BIA response to the R&D Roadmap

August 2020

UK BioIndustry Association

About the BIA

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 communications agencies

The BIA's members are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

The BIA's over-arching response to the themes and priorities identified in the Roadmap

The BIA and wider UK life sciences sector is highly supportive of the Government's R&D agenda, including the overarching target to invest 2.4% of GDP in R&D by 2027.

We agree with the broad themes and priorities identified and strongly support the intention to **use the increased investment in R&D to raise domestic and international business investment** into UK R&D. This outcome is essential if the Government's efforts and investment are to lead to the economic, environmental and societal benefits it hopes to secure.

First and foremost, this Roadmap must identify what works well and build on it. Spreading resources and efforts too thinly will lead to poor returns. **Institutions that carry broad industry support will be best placed to help the Government achieve its desired outcome** and so should be strengthened. Innovate UK and its catapult centres are a good example and ripe for expansion. **Increasing the proportion of public funding for applied research and experimental development, cutting bureaucracy and providing institutions with greater autonomy will allow innovation to thrive**. Moonshots can be inspirational and catalytic; ambition, clarity and freedom from short-term political priorities are prerequisites for their success.

There are many examples of exemplary UK programmes supporting the translation of blue-skies research into commercial success, the Biomedical Catalyst chief among them. Best practice in both funding programmes and how universities and public research establishments operate technology transfer

should be spread across the system. The BIA would welcome the opportunity to represent the UK life sciences SME sector on the Innovation Expert Panel.

The essential role of the private sector in turning research into value means the Roadmap is right to **focus on key industries such as the life sciences**, and on supporting entrepreneurs and increasing the flow of capital into start-ups and scaling innovative businesses. **Unlocking new sources of private finance, such as from pension funds, must be a key objective and will maximise returns from public R&D funding by ensuring industry's ability to "pick up the baton".** Regulators also can be enablers of innovation and a world-leading life sciences industry industry is dependent on a world-leading regulator.

A vibrant life sciences sector requires a diverse workforce, with talent drawn from across the world and different backgrounds. It requires R&D and high-value manufacturing professionals at all technical levels. **Establishing a function and priority at the heart of Government to ensure the UK is attractive to global talent is long overdue**. The Office for Talent must serve both academia and industry, both require talent in equal measure; and it must recognise that desirable talent doesn't exist just in the top tier of professions, the UK will need talented individuals at every stage of their career if we are to maintain our world-leading position.

In summary: if this Roadmap wishes to secure the greatest benefit from the Government's R&D investment, it must **take a holistic approach to policy, looking far beyond the research ecosystem to ensure the business environment – from tax incentives to immigration – is optimised** to support the UK's innovative industries to translate academic research into economic, environmental and societal benefit.

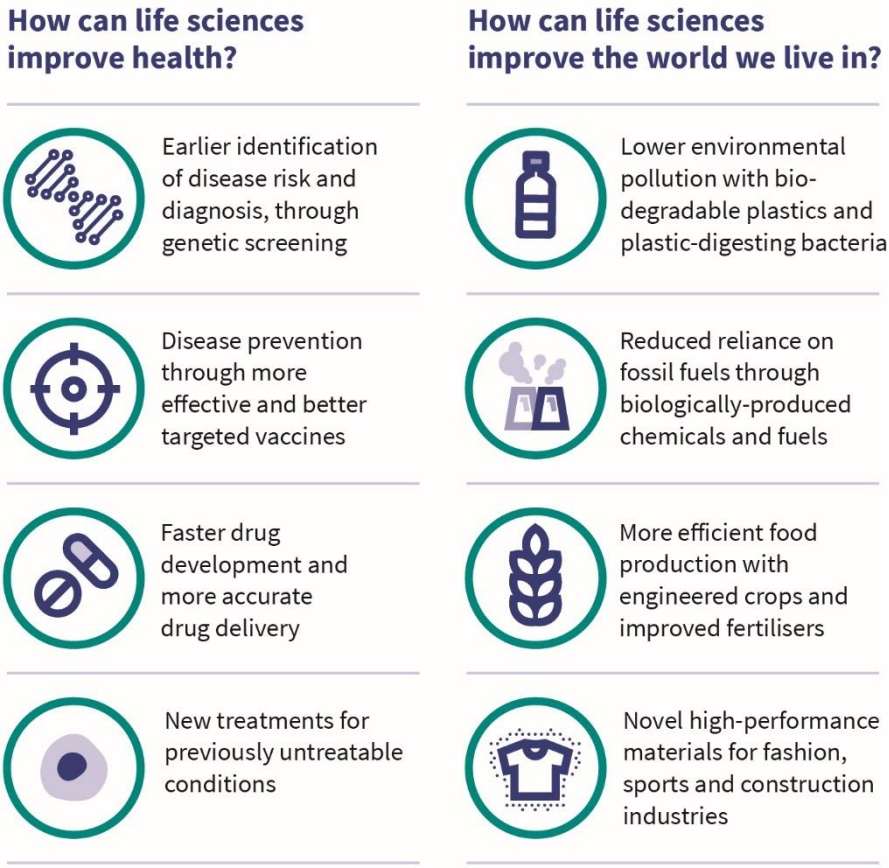
The R&D Roadmap is timely as the UK emerges from the pandemic with a fresh understanding of the importance of research and innovation to mankind's survival, and as the UK charts a new path outside the European Union. The BIA is pleased to have the opportunity to input and in this response we have selected key top-level areas that we feel are a priority for industry. However, **the BIA and our members have interest and expertise across the breadth of the issues the Roadmap addresses and would welcome opportunities for further, more in-depth input.**

Overview of the UK's life sciences sector and its contribution to UK R&D

The UK's R&D-intensive life sciences sector is universally recognised as world-leading, and it delivers great benefits to the economy, the health of the nation and it is key to the Government's net-zero agenda. From improving patients' lives through new treatments and digital healthcare, to the development of environmentally-sustainable technologies, such as fossil fuel substitutes, biodegradable bioplastics and the cleaning of polluted waters, our deep understanding of biology is helping the UK address humankind's greatest challenges. We have provided case studies in appendix one to illustrate some of the value being created by UK life science companies.

It is as a result of having a vibrant UK life science ecosystem that the UK has been able to play a globally leading role in the global response to the pandemic, putting the UK in a strong place to benefit rapidly from vaccines, diagnostics and therapies. The Medicines Discovery Catapult has been the backbone of the Lighthouse Labs, Oxford Nanopore and DNA nudge have developed the new flu and COVID-19 test and the UK medicines manufacturing base has come together rapidly to scale-up production capacity for vaccines, with established manufacturing sites in Wales, Scotland and England utilised. This demonstrates the value of the regional spread of the sector.

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. Our pharmaceutical industry consistently invests more in R&D than any other



sector (£4.5bn in 2018). The UK has almost 5,870 life science companies, 80% of which are SMEs[1], and these employ almost a quarter of a million people, with the average GVA per employee over twice the UK average at £104,000.[2] Two-thirds of these jobs are outside London and the South East.[3] Private investment in the UK's life sciences start-ups and scale-ups has also increased 400% since 2012, signalling a bright and innovative future.[4]

The sector is committed to using this strength and opportunity to support UKRI's ambitions to build a more diverse and socially beneficial research and innovation community. The UK life sciences sector has a competitive advantage in cell and gene therapies and the Advanced Therapies Apprenticeship Community (ATAC) has been established to develop the first apprenticeship programme designed specifically to train and upskill individuals to develop, manufacture and deliver these innovative therapies at scale. The ATMP Technician Scientist, which is the first operational ATAC apprenticeship has 60% female and 25% BAME participation. Another programme, providing training to develop senior leaders, is 40% female and approximately 20% BAME. Overall, out of 68 apprentices (a combination of upskilling and new talent programmes) the cohort is 45% female and 25% BAME. These programmes are small scale at the moment

[1] UK Government (2019), *Bioscience and health technology sector statistics 2018*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2018
[2] PwC (2017), The economic contribution of the UK life sciences sector: https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf
[3] UK Government (2019), *Bioscience and health technology sector statistics 2018*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2018
[4] BIA (2020), *Global and growing: UK biotech financing in 2019:* https://www.bioindustry.org/resource-listing/global-and-growing---uk-biotech-financing-in-2019.html

but also only a few years in existence; the BIA and our partners are committed to building on this early progress and improving the diversity further.

These benefits are the result of a continuous and supportive industrial strategy delivered by successive governments, through the creation of R&D tax credits by the Labour Government in 2000, the Biomedical Catalyst by the Coalition Government in 2012, and the establishment of the £200m Life Sciences Investment Programme by Boris Johnson in 2019. 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. This Government can build on historical success by working with the life sciences industry to improve the health of the population, including building resilience to future pandemics, and to develop and implement environmentally sustainable technologies. In doing so great economic, environmental and societal benefits can be captured, including high-value job creation across the country, new industries of the future and the continuation of the UK's standing as a research and innovation superpower.

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.

How can we best increase knowledge and understanding through research, including by achieving bigger breakthroughs?

A new ambitious approach to R&D funding could energise the already high-performing ecosystem in the UK and maximise the benefits for our environment, society and economic prosperity.

Innovate UK has been pivotal to the success of the UK life sciences sector, with the Biomedical Catalyst (BMC) successfully bridging the "Valley of Death", which was holding back the sector a decade ago. The funding programme has supported the translation of academic research – primarily funded by the Medical Research Council – into commercial projects supported by Innovate UK[5]. Its continuation and expansion is essential.

Innovate UK, its sector-specific funding programmes such as the BMC and the catapult centres are all excellent examples of successful industrial strategy. They carry strong support within industry and, with greater funding and autonomy, we believe they could be the driving mechanism through which the increased public investment in R&D raises domestic and international business investment into UK R&D. This outcome is essential if the Government's efforts and investment are to lead to the benefits it hopes to secure.

The vast majority of Innovate UK's funding for life sciences rightly 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.[6] 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 can be found in appendix 1.)

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

[5] Ipsos MORI (2019) Biomedical Catalyst impact evaluation: https://www.gov.uk/government/publications/biomedical-catalyst-impact-evaluation
[6] Innovate UK: Grants: Written question – 237126: https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2019-03-26/237126/

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

1. **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 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.

3. **Grants, not loans**

Innovation funding should be carefully tailored to match the policy ambition and needs of a particular sector. 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 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. While some debt products have entered the innovation policy environment in recent years (Innovation Loans and the Future Fund), these have not been a catalytic driver of life sciences innovation or business growth; the role of debt in financing innovation should be carefully examined before further roll-out of such products.

4. **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.

The role of UK ARPA

A new high-risk, high-reward funding programme, as imagined in a UK Advanced Research Project Agency (ARPA), could add another well-needed dimension to the UK's innovation capabilities by funding strategic projects leveraging UK strengths in transformative technologies, such as artificial intelligence and engineering biology. It should do this by funding projects both in academia and industry.

However, the role of such a programme must be unique. It must not be just another funding source. The key aspect that sets US DARPA apart from other R&D funders is its vision, which is driven by extraordinary ambition. While US DARPA projects often have a very specific problem that is quite practical (e.g. prepare for the next pandemic by learning to quickly develop and deliver a vaccine), the agency's unique remit means that it seeks a solution that goes way beyond the minimum required to resolve the need (e.g. develop 100,000 doses of any vaccine made from DNA within 24 hours in a container in the desert). The scope of this ambition pushes academics and companies alike to find ways to meet the target. For a UK ARPA-like initiative to truly differentiate itself from existing R&D funders in the UK, it must embrace an equally extraordinary ambition and vision.

The US DARPA has not been successful by funding blue skies research. Rather, its success can largely be attributed to addressing the "valley of death"[7]. It is important to note that the US DARPA is not bridging the "valley of death" by only providing funding to these high-risk projects; the agency also has an important role in guiding projects through the R&D process to ensure the new technologies ultimately reach the market and are applied in practice.

The US DARPA is a small organisation within the large US innovation system and has a proportionally small budget. However, the proposed annual budget of £200m for UK ARPA is small and not sufficient for the agency to fund a novel idea from discovery all the way through to market. Bringing a product to market is expensive and requires considerable private investment, especially in life sciences. Project managers will need to work with the private sector and investors to secure additional investment and/or industry partnerships as the R&D projects progress. The Sand Hill Road VC community in Silicon Valley helped generate DARPA's impact; as described below, innovation policy will need to focus on access to private finance for innovative UK businesses if the UK ARPA is to succeed.

The success of a high-risk, high-reward funding programme should be measured over a long timeline that stretches 10+ years. As such, the Government should not expect it to contribute to the 2.4% target. The bureaucratic oversight by government must also be minimal to ensure the programme can develop an extraordinary ambition and fund the high-risk R&D projects necessary to deliver on its core function and promise.

Whether it needs to be a new entity or a programme supported by one or more existing research funders requires further examination. The Government should be cognisant of the UK's heritage, expertise and capabilities within existing institutions and ensure a UK ARPA, in whatever shape it takes, complements these, integrates seamlessly and avoids past mistakes in the Government's management of innovation policy. A recent article[8] by Ian Campbell, the Interim Executive Chair of Innovate UK, and David Bott, a former director of the Technology Strategy Board, explores this and should be considered.

Recommendation: the government should establish a high-risk, high-reward research and innovation funding programme, which to succeed must:

- **Clearly identify, articulate, design and address challenges that are under-served by existing public funders, industry, and investors**
- **Fund research from any discipline in a technology-agnostic way at any stage of the innovation pipeline**
- **Actively manage the overall R&D process throughout its projects whilst providing flexibility and freedom to the individual researcher groups and companies which it funds**
- **Work with end-users (customers), industry and downstream investors to ensure the solutions its projects are developing are implemented in practice**
- **Operate with a high degree of autonomy from central government and have long-term horizons**

[7] William B. Bonvillian (2020), 'A Summary of the Darpa Model': https://policyexchange.org.uk/wp-content/uploads/Visions-of-Arpa.pdf
[8] Ian Campbell and David Bott, The Telegraph (2020), A 'British DARPA' can't solve the UK's innovation woes: https://www.telegraph.co.uk/technology/2020/07/20/british-darpa-cant-solve-uks-innovation-woes/

How can we maximise the economic, environmental and societal impact of research through effective application of new knowledge?

AND

How can we encourage innovation and ensure it is used to greatest effect, not just in our cutting-edge industries, but right across the economy and throughout our public services?

Key to securing the benefits of research investment is ensuring that the UK has the right environment for business investment and growth so that discoveries can be translated into services, processes and products that have value, be in economic, environmental or social. The vast majority of this translation and delivery to "consumers" is done by the private sector, hence it must be a primary focus for the Roadmap.

We welcome the Roadmap's attention to the R&D Tax Credit schemes, which are enormously valuable to innovative businesses. They provide a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D, stimulating further investment. R&D tax credits are particularly critical for young companies yet to generate revenue. Government plans to update eligible costs to reflect how research is conducted in the 21st Century is welcome and overdue[9]. Expanding the R&D tax credit scheme further to include capital would greatly incentivise investment in the equipment and infrastructure UK industry requires to scale here in the UK, anchoring downstream benefits, such as high-value manufacturing jobs and tax revenues. The Patent Box is another valuable fiscal driver of R&D investment and commercialisation. It incentivises companies to maintain their R&D and commercial operations in the UK.

An SME developing a new medicine or technology requires an investment of many hundreds of millions of pounds to bring their product to market. Securing this private investment is a challenge and a lack of scale-up capital has historically been – and continues to be – a drag on the growth of UK high-tech businesses. The UK's innovation economy is U-shaped, with a large community of start-ups and SMEs, some very large established companies but few medium-sized scaling companies. We need policy to support scale-up and growth, as this is what delivers sticky long-term jobs and tax revenue. Without sufficient working capital, industry will be unable to "pick up the baton" from academic research to translate it into the final benefits the Government wants to see. This not only applies to the capital required for spin-outs and start-ups, but also more established companies that are scaling up. For too long the UK has seen these businesses follow the money across the Atlantic. As the 2017 Patient Capital Review demonstrated, this problem is particularly acute in life sciences and there is a reliance on overseas private capital; the City of London is too risk-averse and does not invest enough in early-stage innovative businesses.

The Roadmap rightly identifies pension funds and the need to unlock the capital to support R&D. As the Scale-Up Institute noted in its recent Future of Growth Capital Report[10], unlocking defined contribution pension funds is attainable and if their capital is invested into UK enterprises and scaling businesses, the effect could be enormous. The Government's progress here is welcome – regulatory barriers have been largely addressed and the British Business Bank has made a convincing economic case for the pensions industry to invest in venture capital – but the response from the financial sector has been lukewarm. The Government has an active role to play here and should be bold and ambitious.

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[9] HM Treasury (2020), The scope of qualifying expenditures for R&D Tax Credits: consultation: https://www.gov.uk/government/consultations/the-scope-of-qualifying-expenditures-for-rd-tax-credits-consultation

[10] The Scale-Up Institute (2020), The Future of Growth Capital: https://growthcapital.report/

Recommendation: Establish a large new venture capital and scale-up fund, backed by the Government and incorporating UK and global private capital, including from British pension funds, multinational corporations and other financial institutions. It would invest in the UK's biotech industries – a broad range of innovative and R&D-intensive companies that all have biology-driven tech at their heart.

The impact of trade policy on innovation

As the UK forges new free trade agreements, it can create great opportunities to build new research collaborations, attract investment and generate business for the UK's innovative sectors. But there can also be negative impacts that hold back innovation. The EU, China and the US are developing specific industrial policies and trade relations will be an increasingly important factor in innovation policy. The R&D Roadmap and funding agencies should therefore engage in the development of the UK's new trade policies, working closely with the Department for International Trade.

State aid is a central component of almost all trade deals, and indeed is core to the EU single market policy and therefore at the heart negotiations for its future relationship with the UK. Innovative companies in the UK and across Europe have been impacted by a state aid rule called "Undertaking in Difficulty". This prevents companies from receiving state aid (i.e. R&D grants) if they have expended more than half of the total capital they have raised. This captures most biotech companies because they invest all the equity capital they raise in R&D. The rule is highly problematic and not designed for innovative growth sectors. The UK Government and UKRI should work collaboratively with EU partners to address this state aid restriction and ensure that UK innovation policy is not prevented from supporting the companies it has been established to back.

Recommendation: UK trade policy should be aligned with the principles of the R&D Raodmap to support research and innovation

The value of a world-leading regulator

The UK is in a position to lead the world into a new age of medical advances, from gene-editing therapies that could permanently cure many diseases to novel antibiotics that could address the global challenge of growing antimicrobial resistance (AMR). This world-leading innovation requires a world-leading regulator. The Medicines and Healthcare Regulatory Agency (MHRA) must remain a globally respected and innovation-supportive regulator.

The MHRA's expertise, and the UK's robust, supportive and innovative regulatory environment is seen as a major draw for global life sciences businesses. As the UK leaves the EU, the MHRA is facing new challenges, not least the loss of funding from EU assessment and inspection activities, which the Government has already recognised through additional funding in the short-term, which we welcome. The MHRA is funded from industry fees under the Trading Fund Order. Its funding model will need to be reviewed and if the UK is to remain competitive it will need to offer services to SMEs on at least as good terms as the European Medicines Agency's SME Office, so may require further Treasury support.

The R&D Roadmap is an opportunity for the Government to ensure the MHRA has the capability and funding to maintain its influential and progressive voice at the global level outside the UK and build its capacity to support healthcare innovation in the UK. This will require initiatives across the range of MHRA activities.

Recommendation: Invest in the UK's regulators to:

- **retain the capacity and capability to support researchers and businesses to innovate and develop new treatments and vaccines for the benefits of patients; and**
- **maintain its global leading position in regulatory science and influence global standards for clinical trials and medicines.**

Government procurement as a driver of innovation

A viable end market for medicines in the UK is also an important factor. When companies are looking at where to site clinical trials and early stage research, they will consider the likelihood that the output of that work will be made accessible in that country and whether that country offers the current gold standard of care for comparison against their innovative product. There is therefore a direct link between access to innovative medicines and the strength of the R&D base in the UK. The bodies primarily responsible for the assessment of the value medicines – NICE and NHS England – should also, therefore, have regard for the impact their decisions will have on R&D in the UK.

Promoting innovation should be an explicit part of NICE's role and innovation should be a part of its assessment of the value of medicines. For NHS England, we would like to see this role in promoting innovation, and consequently R&D, included in the Mandate the NHS England and NHS Improvement. In addition, the sector was encouraged by the progress being made by the Accelerated Access Collaborative prior to the start of the COVID-19 pandemic. While we understand that priorities have rightly shifted and the work of the AAC paused, we are keen to ensure that the progress gained is not lost.

Finally, we note that the Innovative Medicines Fund policy included in the Conservative Party manifesto in 2019 is still being developed. We believe this presents a great opportunity to advertise the UK globally as a place where innovative medicines can be developed and made accessible to patients, often for the first time in the world, allowing real-world data collection for further R&D. More discussion is needed on the meaning of the word 'innovative' in this context to ensure that it does not solely mean cost-reductive and that the Fund genuinely rewards breakthrough scientific advances that will highlight the UK's unique role in driving discovery.

Recommendation: Promoting R&D and innovation should be at the heart of NICE, NHS England and NHS Improvement policy.

This top-level submission is the start of a conversation. We would welcome further opportunities to provide more detail.

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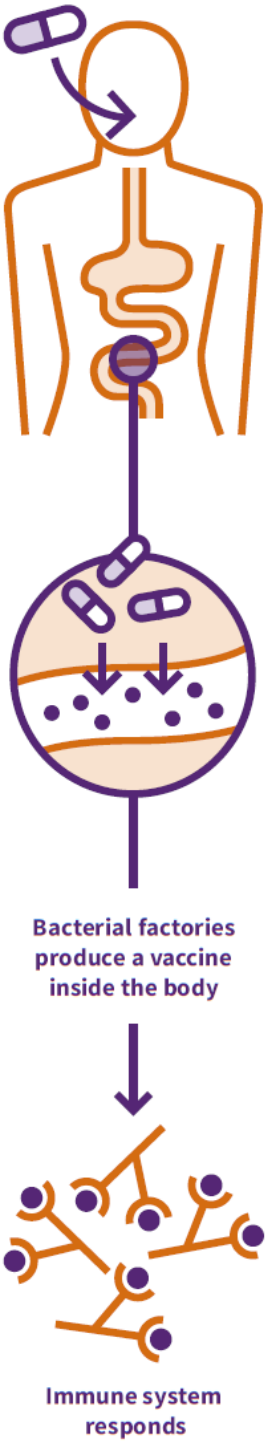
Prokarium

London

Innovation support: Innovate UK

Sub-sector: Health



Prokarium is an engineering (synthetic) biology company that develops a new, more convenient way to produce and administer vaccines.

The company's oral vaccine delivery platform, Vaxonella®, uses a modified, harmless version of *Salmonella* bacteria to deliver vaccines via the lining of the gastrointestinal tract. This approach may generate medicines that are cheaper to make and easier to store and distribute than existing injectable vaccines. It may also expand the range of diseases that can be targeted.

Prokarium has received funding from Innovate UK in various stages of the company's growth, which have been instrumental to the development of the company. A government grant enabled the company to spin-out from Cobra Biologics, a contract manufacturing organisation. Prokarium 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 of £374,000 from the Newton Fund has helped fund the development and manufacture of a novel vaccine for enteric fever (typhoid and paratyphoid), which will enter a Phase 1 clinical trial later in 2019. Prokarium is also working on a £1 million Innovate UK-funded project 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. The data package generated from the Innovate UK-funded grants was critical in securing this 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 £13 million from overseas angel and institutional investors – generating £4 for every £1 of public funding and accelerating the development of vaccines for unmet medical needs worldwide.

CHAIN Biotechnology

Nottingham

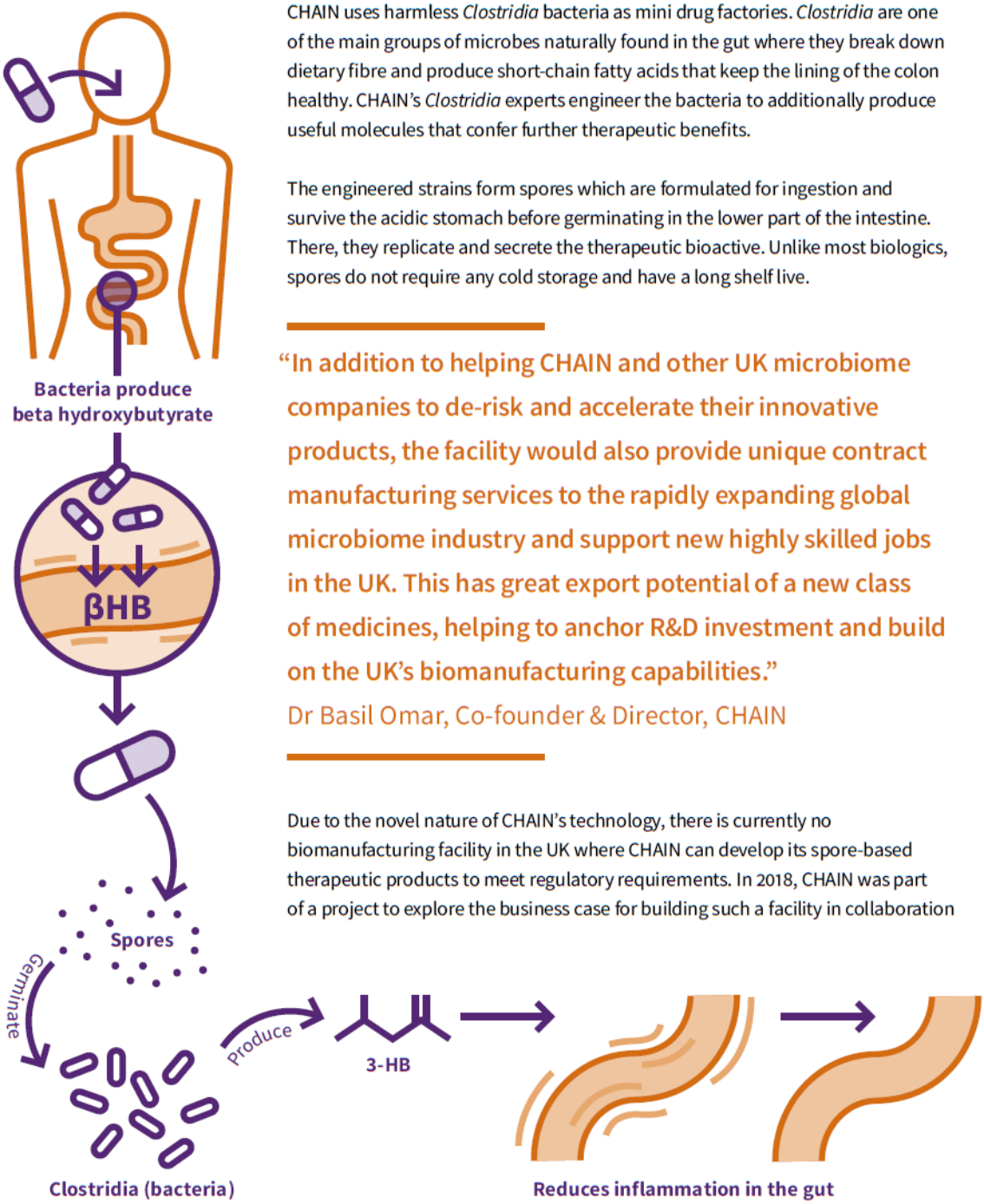
Innovation support:
ISCF Wave 1
Sub-sector: Health

CHAIN Biotechnology is a privately-held microbiome therapeutics company based at Medicity in Nottingham.

CHAIN develops a disruptive technology for the production and delivery of therapeutic molecules to relevant targets in the human gut. Its lead product produces a potent anti-inflammatory targeting ulcerative colitis.

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 that confer further therapeutic benefits.

The engineered strains form spores which are formulated for ingestion and survive the acidic stomach before germinating in the lower part of the intestine. There, they replicate and secrete the therapeutic bioactive. Unlike most biologics, spores do not require any cold storage and have a long shelf live.



"In addition to helping CHAIN and other UK microbiome companies to de-risk and accelerate their innovative products, 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. This has great export potential of a new class of medicines, helping to anchor R&D investment and build on the UK's biomanufacturing capabilities."
Dr Basil Omar, Co-founder & Director, CHAIN

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 was part of a project to explore 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.

The funding received through the ISCF facilitated new collaborations and helped to de-risk the project. CHAIN and its collaborators are in discussions with private investors and local government to secure funding for the spore manufacturing facility.

CustoMem

London

Innovation support:
Innovate UK + Horizon 2020
Sub-sector:
Environment

CustoMem 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 at White City in London.

In 2017, CustoMem was awarded a £100,000 grant from Innovate UK. The award was key to develop and produce CustoMem's first product, a novel material that can selectively and efficiently remove dangerous chemicals from industrial wastewater. CustoMem 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 CustoMem 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 eleven today, with seven more due to join in 2019.**" Henrik Hagemann, Co-founder and Chief Executive Officer, CustoMem

CustoMem's technology has already attracted large industrial companies which are facing increasingly stringent waste-regulations. In Spring 2019, CustoMem completed a £2.5 million private funding round, further enabling the company to grow and scale its technology.

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.

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

Green Biologics

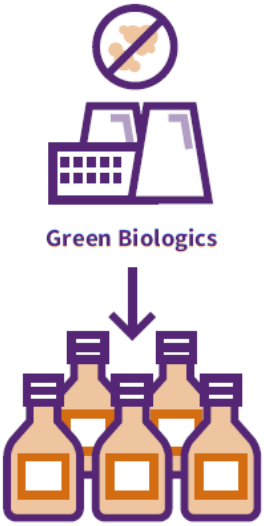
Oxfordshire

Innovation support:
Innovate UK
Sub-sector:
Environment

Green Biologics is an industrial biotechnology company that engineers biology to manufacture cleaner speciality chemicals, used to make a wide range of products, from pharmaceuticals and cosmetics to paints and plastics.

Green Biologics has re-commercialised the clostridial Acetone-Butanol-Ethanol (ABE) process, which allows the company to produce bio-based chemicals that avoids the high environmental cost of standard hydrocarbon-based manufacture.

Headquartered in Oxfordshire, Green Biologics benefits from the UK's strength in training scientists and the emphasis on interdisciplinary collaboration. Strong links with university groups, encouraged and supported by funding from the research councils, such as the BBSRC and the EPSRC, have resulted in a productive environment in which to carry out applied industrial research. The Networks in Industrial Biotechnology and Bioenergy, funded by the BBSRC, have been particularly beneficial in promoting collaborations between Green Biologics and academics from across the UK.



Innovate UK grant funding of just over £3 million since 2009 has been a key factor in supporting Green Biologics' long-term growth and securing over £100 million of investor funding.

Green Biologics benefits from R&D tax credits, which has allowed the company to focus on the development of their technology and retain talented staff. Green Biologics has also had the support of several Innovate UK grants, totalling a value of just over £3 million since 2009, which have been used to develop the company's sustainable solutions.