmatic nature of the UK’s IBBE regulatory environment internationally, with a view to encouraging FDI and investment in innovative science and technology; and
- Put in place financial and advisory support to help businesses, especially start-ups and SMEs, to navigate efficiently regulatory requirements and hence not impede innovation.

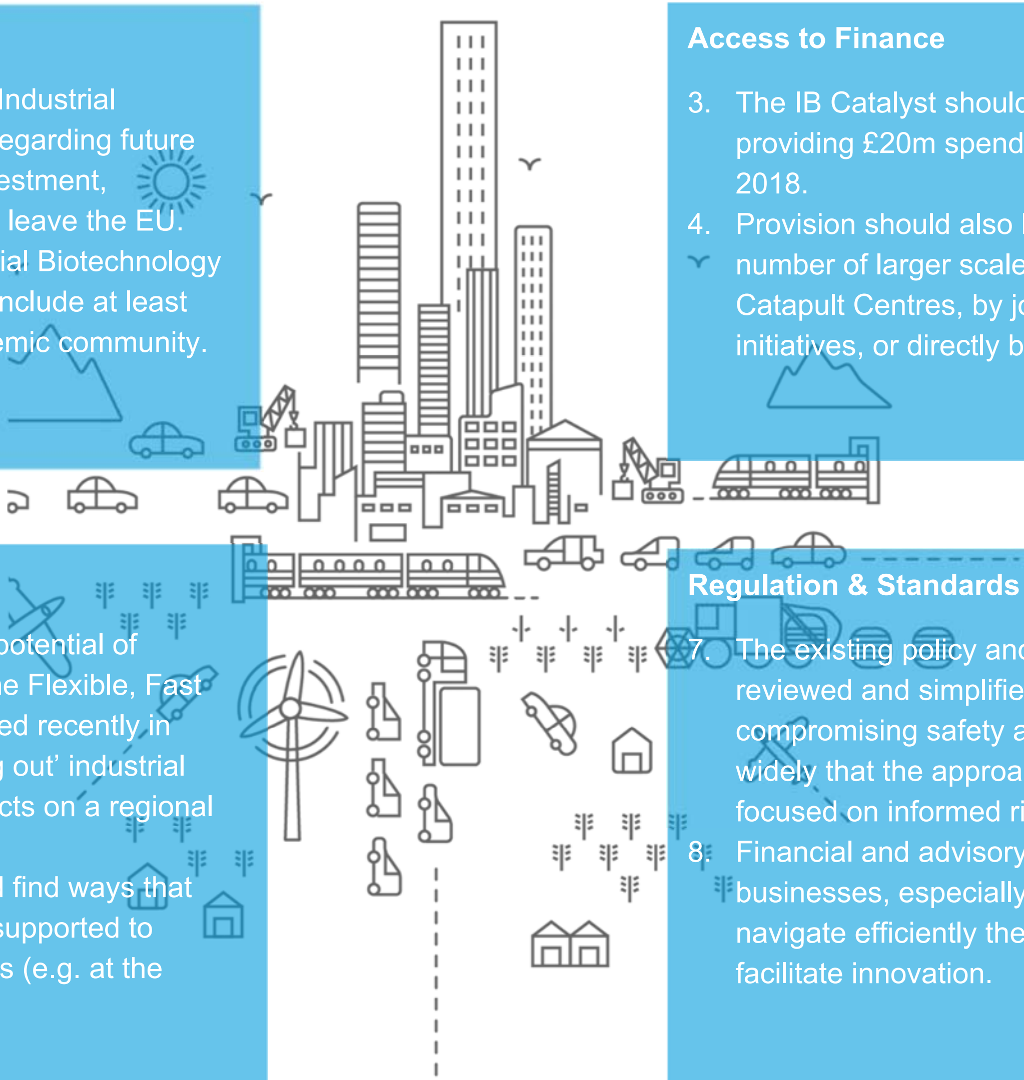
Core recommendations

IBBE Strategy & Leadership

1. BEIS identifies a long-term plan for Industrial Biotechnology that provides clarity regarding future policy direction and government investment, particularly in light of the decision to leave the EU.
2. The core membership of the Industrial Biotechnology Leadership Forum be expanded to include at least one strong advocate from the academic community.

Access to Finance

3. The IB Catalyst should be reinstated as a priority, providing £20m spend in a fifth round no later than Q2 2018.
4. Provision should also be made for funding a small number of larger scale projects (c.£10 – £50m) via Catapult Centres, by joint government / industry initiatives, or directly by BEIS.



IBBE Infrastructure

5. BEIS and UKRI should explore the potential of modular manufacturing (similar to the Flexible, Fast and Future (F3) Factory project tested recently in Leverkusen) as a method of 'scaling out' industrial biotechnology processes and products on a regional basis.
6. UK Research and Innovation should find ways that allow SMEs to be better financially supported to access existing UK scale-up facilities (e.g. at the Centre for Process Innovation).

Regulation & Standards

7. The existing policy and regulatory frameworks are reviewed and simplified where appropriate, without compromising safety and security, and communicate widely that the approach to regulation and standards is focused on informed risk management.
8. Financial and advisory support be put in place to help businesses, especially start-ups and SMEs, to navigate efficiently the regulatory requirements to facilitate innovation.