Life sciences: Catalysing investment and growth **(**

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Updated interim report January 2020

S INVESTMENT AND GROWTH

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Foreword by Steve Bates

Steve Bates OBE CEO, BIA

Twenty years into the 21st Century, there is no doubt that we are living in the most exciting and prolific period of innovation in bioscience and healthcare the world has ever witnessed.

Since the turn of the millennium, UK innovators have deepened our understanding of biology to create game-changing solutions to some of the most complex challenges of our time: from developing life-saving treatments and empowering an ageing population to live healthier lives; to tackling climate change by enabling clean growth; and capitalising on the artificial intelligence revolution. The UK is truly a global leader in life sciences and it is delivering great social and economic rewards to our country.

The strength of the UK life sciences sector is the result of many years of support from successive governments. The Government's commitment to make the UK the leading global hub for life sciences builds on the two Life Sciences Sector Deals published by the previous Conservative Government and demonstrate strong support for the sector through effective industrial strategy.

The strong cross-party support for increasing R&D investment is a real opportunity to kickstart a decade of renewal. It will transform the economy by creating new highly skilled jobs all around the country, solving pressing societal challenges and reinforcing the UK's place as a world-leader in innovation.

The Government's pledge to boost public investment is welcome, but private investment must also increase to meet the 2.4% target. As consistently the largest R&D investor in the UK, the life sciences sector is well-placed to leverage and attract the new investment needed to meet the target. In 2019, UK biotech SMEs raised £1.3 billion in equity finance, an increase of over 400% from 2012 when the Conservative-led Government published the first strategy for UK life sciences and launched the Biomedical Catalyst.

As the Government develops new R&D funding plans, it is crucial that government and industry work together to unleash Britain's bioscience potential. This means ensuring public funding of research and innovation is as effective as possible and recognising the success of existing programmes, such as the Biomedical Catalyst, which can be deployed rapidly and reformed over time to meet government priorities. It also means creating a business environment in which entrepreneurialism can thrive and training a workforce ready to innovate and commercialise research in the UK.

Our sector's heritage shows that investments in bioscience – such as the pioneering efforts by Eli Lilly in the early 80s, which resulted in large-scale advanced manufacturing in the North East – can ensure prosperity across the whole country and play a key role in narrowing the productivity gap.

As the 2020 Spending Review approaches and the Government and UKRI prepare to set out plans to boost R&D funding to meet the 2.4% target, we hope this report provides helpful evidence for policy makers into what the life sciences sector needs in order to continue its successful trajectory. Once the timelines of the Spending Review become clearer, we will update this work into a full report.

Like the rest of the business and science community, our members need certainty on the future relationship with the EU and a long-term Spending Review settlement will help companies plan and make investments. As always, we stand ready to work with the Government to make that happen.

1. Executive summary

This report makes the case for continued and cost-effective public investment in the life sciences sector. The report aims to inform the Government, UK Research and Innovation (UKRI), and other policy-makers as they prepare for the forthcoming Spending Review and develop new R&D funding plans to reach the target of raising R&D investment to 2.4% of GDP by 2027.

As a global leader in life sciences, the UK sector is well-placed to leverage and attract new investment to help meet the 2.4% target. It consistently invests more in R&D than any other sector, supports almost half a million jobs, two-thirds of which are outside London and the South East, and consists of almost 5,900 companies, 80% of which are SMEs. Private investment in the UK's life science start-ups and scale-ups is also increasing, signalling a bright and innovative future.

The sector is not only a strong contributor to the UK economy but also improves the health of the nation and enables clean growth. From improving patient lives through new treatments and early diagnosis, to the development of environmentally sustainable technologies, such as biodegradable bioplastics and the cleaning of polluted waters, our deep understanding of biology is helping the UK address humankind's greatest challenges.

These benefits are the result of a continuous and supportive industrial strategy delivered by successive governments. However, the world does not stand still, and neither should research and innovation policy. We have therefore consulted widely and taken a whole-system approach to develop the following recommendations to ensure the UK remains a world-leader in the life sciences.

Recommendations

Industrial strategy – Section 2

- The Government should work with the life sciences sector to deliver on its ambition to make the UK the leading global hub for life sciences and prioritise the sector as a catalyst to help deliver the 2.4% target.
- The Government should use the Biomedical Catalyst as an existing and proven vehicle for rapid deployment of public R&D funds into the life sciences sector in 2020.

Public funding streams – Section 4

- The Government and UKRI should adopt the below five principles to ensure that increases in public
 R&D investment successfully crowds in the private investment necessary to reach the 2.4% target.
 - Balance responsive and challenge-led programmes – to allow all types of innovation to thrive
 - 2 Sector-specific to provide long-term consistency and assurance to researchers and investors
 - **3** Grants, not loans to ensure it pays to start and grow innovative companies
 - **4 Maintain a variety of funding streams** to support the varied needs of life science SMEs
 - 5 Unbureaucratic and informed by the needs of the sector – to ensure SMEs are consulted and the right areas are funded

Fiscal R&D incentives - Section 5.1

- In its review of R&D tax credits, the Government should: ensure that anti-abuse measures do not impact genuine SMEs and harm the growth of the life sciences sector; benchmark the R&D tax credits system to ensure it remains internationally competitive to attract investment; and ensure the coverage of eligible costs remains relevant to R&D as the life sciences sector evolves, particularly the acquisition, storage, processing and analysis of data.
- In its review of Entrepreneurs' Relief, the Government should: maintain the benefits of the Enterprise Management Incentive to ensure the scheme is equitable and supports young businesses to access the talent and skills they need to grow; and ensure it truly supports the growth of Knowledge Intensive Companies.

- The Government should maintain all venture capital schemes and increase the amount of tax-advantaged capital companies can receive to reflect the high levels of investment such companies require.
- The Government should adjust the Patent Box rate to maintain at least ten percentage points difference between it and the standard corporation tax rate to ensure it remains internationally competitive to attract investment.
- The Government should create a fund of up to £450 million of financial support in the form of targeted capital grants to deliver on the Life Sciences Industrial Strategy's ambitions to attract ten large (£50–250 million) and ten smaller (£10–50 million) commercial scale manufacturing facilities in the next five years.

Patient Capital – Section 5.2

- If funding from the European Investment Fund ceases when the UK leaves the EU, the British Business Bank should be provided additional capital to address the finance gap.
- As pension funds are well-placed to be patient investors in innovation and could contribute significantly to the 2.4% target, the Government should continue to work proactively to unlock pension fund investment in innovative companies.

Support for the ecosystem – Section 5.3

- The Government should provide multiyear settlements for the UKRI Councils and NIHR to underpin the science base to maintain the UK's globally competitive life science ecosystem.
- The Government should commit investment
 to the MHRA embedding in the science base to
 support innovation and deliver patient benefits.
- The UK should develop the closest possible relationship to Horizon Europe.
- The post-Brexit immigration framework must protect and support the international movement of all levels of researchers and the Government must ensure that the country is – and is seen to be – welcoming to international researchers.

2. UK life sciences – an industry of the future

The life sciences sector is a major contributor to the UK economy. The sector generates an annual turnover of over £73 billion,' supports 482,000 jobs, two-thirds of which are outside London and the South East,² and consists of almost 5,900 companies, 80% of which are SMEs.³ Many of these SMEs are improving productivity through the development of disruptive technologies, such as artificial intelligence (AI), genomics and engineering (synthetic) biology. The impact of these disruptive technologies is enabling the sector to grow rapidly; between 2016 and 2017, the sector's turnover grew by 9.3%.⁴

By harnessing the power of biology, the innovations developed by the sector have a wide range of benefits – from improving patient lives through new treatments and early diagnosis, delivering cost-savings for the NHS, to the development of environmentally sustainable technologies, such as biodegradable bioplastics and the cleaning of polluted waters. As such, the life sciences sector is not only a major part of the UK economy, it also improves the health of the nation and enables clean growth. The Government's support for the sector is enabling these benefits to be realised in the UK.

2.1 The result of years of successful industrial strategy

The strength and breadth of the sector is the result of many years' successful industrial strategy, stretching from the founding of Celltech in 1980 by Prime Minister Margaret Thatcher, through the creation of R&D tax credits by the Labour Government in 2000, to the current Government's manifesto commitment to "make the UK the leading global hub for life sciences".⁵ The UK is not alone in recognising life sciences as an industry of the future; both the United States and China, among many others, are committing considerable public investment to support their life sciences sectors.

Despite these efforts by competing countries, the UK's sector remains strong. The sector is the clear leader in Europe and continues to challenge the dominant clusters in California and Massachusetts.⁶ This would not have been possible without sustained industrial strategy by successive governments and continuous public investment in research and innovation.

The UK life sciences sector



Generates an annual turnover of **£73.8 billion**



Supports **482,000** jobs, two-thirds of which are outside London and the South East



5,870 companies, 80% of which are SMEs

2.2 The life science sector's commitment to supporting the 2.4% target

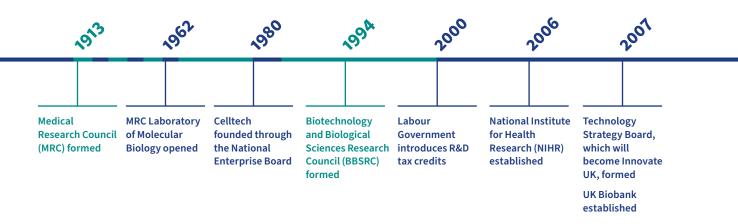
The Government's commitment to the fastest ever increase in public R&D investment and to raise overall R&D investment from 1.69% of GDP to 2.4% by 2027 is welcome. The Government is right to prioritise investment in industries of the future where the UK already has a competitive advantage, such as life sciences.⁷

This is because while estimates show more public investment is needed to ensure the 2.4% target is met, it is also clear that private investment needs to increase by an estimated 70%.⁸ The UK life sciences sector's position as a global leader makes it well-placed to leverage and attract new investment. With more than £4.5 billion invested in 2018, the sector consistently invests more in R&D than any other in the UK.⁹

The sector also has a strong track record of leveraging new investment. In 2019, UK biotech SMEs raised £1.3 billion in equity finance, an increase of over 400% from 2012 when the Conservative-led Government published the first strategy for UK life sciences and launched the Biomedical Catalyst. This investment in companies will translate into R&D expenditure and innovative products in subsequent years. However, the investment is dependent on the UK's research and innovation policy environment remaining supportive of and responsive to the sector's needs.

Recommendation: The Government should work collaboratively with the life sciences sector to deliver on its ambition to make the UK the leading global hub for life sciences and prioritise the sector as a catalyst to help deliver the 2.4% target.

The UK life sciences sector and industrial strategy - a snapshot



The Biomedical Catalyst – a proven vehicle for rapid investment in life science SMEs

The Biomedical Catalyst is an established and proven funding programme for life science SMEs that could be used to rapidly deploy public R&D funds to increase business investment and advance medical research in 2020 and beyond.

The Biomedical Catalyst is a unique partnership between Innovate UK and the Medical Research Council (MRC), that aims to de-risk innovative science and commercialise ideas arising from academia and industry, helping UK SMEs to develop into competitive and sustainable organisations. This accelerates the progress of novel products to market, facilitates onward investment and bridges 'the valley of death'.

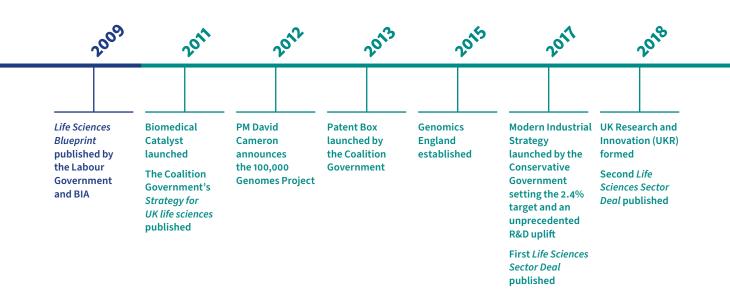
The last round of the programme consisted of £100 million invested between 2016–17 and 2020–21. However, its final SME funding round has closed so no further awards will be made unless the Government recommits to this successful scheme.

In 2019, an independent analysis from IPSOS Mori commissioned by Innovate UK and MRC showed that the Biomedical Catalyst generates £4.72 in public and business value for every £1 invested by the Government.¹⁰ The study also showed that the programme leverages over £5 of private investment per £1 of public expenditure. As such, the programme outperforms other public funding programmes, which leverages £1.40 of private investment from every public £1." The Biomedical Catalyst therefore provides the new Government with a ready-made vehicle for rapid and efficient investment in life sciences to demonstrate its support the sector in its first 100 days in office.

Key statistics on the Biomedical Catalyst:

- Companies in receipt of Biomedical Catalyst grants increased their R&D investment by 93%, which will help the Government reach its target of raising UK R&D investment to at least 2.4% of GDP by 2027.
- Grants increased employment in companies by 11–15% over 3–5 years, equivalent to creation of up to 330 jobs.
- The 150 companies funded by the Biomedical Catalyst raised as much as £710 million in additional VC after receiving the grant. This suggests the grants leveraged £3.99 to £5.09 private investment per £1 of public grant.

Recommendation: The Government should use the Biomedical Catalyst as an existing and proven vehicle for rapid deployment of public R&D funds into the life sciences sector in 2020.



3. Industrial strategy in action: a snapshot of innovative life sciences companies

This section contains a short selection of case studies on innovative life sciences SMEs in the UK. While the companies' technologies differ widely – from new health-focused therapies and diagnostic platforms, to more efficient and environmentally-friendly processes – it is public innovation through industrial strategy support that have enabled these companies to develop their technologies further.

The case studies demonstrate how life sciences SMEs use the wide range of support available to them to leverage private investment, create more highly skilled jobs and provide benefits to the UK economy. All the companies benefit from the UK's thriving life sciences ecosystem, excellent science base and competitive business environment.

These case studies are but a snapshot of the transformative technologies being developed by thousands of life sciences SMEs in the UK. This would not have been possible without continuous public investment through industrial strategy, including public funding streams, fiscal R&D incentives, patient capital and the Catapult centres.

How can bioscience improve health?



Earlier identification of disease risk and diagnosis, through genetic screening

Disease prevention

effective and better

targeted vaccines

through more



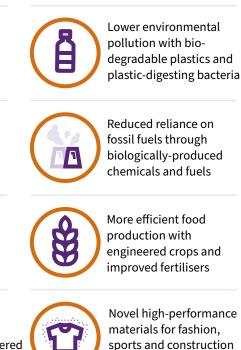


Faster drug development and more accurate drug delivery



New treatments for previously untreatable conditions, e.g. engineered tissue, stem cell therapies

How can bioscience improve the world we live in?



industries

Arecor

Chesterford

Innovation support: Biomedical Catalyst Sub-sector: Health Arecor is a biopharmaceutical company transforming patient care by bringing innovative medicines to market. Arecor is developing a broad portfolio of therapies through its clinical pipeline and in partnerships with leading pharmaceutical and biotech companies.

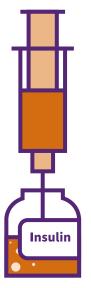
Arecor's proprietary products are focused on people living with chronic disease to simplify patient care and medication adherence. The first products are designed to improve the treatment regimen and healthcare outcomes for people living with Type I diabetes, to advance the diabetic treatment landscape.

In December 2019, Arecor announced positive results of a Phase I clinical trial for its lead product, AT247, an ultra-rapid acting insulin for Type I diabetes. AT247 has the potential to improve blood glucose control after meals and play a critical role in new insulin delivery systems such as the artificial pancreas.

Arecor has received invaluable support from the Biomedical Catalyst, including two recent awards at a total value of ~£1.5 million. These grants, together with fiscal support from R&D Tax credits, have enabled Arecor to accelerate its technological innovation progress towards building a clinical pipeline of proprietary products. This includes the further development of the company's formulation technology platform, Arestat[™], which is used in commercial projects with pharmaceutical and biotech companies.

The company has been able to build on grant funding and commercial partnerships to leverage further recent investment of £6 million from new Venture Capital Trust (VCT) and Enterprise Investment Scheme (EIS) investors and existing shareholders.

Arecor has received invaluable support from the Biomedical Catalyst, including two recent grants of ~£1.5 million, which has enabled the company to develop its technology and build commercial partnerships to leverage further recent investment of £6 million in 2018.

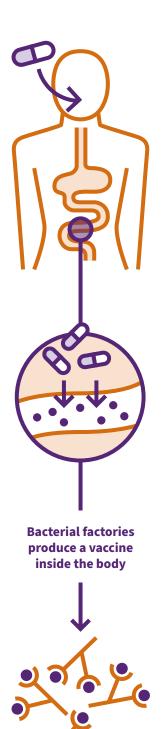




Prokarium

London

Innovation support: Innovate UK Sub-sector: Health



Prokarium is a venture-backed biotech developing new vaccines against infectious diseases and immunotherapy for solid tumours.

The company's oral vaccine delivery platform uses a genetically modified version of *Salmonella* bacteria to deliver vaccines via the lining of the gastrointestinal tract and Prokarium's microbial immunotherapy is a novel approach in the immuneoncology field, creating a new class of therapeutics based on their bacteria's ability to home to solid tumors and boost the natural anti-tumour activity of the immune system.

Prokarium has received funding from Innovate UK in various stages of the company's growth, which have contributed to the development of their vaccine portfolio. Initially, a government grant enabled the company to test combined intellectual property from the US and UK to give early data on Prokarium's Vaxonella platform. The company subsequently secured private investment and Innovate UK grants, which allowed the company to fund collaborations with UK universities and other companies to develop vaccines for various infectious diseases.

A grant from the Newton Fund has helped fund the development and manufacture of Entervax[™], Prokarium's lead programme, a novel vaccine against enteric fever (typhoid and paratyphoid). Entervax[™] has now received the MHRA acceptance to start a Phase I trial in the first quarter of 2020, funded by the Wellcome Trust, who invested £4.6 million to run two clinical trials. Prokarium has also completed work on a £1 million Innovate UK-funded project with the Defence Science and Technology Laboratory (DSTL) to complete the pre-clinical evaluation of its plague vaccine.

The development of these technologies enabled Prokarium to conclude a \$10 million (~£8 million) fundraising round at the start of 2018. Prokarium plans to raise a Series B round in 2020. The data package generated from the Innovate UK-funded grants was valuable in progressing Prokarium's program to a value inflection point for external investment.

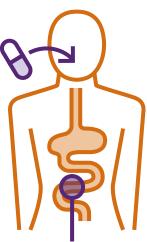
A significant portion of Prokarium's grant funding has been spent at UK-based contract research organisations, contract manufacturing organisations, reagent suppliers and other service providers. In addition to the grants, Prokarium has received significant fiscal support in the form of R&D tax credits.

From grant funding of £3.2 million, Prokarium has raised a total of around £18.5 million from overseas angel and institutional investors – generating almost £6 for every £1 of public funding and accelerating the development of vaccines for unmet medical needs worldwide.

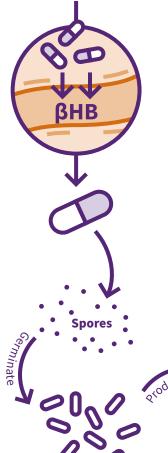
CHAIN Biotechnology

Nottingham

Innovation support: ISCF Wave 1 Sub-sector: Health



Bacteria produce beta hydroxybutyrate



Clostridia (bacteria)

CHAIN Biotechnology is a microbiome therapeutics company and technology leader in the engineering of *Clostridia* and develops 'living medicines' with the potential to transform patients' lives.

The company uses proprietary engineering biology to transition probiotics into advanced therapeutics. This novel class of medicine has new and specific functionality giving it broad commercial applicability in areas of high unmet medical need including diseases associated with inflammation, infection and metabolic imbalance.

CHAIN uses harmless *Clostridia* bacteria as mini drug factories. *Clostridia* are one of the main groups of microbes naturally found in the gut where they break down dietary fibre and produce short-chain fatty acids that keep the lining of the colon healthy. CHAIN's *Clostridia* experts engineer the bacteria to additionally produce useful molecules, such as beta-hydroxy butyrate (BHB) towards the treatment of Inflammatory Bowel Disease.

The engineered strains form spores which are formulated into capsules for oral ingestion. The spores survive the acidic stomach and only germinate in the lower part of the intestine where they grow and secrete the therapeutic bio-actives. Unlike most biologics, spores do not require any cold storage and have a long shelf live.

Due to the novel nature of CHAIN's technology, there is currently no biomanufacturing facility in the UK where CHAIN can develop its spore-based therapeutic products to meet regulatory requirements. In 2018, CHAIN led a project that demonstrated the business case for building such a facility in collaboration with two other UK companies. The project size was £100,000 and funded through the Medicines Manufacturing Challenge of wave 1 of the ISCF.

"In addition to helping CHAIN and other UK microbiome companies to accelerate bringing their breakthrough drugs to the market, the facility would also provide unique contract manufacturing services to the rapidly expanding global microbiome industry and support new highly skilled jobs in the UK." Dr Basil Omar, Co-founder, CHAIN



Reduces inflammation in the gut

The funding received through the ISCF identified a route for scale-up and manufacture. CHAIN and its partners now seek public and private funding to support the establishment of a world-class biomanufacturing facility for this novel class of medicines. This will help position the UK at the leading edge in the development and global provision of advanced microbiome therapeutics.

Puraffinity

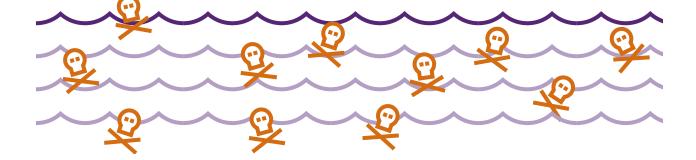
London

Innovation support: Innovate UK + Horizon 2020 Sub-sector: Environment Puraffinity helps to protect global environmental and human health by engineering bio-based materials to capture target chemicals in wastewater. The company was spun-out from Imperial College London in 2015 and is today is headquartered in White City in London.

In 2017, Puraffinity was awarded a £100,000 grant from Innovate UK, following an initial SynbiCITE Proof of Concept grant of £50,000. The Innovate UK award was key to develop and produce Puraffinity's first product, a novel material that can selectively and efficiently remove dangerous chemicals from industrial wastewater. Customised Granular Media (CGM) is a bio-based material and can be customised to bind some of the most polluting, resistant artificial substances. It does so in a manner that allows both the material, and the pollutants it removes, to be recycled.

The Innovate UK grant also enabled Puraffinity to initiate three customer trials to prove the performance of CGM. The success in these trials enabled the company to win a two-year €1.4 million Horizon 2020 award. The award is funding a project, started in April 2018 and currently underway, which will ensure that CGM is scaled and deployed for water treatment.

"Funding from Innovate UK and Horizon 2020 was vital to allow us to develop, produce and scale our product. The awards have also allowed us to grow our internationally diverse team of experts from four full-time employees in 2017, to 13 today, with 10 more due to join in 2020." Henrik Hagemann, Co-founder and Chief Executive Officer, Puraffinity



Puraffinity's technology has already attracted large industrial companies which are facing increasingly stringent waste-regulations. In June 2019, Puraffinity completed a £2.8 million oversubscribed private funding round, further enabling the company to grow and scale its technology. The investment round attracted leading US and Swiss sustainability investors, representing £1.5 million of foreign investment.

BioAscent

Glasgow

Innovation support: Medicines Discovery Catapult Sub-sector: Health BioAscent provides comprehensive integrated drug discovery services to companies, universities and research institutes.

The company's Compound Cloud contains approximately 120,000 compounds, which can be accessed on-demand. Typically, these compounds are tested against disease targets to identify the specific active compounds for optimisation. The active compound(s) then become the starting point for drug development.

To enhance the Compound Cloud further, the compounds could be analysed and grouped together into targeted subsets. As an SME with limited resources, BioAscent required external support to leverage scarce expertise. BioAscent partnered with Medicines Discovery Catapult (MDC) which helped to deliver the project.

The MDC, based in Cheshire, is a national facility providing unique scientific capabilities and expertise, connecting the UK community to accelerate innovative drug discovery. The MDC team helped BioAscent to apply artificial intelligence (AI) across the entire Compound Cloud library to learn which features of a compound make it active towards different drug targets. The project added value to the Compound Cloud and enabled the creation of compound subsets – ultimately helping BioAscent's clients to conduct faster and more efficient drug discovery.

"It has been great to access the AI expertise at MDC for this collaboration. The MDC team have taken an innovative approach to characterising the compounds in Compound Cloud which we believe adds value to the collection. From our perspective the collaboration was easy to establish and worked extremely well, and we look forward to working with MDC on further AI initiatives in the future." Phil Jones, Chief Scientific Offier, BioAscent Cambridge Innovation support: Innovate UK Sub-sector: Health Congenica is a pioneering digital health company enabling genomic medicine with the world's leading clinical decision support platform for the interpretation of complex genomic data. Congenica is building a future where clinical genomics is fully integrated into healthcare.

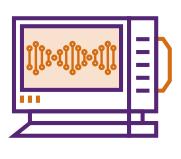
Headquartered at the Wellcome Genome Campus in Cambridge and with a footprint in the US and China, Congenica is born out of pioneering research from the Wellcome Sanger Institute and the NHS, with a software platform validated by the ground-breaking 100,000 Genomes Project.

A large part of Congenica's expenditure is R&D as it invests to advance genomic medicine and its implementation. The company has spent over £8.3 million on R&D to date, supported by £1.2 million in R&D tax credits.

In addition, Congenica has received approximately £2.7 million of grants from Innovate UK and the Small Business Research Initiative (SBRI), which has enabled the company to establish valuable research collaborations with academic partners. The establishment of a pipeline of novel innovations has been key to leveraging ongoing venture capital investment and is critical to differentiating Congenica's products and services in a competitive marketplace.

Congenica has benefited from a close partnership with Genomics England since the inception of the 100,000 Genomes Project. Congenica's experience in the project allowed the company to compete effectively in the Genomics England tender to become the exclusive decision support platform provider for the world-leading NHS Genomic Medicine Service. Congenica plans to commercialise the core technology developed for the NHS on a global basis with an initial focus on Europe, the US and China.

"Congenica's future looks extremely positive as we continue to be strong exporters of world class, home-grown UK innovation to bring significant benefit to patients and families across the globe. Without question, we would not be where we are today without the financial support received from both public and private sources." David Atkins, Chief Executive Officer, Congenica







GE Healthcare Life Sciences – Puridify

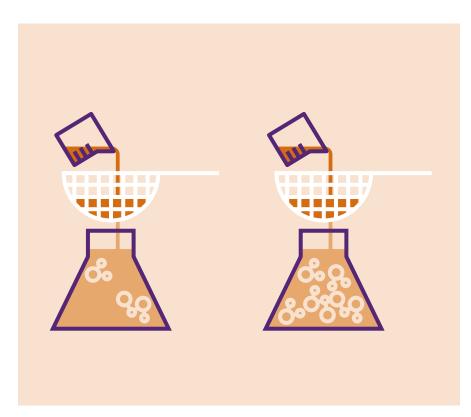
Stevenage

Innovation support: Innovate UK Sub-sector: Productivity GE Healthcare Life Sciences' Puridify team began as venture backed spin-out from the Department of Biochemical Engineering at University College London in 2013. Puridify is based at the Stevenage Bioscience Catalyst, which has allowed the company to access a key pool of talent coming from London and Cambridge.

The Puridify purification platform technologies improve productivity in biomolecule manufacturing. By operating at 50 times throughput, new bioprocessing methods can meet global demand for more output. Collaborating with drug manufacturers, GE Healthcare Life Sciences helps run unit operations in new flexible ways, which is enabled by the company's ability to purify proteins in just a couple of minutes rather than hours typically required by traditional purification methods.

Before being acquired by GE Healthcare Life Sciences, Puridify was awarded six Innovate UK grants, totalling over £5 million in project costs. These awards supported Puridify in its early years, enabled the company to grow from two employees to over 20, and develop expertise in the UK through collaborations with industry and academic partners. The grants also fostered a high degree of collaboration with a focus on cross-discipline learning and a higher level of dissemination.

The Innovate UK grants allowed the development of a novel technology towards a commercial offering that was subsequently acquired by GE Healthcare Life Sciences in November 2017.



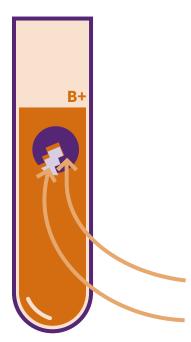
"The Innovate UK grants undoubtably allowed us to leverage higher levels of venture capital investment, which culminated in success as an SME by acquisition. Importantly, the acquisition has led to a great deal more investment into the continued R&D efforts of the UK based group and also enabled the establishment of the first manufacturing base for the technology to be supplied to the global biopharmaceutical industry." Dr Oliver Hardick, founder of Puridify

In the short term, the Innovate UK funding ensured Puridify's R&D activity progressed and remained in the UK. In the long-term, it allowed Puridify to advance the UK as the world's most innovative economy by attracting significant global investment. GE Healthcare Life Sciences now has a long-term plan to continue investing in their UK manufacturing capacity and create high-value products to supply a global market.

KalVista Pharmaceuticals

Porton Down

Innovation support: Biomedical Catalyst Sub-sector: Health



KalVista Pharmaceuticals is a pharmaceutical company focused on the discovery, development, and commercialisation of small molecule protease inhibitors for diseases with significant unmet need.

Over the last six years, KalVista Pharmaceuticals has been awarded approximately £5 million through two Biomedical Catalyst grants. These grants enabled KalVista's first drug discovery efforts, particularly in early efforts to develop a therapy for diabetic macular edema (DME). The company has subsequently raised over £75 million in equity financing and has contributed approximately £20 million each year to the UK economy in the form of jobs and other spending. KalVista is now a publicly listed company in the US and recently announced a £600 million partnership with one of the world's leading pharmaceutical companies.

Two-thirds of KalVista employees are based in the UK, and as the company grows, KalVista anticipates that the company will continue to maintain the majority of its operations in the country. The opening of the company's new facility at the Porton Science Park in September 2018 was another step in its UK growth. KalVista's UK drug discovery and development group are based in this new facility and will continue its work of developing new medicines for diseases with significant unmet need.

plasma kallikrein inhibitors

kallikrein

KalVista has been able to maintain and grow its UK presence particularly through the benefit of the Government's R&D tax credit scheme, which provides a strong incentive to conduct research work in the UK. Without this benefit, the company likely would not have been able to advance its programs as quickly and may have been forced to relocate its research activities to other countries.

"We are very thankful for the progress made possible from our Biomedical Catalyst grants and the R&D tax credit. The available talent in the UK has always been rich and I hope that the Biomedical Catalyst will continue in helping bring innovative medicines to patients who need them." Andrew Crockett, Chief Executive Officer, KalVista

Nightstar

London
Innovation support:

Patient Capital Sub-sector: Health



Edited cells remove waste product build up from the back of the eye Nightstar Therapeutics is developing gene therapies to help restore the vision of patients suffering from rare inherited retinal diseases that would otherwise progress to blindness.

In the space of five years, Nightstar has progressed from an academic programme at Oxford University led by a single academic to a publicly listed company at the cutting edge of gene therapy and leader in its field.

Syncona, a healthcare company focused on building global leaders in life science, partnered with Robert Maclaren, a Professor of Ophthalmology at Oxford to found Nightstar. The company was set up with the intent of global success in the way it was funded. The Syncona team developed the company's vision and strategy and then built the business plan.

Syncona provided Nightstar with £16 million Series A financing, \$35 million of financing along with US life science investor NEA in Series B in November 2015, and \$45 million of funding alongside leading biotech partners in Series C in July 2017. Finally, the business was successful in raising a further \$76 million in an IPO on NASDAQ in September 2017 and a subsequent fund-raising of \$83 million in September 2018, both also supported by Syncona. Through this approach, the company was also able to avoid the distraction of regular, small funding rounds allowing it to focus on its product development strategy.

This strategy and subsequent success have culminated in Nightstar's recent acquisition by US listed pharmaceutical company Biogen for \$877 million in 2019. This resulted in a £255 million cash return for Syncona, representing a 4.5-times return and 72% internal rate of return in just over five years and a 9.5-times on the original Series A investment.

B-Secur

Belfast

Innovation support: British Business Bank Sub-sector: Health B-Secur is pioneering next-generation biometrics using the heart to secure health and wellness insights in the connected world. Their HeartKey® technology captures users' ECG signals using small and seamless sensors within smart clothing, wearables, or physical touch points.

As an early stage company, the nature of the business required heavy R&D investment and, starting with private equity, B-Secur progressed to include UK institutional venture capital investment. This was a difficult process and like many other innovative SMEs, B-Secur struggled to find funding due to attitudes to risk, patient capital and debt capital.

The British Business Bank is working to make finance markets work better for innovative SMEs and helping companies find suitable investors. The Bank's Finance Hub provides independent information on finance options for scale-up, high growth and potential high growth businesses.

In addition, the Bank's UK Network has a remit to identify and help reduce geographical imbalances in access to finance for smaller businesses across the UK. The Bank also has three regional funds and several supply-side finance interventions to increase the supply and diversity of finance in the regions.

B-Secur found funding from Accelerated Digital Ventures (ADV), one of the Bank's Enterprise Capital Fund partners. This allowed B-Secur to find investors that understand the value of its technologies, allowing it to develop its groundbreaking technology and introduce it to the world.

4. A new approach to investing in research and innovation

The Government's commitment to the 2.4% target and the fastest ever increase in public R&D spending represent a new and welcome approach to investing in and supporting research and innovation. The proposed establishment of a British Advanced Research Project Agency, modelled on the US DARPA, could add another well-needed dimension to the UK's innovation capabilities by funding strategic high-risk, high-reward technologies, such as artificial intelligence and engineering biology. In addition, the plan to introduce a dedicated Innovative Medicines Fund could go a long way towards ensuring that patients – and in particular those with rare diseases – are able to access the latest lifesaving medicines.

This new ambitious approach to R&D funding could energise the already high-performing ecosystem in the UK and maximise the benefits for our health, society and economic prosperity. It is now important that government and industry work together to ensure that the new system and funding streams are efficient and effective.

Through established funding streams and new ones, the Government invested more than £5.1 billion in the life sciences sector between 2016 and 2018.¹² Much of this supports a world-class science base in the UK's universities and public research institutes. A smaller but crucial portion of around £540 million has been invested through businesses by Innovate UK.¹³ In a recent report, former Science Minister Lord David Willetts rightly highlighted Innovate UK's vital role in leveraging the private investment needed to meet the 2.4% target and called for Innovate UK's budget to be increased.¹⁴

The vast majority of Innovate UK's funding for life sciences goes to SMEs. Since Innovate UK's inception, 89% of grant funding awarded to life sciences companies has gone to SMEs, compared to just 44% across all sectors.¹⁵ The funding for life sciences through Innovate UK is therefore being successfully channelled to support the vibrant, entrepreneurial, and scaling community of life sciences businesses that will deliver maximum benefit and growth for the UK. Case studies of these businesses were presented in the previous section.

The Government's approach to investing in research and innovation is evolving and so is the UK life sciences sector and the global dynamic in which the UK and its industries must compete. It is therefore right that, through a Spending Review and the development of new R&D funding plans to reach the 2.4% target, a pragmatic and evidence-based analysis informs funding policy. For public R&D investment to remain efficient and sustain the UK's competitiveness, channels through which public research and innovation support is distributed must operate efficiently and without needless bureaucracy for companies.

Since Innovate UK's inception, 89% of grant funding awarded to life sciences companies has gone to SMEs, compared to just 44% across all sectors. The BIA has consulted members and analysed what does and does not work in research and innovation funding policy. We have developed five principles, detailed below, which will ensure that public funding streams remain attuned to industry needs and leverage private investment most efficiently. We encourage the Government, UKRI, the Councils and Innovate UK to adopt these principles to ensure that increases in public R&D investment successfully crowds-in the private investment necessary to reach the 2.4% target. These have been developed with the life sciences sector, but we believe they apply equally to other sectors and academia.

Recommendation: The Government and UKRI should adopt the below five principles to ensure that increases in public R&D investment successfully crowds in the private investment necessary to reach the 2.4% target.

Five principles for effective public funding streams

Balance responsive and challenge-led programmes: As it is difficult to predict where innovations will come from, it is important for SMEs to have access to responsive funding streams, such as Innovative UK grants. Responsive grants foster innovation by providing SMEs with the freedom to apply public funding to the technologies under development which they, private investors, and the market judge to be the most promising.

By comparison, challenge-led funding streams, such as the Industrial Strategy Challenge Fund (ISCF), are well-placed to deliver specific government priorities. However, as the nature of challenge-led funding streams means that funding will be directed towards clear industrial challenges, there is a risk that new innovations which do not clearly fall under the challenges will not receive any funding. It is therefore vital that challenge-led funding streams do not replace responsive ones. The BIA recommends that some of the uplift in R&D spending is targeted to increase existing response-mode funding programmes, such as the Biomedical Catalyst.

2 Sector-specific: Sector-specific funding streams provide long-term consistency and assurance to researchers and investors that the Government is committed to delivering targeted support for the sector, that funding will be available to their company in the future, and that the grant application will be reviewed by industry experts.

By contrast, funding streams open to all sectors do not signal the same level of government support to life sciences envisaged in the Conservative Manifesto and make the grant application evaluation process ambiguous. Importantly, open funding streams also put SMEs at risk of being crowded-out by larger, better-resourced companies; large companies dominate Innovate UK funding but not in health and the life sciences. Put simply, all companies and sectors are not the same and grant programmes need to reflect this.

Grants, not loans: Life science SMEs invest heavily in R&D over several years to develop their technologies, and during this time many of them do not generate any revenue. Government R&D grants and equity from private investors complement each other to allow SMEs to finance their early R&D

INVESTMENT AND GROWTH

stages in a sustainable way as they progress from innovation to market. Innovate UK grants are intended to address market failures by supporting R&D that is too risky to be commercially viable for an SME. By contrast, debt-funding favours 'playing it safe', which does not drive innovation, acts as a drag on a business and can deter future investors.

Maintain a variety of funding streams: The R&D conducted by life sciences SMEs differs depending on their business models, size, location and the type and stage of their research. As a result, a funding stream that is ideally suited to one SME or area of research may not suit another at all. For example, antimicrobial research poses specific challenges not present in most other therapeutic areas. Life sciences R&D currently benefits from a variety of funding streams, which should be maintained. However, it is important that they are easy to navigate and that there is delineation between funding streams. There should not be so many funding streams that their purpose and accessibility is not clear.

5 Unbureaucratic and informed by the needs of the sector: Funding decisions should be rigorous but that does not mean they need to be bureaucratic. The application processes for R&D grant funding should be simple, straightforward and transparent in order to ensure SMEs' limited capacity is deployed effectively. The processes of different funding streams should be harmonised as much as possible without impeding function and staff within funding bodies should be available to help applicants.

As communication between government and industry is vital in a constantly changing business and scientific environment, the Government should work in partnership with life sciences SMEs to ensure public funding streams are responsive to the dynamic needs of the sector. This partnership should be conducted through formal channels and forums to allow SMEs to inform the design and priorities of the funding streams. This would maximise the value of the public investment and drive the sector's global competitiveness.

5. Building towards the 2.4% target

The previous section focused on public funding streams and the vital support they provide to life sciences SMEs. However, as the case studies on innovative UK SMEs in section 3 demonstrate, public funding streams are complemented by other policy levers, which the Government and UKRI have at their disposal to ensure the UK maintains a globally competitive business environment and a strong life sciences ecosystem.

These policy levers fall into three broad categories: fiscal R&D incentives, patient (long-term) capital and support for the ecosystem. This section expands on each category and sets out how they are a key part of the Government's aim make the UK a global hub for life sciences and instrumental in achieving the 2.4% target. Crucially, responsibility for these spans government and requires departments to work towards the collective goal of 2.4%.

5.1 Fiscal R&D incentives

Fiscal R&D incentives utilise the tax system to promote R&D investment and commercialisation to benefit the UK socially and economically. They not only provide critical support to innovative SMEs throughout their lifespans, but also help to attract globally mobile investment from overseas investors and international companies that would otherwise locate elsewhere. Non-R&D related tax policies, such as the Corporation Tax rate and business rates are also of great importance here and must be kept internationally competitive. However, we have limited ourselves to R&D fiscal incentives in this report.

For every pound spent on R&D tax credits, between £1.53 and £2.35 is additionally spent on R&D by UK companies.

R&D tax credits

The small and large R&D Tax Credit schemes are enormously valuable to life sciences SMEs. Tax credits provide a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D, stimulating further investment. A 2015 government review of the regime estimated that for every pound spent on R&D tax credits, between £1.53 and £2.35 is additionally spent on R&D by UK companies.¹⁶ The review found that these results are in line with previous international studies, which have found tax credits stimulate from around 0.3 to around 3-times their value in R&D investment. In addition, a study by the

University of Oxford in 2019 found companies increase their R&D investment approximately 33% in response to more generous tax credits.¹⁷

R&D tax credits complement public hypothecated funding streams, such as the Biomedical Catalyst, by providing flexible funds for R&D that are not tied to a specific project. As the precise research project that will lead to a scientific advance can be difficult to predict, this supports innovation by providing flexibility to companies. In this respect, tax credits and Innovate UK grants mirror the dual-funding system, which uses response-mode funding from UKRI councils and quality-related block grants to support flexibility in academic research institutions and is enshrined in law through the Higher Education and Research Act 2017.

Tax credits are particularly important for the survival of small companies with negative cash flows (i.e. pre-revenue), as they provide an additional and flexible source of non-dilutive finance. This is often a lifeline that provides additional time to raise further private investment.

However, the previous government considered amending the SME tax credit scheme to make it more restrictive by linking payments to payroll size.¹⁸ This proposal could fundamentally undermine the UK's biotech SME sector because many companies use a business model involving outsourcing R&D to reduce capital risk. Biotech companies in the UK and around the world have evolved a lean and efficient business model involving a network of specialist companies, complemented by universities and hospitals, each contributing to a specific part of the R&D process. This 'virtual biotech' model has evolved to manage the risk associated with biotech R&D programmes but is also more efficient than the traditional 'large pharma' R&D model and creates more stable employment in UK regions. It is vital for the future of the sector that the Government ensures that anti-abuse measures, such as the PAYE cap proposed by the previous government, do not impact genuine SMEs and harm the growth of the life sciences sector.

It is also important that both the SME and large company schemes are kept relevant for R&D in the 21st Century. The Government's manifesto commitments to increase the tax credit rate to 13% and review the definition of R&D to include cloud computing and data are welcome. The promised review provides an excellent opportunity to enhance the UK's regime to ensure it is internationally competitive to attract investment, and ensure the coverage of eligible costs remains relevant to R&D as the life sciences sector evolves.

Recommendation: In its review of R&D tax credits, the Government should:

- ensure that anti-abuse measures, such as the PAYE cap proposed by the previous government, do not impact genuine SMEs
- benchmark the R&D tax credits system to ensure it remains internationally competitive to attract investment
- ensure the coverage of eligible costs remains relevant to R&D as the life sciences sector evolves, particularly the acquisition, storage, processing and analysis of data

Enterprise Management Incentive and Entrepreneurs' Relief

It is important that those who take risks and dedicate themselves to starting and scaling R&D-intensive businesses are rewarded, and that the tax regime allows SMEs to attract the talent they need. The Enterprise Management Incentive (EMI), which provides capital gains tax relief on employee-owned shares through the Entrepreneurs' Relief Scheme, helps start-ups and scale-ups to attract talent despite not being able to offer competitive salaries. This is true for cash-burning early-stage bioscience companies. However, there is a risk that some individuals, for example part-time directors or management, are not able to benefit due to the requirements for the employee to spend either more than 25 hours a week or over 75% or their working time working for the company. It is common practice in lean and agile biotech businesses for senior R&D directors and other staff to share their time between multiple companies, meaning they do not qualify. In its review of Entrepreneurs' Relief, the Government should maintain the benefits of the Enterprise Management Incentive to ensure the scheme is equitable and supports young businesses to access the talent and skills they need to grow. The Government should review the scheme to ensure it is equitable and supports young businesses to access the talent and skills they need to grow.

Entrepreneur's Relief is also a valuable scheme for rewarding individuals who start and grow a business. However, the scheme's value to the sector has been diluted significantly by multiple policy changes and continues to penalise those who take on significant equity investment, which rapidly dilutes founding shareholders below 5%. They are therefore ineligible for the relief, even though they have built a personal company at risk over several years.

This can be a barrier to successful bioscience entrepreneurs exiting companies in a financial position where they are able to reinvest in new ventures, creating a virtuous cycle of entrepreneurism. The Government's manifesto commitment to review and reform the scheme is an opportunity to promote this virtuous cycle. In addition, recent changes to the scheme have further devalued the scheme, so it is important that the Government does not seek to introduce any more negative reforms in its review. In the review, the Government should also ensure the scheme truly supports the growth of Knowledge Intensive Companies.

Recommendation: In its review of Entrepreneurs' Relief, the Government should:

- maintain the benefits of the Enterprise Management Incentive to ensure the scheme is equitable and supports young businesses to access the talent and skills they need to grow
- ensure it truly supports the growth of Knowledge Intensive Companies

Venture capital schemes

Companies require significant levels of private capital to invest in R&D and commercialise it to the benefit of society and the economy. The Enterprise Innovation Scheme (EIS), and its associated seed scheme (SEIS), have been highly effective in stimulating venture capital investment into start-ups, including bioscience companies. Venture Capital Trusts (VCTs) are also valuable for raising money

for later-stage companies. In recent years the focus of these schemes has been honed to support Knowledge Intensive Companies, which is a welcome prioritisation.

All venture capital schemes should be maintained, and the amount of tax-advantaged capital companies can receive through them should be increased to reflect the high levels of investment such companies require.

Recommendation: The Government should maintain all venture capital schemes and increase the amount of tax-advantaged capital companies can receive through them to reflect the high levels of investment such companies require.

The Patent Box

The Patent Box is highly effective in supporting R&D-intensive companies and ensuring that the products of R&D are exploited in the UK. The policy intention of the Patent Box was not to stimulate innovation *per se* but to "encourage companies to locate the high-value jobs and activity associated with the development, manufacture and exploitation of patents in the UK."¹⁹ The Patent Box enhances the international competitiveness of the UK tax system for high-tech companies that obtain profits from patents, which includes the life sciences sector and is a strong draw for international industry and investors.

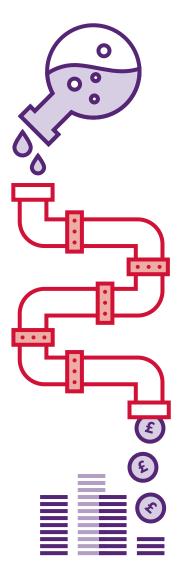
However, the Patent Box rate must be seen in relation to the rates in competitor countries, for example, Ireland (6.25%) and Belgium (6.98%). The lower rate of corporation tax under the Patent Box is 10%, compared with the standard corporation tax rate of 19%. As the Government has made welcome reductions in the standard corporation tax rate,²⁰ the relative value of the Patent Box has decreased. The Government should therefore adjust the Patent Box rate to maintain at least ten percentage points difference between it and the standard corporation tax rate to ensure it remains internationally competitive to attract investment.

Recommendation: The Government should adjust the Patent Box rate to maintain at least ten percentage points difference between it and the standard corporation tax rate to ensure it remains internationally competitive to attract investment.

Support for investment in medicines manufacturing capacity

Medicines manufacturing is a vital part of the life sciences sector, increases the UK's productivity and supports highly skilled jobs around the country. Due to their large costs and long timelines, medicines manufacturing investments are long-term commitments by life sciences companies.

The Life Sciences Industrial Strategy set out the ambition for the UK to attract ten large (£50–250 million capital investment) and ten smaller (£10–50 million capital investments) in life science manufacturing facilities in the next five years.²¹ The BIA and the Medicines Manufacturing Industry Partnership (MMIP) believe that for the Government to meet this ambition, and for the UK to increase its share of traditional



medicines manufacturing and attract a significant share of next generation medicines, it must be more globally competitive.

The UK should therefore focus on securing the next wave of manufacturing, both the traditional pharma capacity and particularly that associated with the next generation of medicines such as the emerging cell and gene therapies. In the current environment with global reticence arising from Brexit, more needs to be done to deliver the ambitions of the Life Sciences Industrial Strategy.

The BIA recommends that a fund of up to £450 million of financial support in the form of targeted capital grants in order to deliver on the ambitions to attract ten large (£50–250 million) and ten smaller (£10–50 million) commercial scale manufacturing facilities in the next five years.

At an intervention rate of 10–15%, the low impact scenario (ten £10 million and ten £50 million investments) would need £60–90 million public sector finance and the high impact scenario (ten £250 million and ten £50 million investments) would need £300–450 million. This should be delivered through tailored flexible financial support, primarily through grants which can include retention.

Recommendation: The Government should create a fund of up to £450 million of financial support in the form of targeted capital grants in order to deliver on the ambitions set out in the Life Sciences Industrial Strategy to attract ten large (£50–250 million) and ten smaller (£10–50 million) commercial scale manufacturing facilities in the next five years.

5.2 Patient capital

The UK has historically lacked sufficient patient (long-term) capital to support the growth of innovative companies at scale. Patient capital enables SMEs to develop their technologies with a long-term view, instead of hampering their growth by focusing on the generation of immediate returns to investors, for example through an early IPO. As important as the long-term view, is the quantum of funding; UK companies have traditionally been drip-fed funding, hampering their growth. As the Nightstar case study on page 19 shows, UK companies can grow rapidly and compete internationally when sufficiently financed. Unlocking greater sums of patient private capital is a key part of achieving the 2.4% target and should be a focus across government departments and funders.

In no other sector is the need for patient capital more acute than in the life sciences. Companies in the sector face long and expensive R&D timelines²² and as SMEs are generally focused on developing a specific technology, they often not have any other assets to generate a profit while the technology is developed. This means SMEs are dependent on successive fundraising rounds to maintain cash flow while carrying high levels of risk. A key challenge for the whole sector is to find enough investors willing to commit their capital to illiquid assets for five to fifteen years.

Through the Patient Capital Review,²³ the previous government made welcome commitments, including an additional £6 billion to the British Business Bank

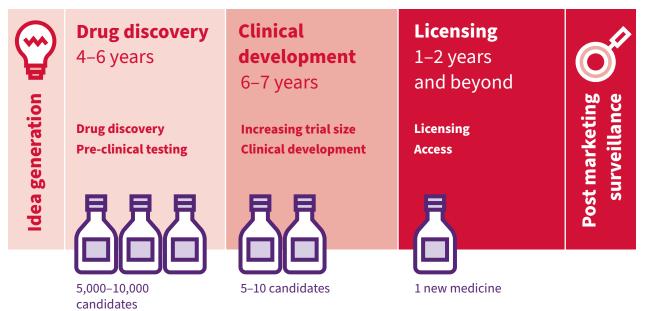
to catalyse venture capital investment over the next ten years and a pledge to work with the pension fund industry to address the concerns of businesses that pension funds do not invest in UK early-stage companies. The British Business Bank provides valuable support to innovative companies by providing finance to venture capital investors, particularly through the new £2.5 billion British Patient Capital entity, the Angel Co-Fund and the Enterprise Capital Fund. The European Investment Fund has also supported innovative companies in a similar way but as the UK leaves the EU, this support will cease, and the British Business Bank will need to be financed to step into the gap.

More private investment is also needed. With £2.2 trillion under management,²⁴ UK pension funds are well placed to be significant patient investors in UK innovation. However, as the Patient Capital Review noted, they have moved away from investing in equity and investment in early-stage companies is minimal. Government action to tackle this – through addressing regulatory barriers and communicating the advantages of investing in innovative companies with great growth potential – is a low cost for the taxpayer and delivers significant capital for innovation. The BIA welcomed the Government's manifesto commitment, reflected in the Queen's Speech, to unlock pension funds to invest and commercialise in scientific discoveries. The BIA is currently also engaging directly with pension fund managers and other institutional investors to promote the opportunity of the life sciences sector.

Recommendation: If funding from the European Investment Fund ceases when the UK leaves the EU, the British Business Bank should be provided additional capital to address the finance gap.

Recommendation: As pension funds are well-placed to be patient investors in innovation and could contribute significantly to the 2.4% target, the Government should continue to work proactively to unlock pension fund investment in innovative companies.

To develop one successful medicine, it can take the testing of up to 10,000 drug candidates over a decade and over \$1 billion



5.3 Supporting the life sciences ecosystem

The UK is renowned worldwide for its excellent science base – it is home to some of the most prestigious universities in the world and responsible for more than 15% of the world's most highly cited scientific articles.²⁵ This thriving science base is the foundation for the whole UK life sciences ecosystem, and to achieve the 2.4% target, it must continue to be supported and well-funded.

The UKRI Councils

The science base and the ecosystem are supported by the UKRI Councils, including MRC and BBSRC. The Councils provide competitive research grants and career awards to scientists, which ultimately enables ground-breaking ideas to progress through the innovation pipeline – from the initial discovery to the finished products on the market that change people's lives. The BIA's Science and Innovation Advisory Committee published a paper in 2018 which emphasises the importance of balance between discovery, analytical and bioprocessing sciences and makes recommendations on those areas of science that are most critical to the ongoing success of the sector.²⁶

In 2017–18, the MRC and the BBSRC invested £814.1 million and £498 million into the science base respectively.²⁷ A significant amount of these investments are longterm commitments to training programmes, projects and research institutes. If the Councils become increasingly dependent on ad hoc funding allocations from UKRI to fund their priorities, there is a risk it will become more difficult for the Councils to commit to long-term funding. Multi-year settlements for the MRC and the BBSRC is important to underpin the science base to maintain the UK's globally competitive life science ecosystem.

Recommendation: The Government should provide multi-year settlements for the UKRI Councils to underpin the science base to maintain the UK's globally competitive life science ecosystem.

The Department for Health and Social Care

The ultimate purpose of the UK's life sciences sector is for patients to have access to lifesaving or life-enhancing new medicines. The BIA therefore welcomed the Government's announcement of the five-year £20.5 billion settlement for the NHS in June 2018. Having a supportive home medicines market is important to increasing R&D investment as uptake of new medicines is front of mind for global decision makers when considering where to invest. We are committed to the Accelerated Access Collaborative (AAC)'s aim of making the NHS one of the most pro-innovation healthcare systems in the world to deliver both patient benefits and growth to the UK economy.

Much of the vital infrastructure support for the life sciences sector comes of other parts of the Department for Health and Social Care (DHSC)'s budget, including funding for the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health Research (NIHR). It is therefore important that the Government commits to the funding of the MHRA and the NIHR in the Spending Review.

Medicines and Healthcare products Regulatory Agency

Key to growing and capitalising on the UK's life sciences sector and attracting foreign R&D investment is ensuring that the UK retains the MHRA's international standing and its regulatory science expertise in the eyes of global companies and investors. The UK is respected around the world for its robust and science-led regulatory regime for the R&D of innovative medicines and other life science-related products.

The MHRA is valued by industry and recognised for its expertise and competence in the European regulatory system, as well as relevant in global R&D. The UK's future participation in the European Regulatory Network and the European Medicines Agency remain uncertain due to Brexit, meaning investment will be needed to maintain the MHRA's expert staff and enable the agency to perform its mission to protect public health and patient safety.

The MHRA forms an integral part of the UK life sciences ecosystem and should be embedded in the science base, fostering innovation and attracting global companies to conduct clinical trials in the UK.

Recommendation: The Government and DHSC should commit investment to the MHRA embedding in the science base to support innovation and deliver patient benefits.

The Francis Crick Institute: Accelerating the translation of ideas into impact

The Crick is a biomedical discovery institute dedicated to understanding the biology underlying health and disease. One of its strategic priorities is to turn discoveries into health benefits. The Crick is an independent charity and a unique partnership between the MRC, Cancer Research UK, the Wellcome Trust and three universities. It is currently home to around 1,500 scientists.

The Crick is located within the King's Cross' 'Knowledge Quarter', a unique cluster of worldleaders across a range of science, business and research disciplines. The 'Knowledge Quarter' provides an ecosystem with the potential to take a world-leading role in the future of data-driven health technologies. To enable early data-driven health companies to thrive in this ecosystem, the Crick has established the spin-out accelerator KQ Labs.

KQ Labs is open to applications from researchers from both within and outside the Crick. KQ Labs provides successful applicants with an initial £40,000 grant (funded by Innovate UK). This grant helps the start-ups to validate their ideas and supports the companies as they seek further investment from government grants, venture capital and other sources. Even though the Crick was only formed in 2015, and moved into its new home in 2016, the institute's research has already generated four spin-out companies. These companies are continuing to develop their technologies to improve human health and three of them have leveraged private investment and formed collaborations with global companies.

The National Institute for Health Research

With an annual budget of around £1 billion, the National Institute for Health Research (NIHR) is the UK's largest funder of health and care research. The NIHR has a critical role in supporting clinical research in the NHS and its significant investments in the UK's research infrastructure enable the whole life science ecosystem to benefit from world-class facilities. In addition, the NIHR provides SMEs with the funding and support needed to conduct expensive clinical trials. As such, the NIHR is a key role in supporting the life sciences ecosystem and the 2.4% target.

Recommendation: The Government should provide multi-year settlements for the NIHR to underpin the science base to maintain the UK's globally competitive life science ecosystem.

Developing a highly skilled workforce

A key part of maintaining the ecosystem's competitiveness is ensuring that researchers have access to the training they need to develop the scientific skills required to discover and advance new bold ideas, but also the leadership and entrepreneurial skills needed to build and progress a company. The MRC's and the BBSRC's many fellowship programmes are a critical component of this and support world-class training at various stages in researchers' careers. The NIHR also invests in people to sustain excellent research capacity throughout clinical and non-clinical academic career pathways and provide high-quality development opportunities for the delivery workforce in our infrastructure.

Many researchers and clinicians go on from these programmes to work in industry and contribute to the growth and success of life science businesses. Industry also has an important role to play in upskilling the workforce and the life sciences sector is committed to this. The BIA champions the development of both scientific and entrepreneurial skills through two programmes: the Programme for Up and coming Life Sciences Entrepreneurs (PULSE) and the Leadership Programme (LeaP) (see box on page 33 for more information).

However, to maintain the UK's globally competitive life science sector, companies and research institutes also need access all levels of talent from around the world. While the Government's manifesto commitment to attract the best scientific talent to the UK is welcome,²⁸ the post-Brexit immigration framework must protect and support the international movement of scientists of all levels, including graduates who may not yet have reached their potential.

As collaborations across borders are an equally important engine for research and innovation, the UK should develop the closest possible relationship to the EU's Framework Programmes, Horizon 2020 and its successor Horizon Europe. Beyond simple monetary returns, the global nature of these programmes helps forge new collaborations, open new markets, and increase the diversity of prestigious funding available.

As the UK establishes a new relationship with the EU and the wider world, the Government must ensure that the country is – and is seen to be – welcoming to international researchers.

Recommendation: The UK should develop the closest possible relationship to the EU's Framework Programmes, Horizon 2020 and Horizon Europe.

Recommendation: The post-Brexit immigration framework must protect and support the international movement of all levels of researchers and the Government must ensure that the country is – and is seen to be – welcoming to international researchers.

Skills programmes supported by the BIA

The Programme for Up and coming Life Sciences Entrepreneurs (PULSE)

PULSE is a three-day leadership and entrepreneurship training programme developed by the BIA and the Francis Crick Institute. The programme is for aspiring entrepreneurs and new chief executives looking for advanced practical advice, support and feedback from leading entrepreneurs, renowned professionals and chief executives. Now in its second year, PULSE gives participants, who are drawn from academia and industry, the invaluable opportunity to gain new skills and build relationships across the sector, from life sciences experts and investors, to other up-andcoming chief executives.

Companies in PULSE's first cohort in 2018 have since successfully completed private funding rounds totalling over £15 million.

The Leadership Programme (LeaP)

LeaP, organised by the BIA's Manufacturing Advisory Committee, focuses on the development of managers in the biopharmaceutical and cell and gene therapy industries. This is an important part of life sciences ecosystem to deliver senior leaders of the future, create new highly skilled jobs and support the growth of the sector.

The two key aims LeaP are firstly to promote cross-sector learning by offering an overview of the work of other companies, and secondly to develop a network with peers to share best practice and develop relationships to encourage possible future collaborations.

The pilot programme was launched in January 2017 and completed in January 2019, following which an alumni group has been set up to support ongoing networking. On the back of the success of the pilot, a second programme is well underway, and a third double cohort started in January 2019. Currently 44 participants from 23 member companies are benefitting from LeaP.

LeaP participants represent the future of our industry and the BIA is committed to supporting participants and alumni now and in the future.

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36 INVESTMENT AND GROWTH

About the BIA

Established over 25 years ago at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

Our members include:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants and IR agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably, and we do this through *Influence*, *Connect*, and Save.

Influence

The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators, to patient groups and the media. We also work with organisations at an international level to ensure that UK biotech is represented on the global stage including Europabio, EFPIA and ICBA. BIA is the key thought leader for the sector – working across a wide range of related issues including policy, finance, science, regulatory, legal and talent.

Connect

The BIA provides many varied opportunities for life science leaders to connect with each other – to network, share and learn from experience, to access sector thought leadership and to take key issues forward. From the famed BIA Gala Dinner, to the CEO & Investor Forum, Women in Biotech networking evenings, quarterly committee meetings and our many regional events, to name but a few, the BIA provides access to a highly respected and diverse network. BIA also works to ensure that we provide opportunities and promotion for our members internationally – through panels and networking events at major events overseas, we are raising the profile of the UK as a global hub. We know that promoting what you do as an organisation is important, and we help organisations to raise their profile – at events and through our online presence and communications.

Save

For many of our emerging members (and a good number of well-established ones too) the BIA Business Solutions Scheme provides significant savings that are helping them to grow more cost-effectively. We believe this is the most competitive scheme of its kind in the UK.



Connect

Online and in person with industry leaders

40+ events across the UK
760+ organisations
2,500+ delegates
5,000+ readership

Join the BIA www.bioindustry.org @BIA_UK















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