

# BIA submission: Priorities for CSR 2020

January 2020



## Summary

The UK is in a position to lead the world into a new age of technological advances that will **address humankind's greatest challenges, from a vaccine to free us from COVID-19 to biological fuels that will deliver net-zero carbon.** These innovations are being developed in the UK by companies that are attracting increasing quantities of inward global investment. This Government can successfully lead the UK out of the pandemic and forward as a global science superpower by backing this growing sector of economy in the spending review with targeted policies that will create more high-value jobs across the UK and leverage even greater private investment. **This is backing winners, not picking them.**

The Government has proven and effective policy levers ready at its disposal to maintain the pipeline of innovation and build an innovation-led economy. According to the Government's own figures, **the UK life sciences industry employs 256,100 people, with two-thirds of these jobs outside London and the South East.**<sup>1</sup> There are 6,300 life sciences businesses, 82% of which are SMEs, and combined they generate a turnover of £80.7bn. The average GVA per employee is over twice the UK average at £104,000<sup>2</sup>, meaning it can **deliver rewarding and well-paid jobs, across the UK in R&D and high-value manufacturing roles.**

The challenges to growth of the sector and crystallizing the economic and social benefits are identified in this submission and implementable solutions suggested.

A lack of finance for start-ups and scale-ups can be addressed with a mix of grants and government-backed equity, which will **return profit to the tax-payer and harness our finance sector to support innovative UK industries.** Continued support for our world-class research and innovation ecosystem will lead to new businesses formed and **create industries of the future.** Incentives, R&D investments and training programmes will **anchor high-value life sciences manufacturing** in the UK. And innovative regulation and NHS funding will **make the UK a world-leading drug development and launch market**, so patients benefit from innovative medicines sooner.

In summary, the BIA urges the Government to use this CSR to deliver the following priorities.

**Increasing access to finance for start-ups and scale-ups**

**Refill the Biomedical Catalyst for the period of this Spending Review and increase its annual budget to £100m to maintain the pipeline of life sciences innovation**

**Deliver the £200m Life Sciences Investment Programme complemented by a bold new co-investment fund of scale to unlock pension funds and other institutional finance to super-charge the growth of innovative UK biotech businesses**

<sup>1</sup> UK Government (2019), *Bioscience and health technology sector statistics 2019*: <https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019>

<sup>2</sup> 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](https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf)

|  |   |
|--|---|
| <b>Supporting world-class R&amp;D</b>                                    | <b>Support the UK's world-leading research and innovation ecosystem</b>   |
|  | <b>Invest in national genomic capabilities to support the growth of a vibrant genomics community</b>  |
|  | <b>Invest in health data infrastructure to deliver better health and increase R&amp;D productivity</b>  |
| <b>Establishing the UK as a destination for high-value manufacturing</b> | <b>Incentivise internationally-mobile manufacturing plant investments into the UK</b>   |
|  | <b>Establish manufacturing centres of excellence to provide infrastructure for SMEs to scale up and deploy their innovations into manufacturing</b> |
|  | <b>Continue to fund R&amp;D to transform medicines manufacturing through challenge-led programmes</b>   |
|  | <b>Promote life sciences manufacturing careers, expand apprenticeship schemes, and deliver a programme of training for existing workers</b>         |
| <b>Making the UK a world-leading drug development and launch market</b>  | <b>Transform the MHRA into a truly innovative, patient centred, global regulatory leader</b>  |
|  | <b>Deliver on the commitment to the Innovative Medicines Fund, making medicines for rare diseases a priority</b>                                    |

## Introduction

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 to 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 leading role in the global response to the pandemic, putting the UK in a strong position to benefit rapidly from vaccines, diagnostics and therapies. The Medicines Discovery Catapult has been the backbone of the Lighthouse Labs, Oxford Nanopore has developed the new 90 minute 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 being utilised. This has been achieved through a public-private partnership that demonstrates the uniqueness of the UK life sciences ecosystem. There is great opportunity to secure spill-over effects from this work, and the UK Vaccine Taskforce work to ensure a lasting legacy has identified areas, such as innovative vaccine delivery technologies (alternatives to needles and vials) and rapid antibody manufacturing, that could lead to long-term UK capabilities. The UK Government should prioritise and fund these as cost effective ways to put the UK in a better place for future pandemic preparedness as well as anchoring long-term industrial activity in the UK.

## How can life sciences improve health?



Earlier identification of disease risk and diagnosis, through genetic screening



Disease prevention through more effective and better targeted vaccines



Faster drug development and more accurate drug delivery



New treatments for previously untreatable conditions

## How can life sciences improve the world we live in?



Lower environmental pollution with biodegradable plastics and plastic-digesting bacteria



Reduced reliance on fossil fuels through biologically-produced chemicals and fuels



More efficient food production with engineered crops and improved fertilisers



Novel high-performance materials for fashion, sports and construction industries

This is a growing sector of the future that poses a unique opportunity. The UK life sciences industry employs 256,100 people, with two-thirds of these jobs outside London and the South East.<sup>3</sup> There are 6,300 life sciences businesses, 82% of which are SMEs, and combined they generate a turnover of £80.7bn. The average GVA per employee is over twice the UK average at £104,000<sup>4</sup> and the sector consistently invests more in R&D than any other (£4.5bn in 2018).<sup>5</sup> 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.<sup>6</sup>

This strength is spread across the UK. The North West is the third most concentrated area for life sciences jobs. Pioneering efforts by Eli Lilly in the early 80s resulted in large scale production of recombinant insulin and human growth hormone there, and the past decade has witnessed significant investments, including Allergan's Biologics R&D Centre of Excellence. Elsewhere, Ipsen manufactures Botox in Wrexham and Fujifilm Diosynth Biotechnologies manufacture complex biological molecules in Stockton-on-Tees. Our sector's heritage shows that when done well, investments in life sciences can deliver long-term prosperity in local regions and play a key role in narrowing the productivity gap.

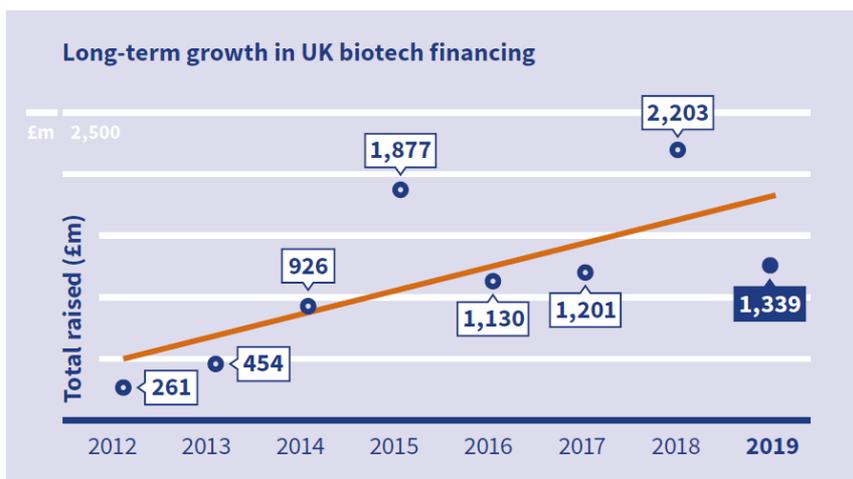
These life science manufacturing centres of excellence provide valuable jobs to local communities, with the potential to deliver more, if the recommendations of this submission are adopted. Moreover, this industry

<sup>3</sup> UK Government (2019), *Bioscience and health technology sector statistics 2019*: <https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019>

<sup>4</sup> 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](https://www.abpi.org.uk/media/1371/the_economic_contribution_of_the_uk_life_sciences_industry.pdf)

<sup>5</sup> ONS (2019), *Business enterprise research and development, UK: 2018*: <https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterprisesearchanddevelopment/2018>

<sup>6</sup> 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>



of the future provides rewarding jobs for people of all backgrounds and at different technical levels. For example, 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.

These benefits are the result of a continuous and supportive industrial strategy delivered by successive governments, stretching back to the founding of Celltech by Margaret Thatcher in 1980, through to the Biomedical Catalyst established by the Coalition Government in 2012, and now 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.

The BIA and our sector are grateful for the sustained support it has received from Conservative governments, most notably through the Life Sciences Sector Deals as part of the Industrial Strategy, and the Patient Capital Review. Sector-specific Innovate UK grant funding has proven an effective mechanism for supporting innovation in businesses, especially the Biomedical Catalyst and the Industrial Strategy Challenge Fund. The creation of the £2.5bn British Patient Capital fund and the fund of funds programme within the British Business Bank also holds great potential to invigorate the UK's venture capital market. In addition, the Government's commitment to address the barriers to pension funds investing patient capital to support the UK's innovative SME community is welcome and requires continued focus. With £2.2 trillion under management<sup>7</sup>, UK pension funds are well placed to be significant patient investors in UK innovation. Finally, the announcement of the Innovative Medicines Fund in the Conservative manifesto shows that the Government is committed to ensuring NHS patients benefit from the latest medical innovations, which is extremely welcome.

<sup>7</sup> OECD (2018), *Pension funds in figures*: <http://www.oecd.org/daf/fin/private-pensions/Pension-Funds-in-Figures-2018.pdf>

The rest of this submission is focused on the key policies that the BIA believes are key to support the life sciences sector and strengthen the business environment for entrepreneurs and SMEs more broadly.

## The BIA's priorities for the 2020 Comprehensive Spending Review

The following programmes have been prioritised by the BIA as they will have the broadest and deepest impact on the whole UK life sciences sector and best support economic recovery as we emerge from the pandemic in the following years.

|  |   |
|--|---|
| <b>Increasing access to finance for start-ups and scale-ups</b>          | <b>Refill the Biomedical Catalyst for the period of this Spending Review and increase its annual budget to £100m to maintain the pipeline of life sciences innovation</b>   |
|  | <b>Deliver the £200m Life Sciences Investment Programme complemented by a bold new co-investment fund of scale to unlock pension funds and other institutional finance to super-charge the growth of innovative UK biotech businesses</b> |
| <b>Supporting world-class R&amp;D</b>                                    | <b>Support the UK's world-leading research and innovation ecosystem</b>   |
|  | <b>Invest in national genomic capabilities to support the growth of a vibrant genomics community</b>  |
|  | <b>Invest in health data infrastructure to deliver better health and increase R&amp;D productivity</b>  |
| <b>Establishing the UK as a destination for high-value manufacturing</b> | <b>Incentivise internationally-mobile manufacturing plant investments into the UK</b>   |
|  | <b>Establish manufacturing centres of excellence to provide infrastructure for SMEs to scale up and deploy their innovations into manufacturing</b>   |
|  | <b>Continue to fund R&amp;D to transform medicines manufacturing through challenge-led programmes</b>   |
|  | <b>Promote life sciences manufacturing careers, expand apprenticeship schemes, and deliver a programme of training for existing workers</b>   |
| <b>Making the UK a world-leading drug development and launch market</b>  | <b>Transform the MHRA into a truly innovative, patient centred, global regulatory leader</b>  |
|  | <b>Deliver on the commitment to the Innovative Medicines Fund, making medicines for rare diseases a priority</b>  |

## Increasing access to finance for start-ups and scale-ups

### Refill the Biomedical Catalyst for the period of this Spending Review and increase its annual budget to £100m to maintain the pipeline of life sciences innovation

The Government has rightly said it will prioritise investment in industries of the future where the UK can take a commanding lead, such as life sciences.<sup>8</sup> 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. These must be balanced with challenge-led funding.

The strength and vibrancy of the UK life science SME community is in large part thanks to the success of the Biomedical Catalyst, a competitive, sector-specific grant funding programme run by Innovate UK. In 2019, an independent analysis from IPSOS Mori<sup>9</sup>, commissioned by Innovate UK and the Medical Research Council (MRC), showed that the Biomedical Catalyst generates £4.72 in public and business value for every £1 invested by government. 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 on average leverage £1.40 of private investment from every public £1.<sup>10</sup> 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 for the sector from the outset.

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 £710m in additional VC after receiving the grant. This suggests the grants leveraged £3.99 to £5.09 private investment per £1 of public grant.

As European innovation funding is no longer available to UK SMEs, the Government is committed to investing some of the money the UK currently sends to Brussels in our science base and in improving productivity. However, at present no further Biomedical Catalyst funding competitions are currently budgeted for, despite the success and cost effectiveness of this UK policy. If not addressed in the spending review, this will create a chasm in the life sciences innovation pathway, risk companies moving outside the UK, and impact downstream private investment, hampering both the Government's ambition to make the UK a global hub for life sciences and reach its target for the UK to invest 2.4% of GDP in R&D. It is also clear that the £30m per annum budget, which has been static since the programme's launch in 2012, is no longer sufficient to service the number of high-quality applications. As a result, the BIA is aware that possibly hundreds of project applications that pass the 70% quality threshold are going unfunded. This means

---

<sup>8</sup> UK Government (2019), The Queen's Speech 2019: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/853886/Queen\\_s\\_Speech\\_December\\_2019\\_-\\_background\\_briefing\\_notes.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/853886/Queen_s_Speech_December_2019_-_background_briefing_notes.pdf)

<sup>9</sup> IPSOS Mori (2019), *Biomedical Catalyst impact evaluation*: <https://www.gov.uk/government/publications/biomedical-catalyst-impact-evaluation>

<sup>10</sup> HM Government (2019), 'Queen's Speech 2019: background briefing notes': <https://www.gov.uk/government/publications/queens-speech-2019-background-briefing-notes>

projects and SMEs that may hold the answer to the next public health threat, or life-changing medical innovation, are not being supported. The BIA therefore encourages the Government to increase the Biomedical Catalyst's annual budget to £100m, with an emphasis on funding more early and late stage projects.

The BIA is also supportive of other sector-specific funding programmes Innovate UK has pioneered, including ones linked with investors, which have been very successful and continued.

### **Deliver the £200m Life Sciences Investment Programme complemented by a bold new co-investment fund of scale to unlock pension funds and other institutional finance to super-charge the growth of innovative UK biotech businesses**

As the UK life sciences SME sector matures, scale-up capital is becoming more critical and a lack of it is holding back growth and global expansion. Despite record sums being raised by the sector, the investment is largely coming from overseas, which is a vulnerability for our domestic sector and means value is not being captured in the UK. Companies are increasingly looking to the US public markets for capital or being sold to larger business before their full potential can be realised, adding a further pull to move operations across the Atlantic, to the possible detriment of the UK science base.

The Conservatives' announcement of a £200m life sciences scale-up fund prior to the General Election was a welcome measure to address this. Crucially, it will invest in larger and later-stage deals, and could provide the British Business Bank/British Patient Capital with in-house expertise to expedite investment in the life sciences sector. However, £200m (+£400m leveraged private capital) is not enough to address the challenge, nor is it specifically leveraging-in UK finance.

The fund must be rolled out as quickly as possible and preferably made more ambitious to ensure the British Business Bank can effectively address the scale-up challenge in the life sciences. We anticipate that a £1bn+ fund is required to provide the scale to support life science companies as they grow and meet demand in the short term as we emerge from the coronavirus pandemic.

To truly address the systemic lack of large-scale investment in UK innovation by our domestic financial industry, the Government must be bolder and lead by example. Initiatives stemming from the 2017 Patient Capital Review have addressed many of the real and perceived barriers for pension and insurance firms to invest in venture capital (the direct contribution pension fee cap remains and we welcome the recent consultation published by the Department for Work and Pensions<sup>11</sup>, removing this remaining barrier is critical and requires HM Treasury drive). Yet we are not seeing a change in behaviour within the financial community. The British Business Bank identified the need for a bespoke collective investment vehicle through which these firms could invest<sup>12</sup>, but the market has not provided one and there is likely a fear of being the first-mover. The UK Government should therefore address this market failure by creating an innovative and bold new fund structure and leading by example.

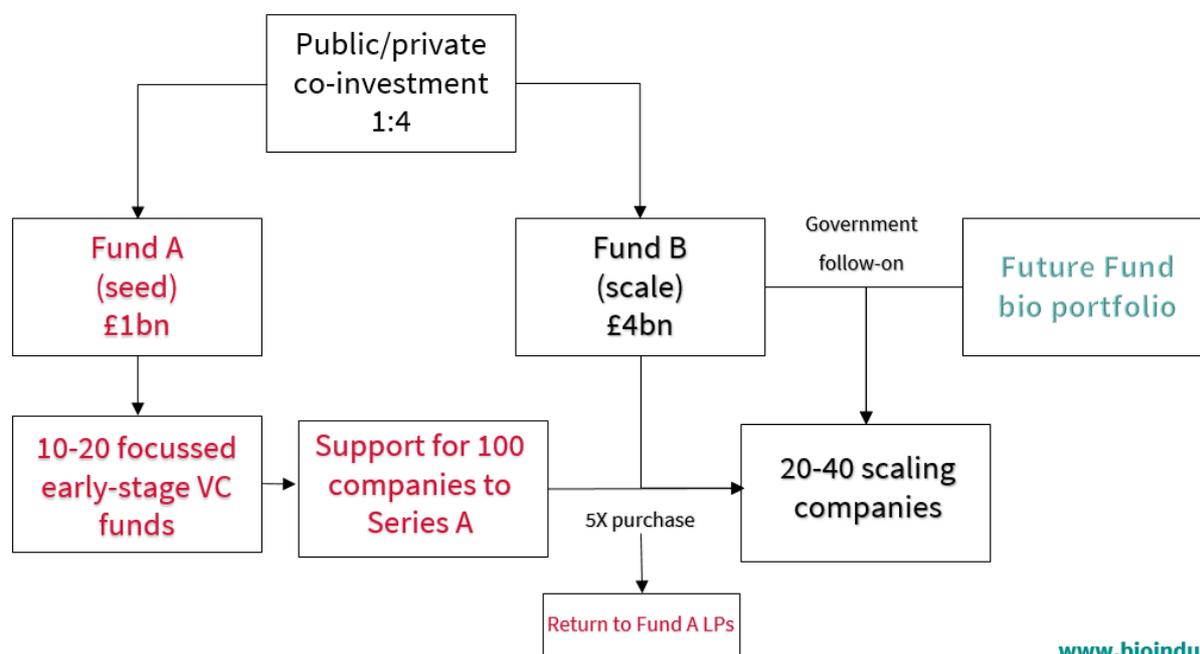
In comparison to other industries, investment in life sciences requires a greater quantum of capital spread over multiple investment rounds as a consequence of extended R&D timelines during which investee

---

<sup>11</sup> Department for Work and Pensions (2020), Improving outcomes for members of defined contribution pension schemes: <https://www.gov.uk/government/consultations/improving-outcomes-for-members-of-defined-contribution-pension-schemes>

<sup>12</sup> Oliver Wyman and the British Business Bank (2019) The Future of DC Pensions: Enabling Access to Venture Capital and Growth Equity: <https://www.british-business-bank.co.uk/research/the-future-of-dc-pensions-enabling-access-to-venture-capital-and-growth-equity/>

**Figure 1. Proposed Bio-Future Fund structure**



[www.bioindustry.org](http://www.bioindustry.org)

companies are pre-revenue. For these reasons, investors in early-stage life sciences companies need to have considerable patience and the ability to make follow-on investments (to off-set dilution) to see a return on their investment. For many institutional investors, this is perceived as a poor risk/reward profile leading to low investment in life sciences, sub-scale VC funds and a reliance on less risk-averse overseas capital.

We propose here an innovative fund structure that addresses not only the funding requirement of companies in the life sciences sector but also the risk/reward profile for investors. Moreover, if it proves to be successful, it could create a sustainable funding mechanism for the life sciences sector that would not require further government funding once it is up and running.

We propose the creation of two linked funds (Figure 1). Investors would be required to commit to both funds, with the Government matching the investment 1:4 public:private. The first (Fund A) is a £1bn seed fund of funds (requiring £200m Government money), which will invest in a portfolio of traditional ten-year VC funds, with geographic or sub-sector focus. This could support the levelling up agenda and allow the Government to create or back industries of the future, such as engineering biology, bio-replacements for fossil fuels, and AI-enabled technologies. Fund B is £4bn privately managed direct investment fund (requiring £800m Government money) that will scale the companies seeded by Fund A.

Fund B would have a call option to buy portfolio companies of the Fund A-backed VC funds for a pre-defined return (we propose 5X), which mitigates conflicts of interest and reduces deal costs. The call option would expire after a set time period (we propose five years after company founding) and any companies Fund B passes on would either look for new investors, be sold off to potential bidders or allowed to fail. The 5X return would provide Fund A investors a good return on their investment but also ensures promising companies are not sold off too early to their detriment (as is often the case with 10-year funds), as they are being sold to a fund with aligned values. Moreover, it would allow the investors in Fund A to begin to receive an earlier return of capital than would normally be expected from such an early-stage investment fund. If

this is successful, it is likely that this capital will then be recycled into another series of early-stage venture funds with similar terms.

Fund B has the scale to support this smaller cohort of promising companies as they scale. While capital would need to be committed at launch, it is likely that it would not be drawn down until companies seeded by Fund A have reached the necessary maturity and are ready to be scaled.

Institutional investors could also be offered co-investment rights in the underlying seed funds financed by Fund A as well as in the individual companies financed by Fund B. This would provide institutional investors some flexibility to adjust the risk profile of their investment – investment in Fund A is likely to be riskier than Fund B.

The Future Fund has been an extremely welcome and crucial solution by the Treasury and British Business Bank to address the real risk that many promising innovative UK companies would have been bankrupted unnecessarily by the COVID-19 crisis. The Government must now decide what to do with the shares that it is starting to amass as the convertible loan notes convert to equity. It is possible that Fund B could provide a solution. In the short term, it will have few investments to make as Fund A must first seed and grow the portfolio companies. Fund B could therefore provide the Government with a potential exit for some of its investments in the Future Fund, with Fund B acquiring the shares of companies that its managers believe have potential and require capital to scale.

We believe this novel structure addresses many of the requirements of pension and insurance funds, as well as other institutional finance houses. It uses the well-understood VC fund structure (under Fund A) but with a realistic exit strategy (the 5X call option) that supports the onward growth of the underlying companies and thereby maximising value for investors. This provides a reduced risk route for pension funds to gain exposure to life science VC. Fund B provides a fund of scale to support growing companies, with a pre-existing portfolio of companies (from the Future Fund) that will provide returns in the medium term whilst the Fund-A backed portfolio is being established. Return timeframes are therefore much better aligned.

It also addresses many challenges the Government is focussed on: the levelling up agenda; zero-net carbon; increasing R&D investment; the scale-up challenge; and the Future Fund portfolio.

Increasing commercial and scale-up skills among our academic and business leaders is also essential to support this agenda and should be supported through this spending review. The BIA has workstreams to support this too. 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 heading into its third 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-and coming chief executives. Companies in PULSE's first cohort in 2018 have since successfully completed private funding rounds totalling over £15 million.

As described previously, the life sciences sector is successfully attracting foreign capital to the UK. The BIA is committed to ensuring this continues and new domestic sources are unlocked to complement the Government's crucial investment in the sector. In September 2020, the BIA published *Opportunity on your doorstep, a guide to investing in the UK biotech sector*<sup>13</sup>, which aims to demystify the sector for generalist investors and inspire them to look deeper at the opportunity it offers. As such, it is written as an

---

<sup>13</sup> BioIndustry Association (2020), *Opportunity on your doorstep, a guide to investing in the UK biotech sector*: <https://www.bioindustry.org/policy/invest-in-biotech.html>

introduction to the sector – it explains the different scientific subsectors and business models, the R&D and regulatory process, the role of IP protection and what government support is available for biotech businesses, and the different ways to invest in it, with the associated risks. We have developed a comprehensive communications campaign, working with the London Stock Exchange and other partners, to engage potential investors directly and through the media and investment platforms, which we hope will lead to meaningful and lasting improvements in the availability of finance to fuel our rapidly growing community. It is focused on increasing private investment and so complements the Government’s Patient Capital agenda and will contribute to the Government’s target to raise R&D investment to 2.4% of GDP by making more capital available for innovative companies.

## Supporting world-class R&D

The thriving UK life sciences sector is built upon the most productive science base in the G7 group of developed countries. The UK has four of the top ten global universities for life sciences and produces 18% of the world’s top life sciences publications. It also benefits from a large medical research charity sector, which invests heavily in research. In large part because of this investment in early-stage research, the UK generates three times as many spin-outs and start-ups as its European counterparts, and over a third of all new biotechs created in Europe since the start of 2012 have been in the UK.<sup>14</sup>

### Support the UK’s world-leading research and innovation ecosystem

The Government’s recent commitment to invest £22bn in R&D by 2022 is extremely welcome and will provide great confidence to businesses and investors that the UK will remain a science superpower. With the central importance of life sciences to the UK’s future, the core budgets of Innovate UK, the Medical Research Council, the Biotechnology and Biological Sciences Research Council and the National Institutes of Health Research should all be increased at least in proportion to the overall rise. As well as supporting vital research, initiatives to accelerate patient recruitment into clinical trials, for example, will greatly increase the attractiveness of the UK commercial clinical trials.

Moreover, medical research charities have faced a drop in income as a result of the pandemic seriously impacting their ability to fund early-stage and translational research; government support to mitigate the negative impacts of this is crucial.<sup>15</sup>

### Invest in national genomic capabilities to support the growth of a vibrant genomics community

The UK is a global leader in genomics. The sector largely consists of innovative SMEs, which are underpinned by a world-leading science base with an unrivalled mix of world-leading research and medical institutions supported by charitable and government funding, as well as the UK’s multinational pharmaceutical companies.

The strength of the UK’s genomics sector is the result of the successful implementation of continuous industrial strategy, stretching from the establishment of the UK Biobank in 2006, through the formation of Genomics England, to the recent completion of the 100,000 Genomes Project. The Government is rightly continuing to build on these world-leading initiatives to boost the development of the UK genomics industry.

---

<sup>14</sup> McKinsey & Company (2019), Biotech in Europe: Scaling Innovation: <https://live-biocentury.pantheonsite.io/sites/default/files/Biotech-in-Europe-Scaling-Innovation-McKinsey-BioCentury-Report-BioEquity-2019.pdf>

<sup>15</sup> Association of Medical Research Charities (2020), Without charities: <https://www.amrc.org.uk/without-charities>

20 years after the first full human genome was sequenced at the UK's Wellcome Sanger Institute, the Government can build on this great British success story by securing the future of Genomics England and embedding genomics into the NHS to deliver on the promise of predictive, preventative healthcare. To deliver on our sector's global ambition in this space, and ensure the UK does not slip behind the US and China, the Government should invest in establishing a world-respected and trusted genomics research environment, including expanding the diversity of datasets (e.g. gender, race and socio-economic) and pioneering programmes to demonstrate and build on the UK's capabilities, such as in functional genomics.

### **Invest in health data infrastructure to deliver better health and increase R&D productivity**

The UK's nationwide health system offers researchers an unparalleled data source, with its cradle-to-grave records and large, diverse population. This data is becoming better integrated and more accessible, thanks to government-funded initiatives designed to enhance innovation and drive meaningful health solutions.

The Government should use this spending review to deliver the next phase of building critical health data infrastructure for research by curating, joining up and ensuring much smoother access to world leading national datasets, including on cancer, cardiovascular disease, diagnostics, and genomics. Building and maintaining public confidence and trust must be at the heart of this.

SMEs should also be at the core of the programme to ensure it drives high-skilled job creation across the regions and doesn't only benefit a small group of large companies. SMEs have the agile technology and innovative approaches to R&D that is required to maximise the value of health data for patients and the UK economy. The rapidly expanding use of data, digital and AI in drug discovery and healthcare, being led by innovative UK SMEs such as BenevolentAI and Congenica, is increasing R&D productivity, improving healthcare system efficiency and leading to better outcomes for patients.

### **Establishing the UK as a destination for high-value medicines manufacturing**

New classes of medicines, including cell and gene therapies, have emerged in recent years, transforming outcomes for patients. The UK has already played a major role in the development of these advances; there are 70 companies developing such therapies in the UK with 25 manufacturing sites and already three unicorn companies.<sup>16</sup> This presents a great opportunity for the UK to establish itself as a destination for high-value manufacturing of the future and also secure resilience to future threats to public health. The BIA, working through Medicines Manufacturing Industry Partnership (MMIP) and with other partners, has developed a suite of policies to capture the full value of advanced therapies and medicines manufacturing for the UK economy. These address a number of key issues and could be delivered by a unified Medicines & Diagnostic Transformation Fund.

### **Incentivise internationally-mobile manufacturing plant investments into the UK**

Despite once being a world leader in medicines manufacturing, and continuing to be a world-leader in the research and development of medicines, the UK medicines manufacturing sector has dramatically shrunk over the last 25 years and we have no commercial scale manufacturing capacity of many types of medicines, including therapeutic antibodies, which are a key focus in the current pandemic. The BIA continues to support the recommendation in the Life Sciences Industrial Strategy that the UK should set a target of attracting ten large (£50-250m) and ten smaller (£10-50m) commercial-scale manufacturing facilities in the next five years. To secure this, MMIP recommends the Government establishes a capital

---

<sup>16</sup> BIA and Alliance for Regenerative Medicine (2019), *Leading innovation: the UK's ATMP landscape*: <https://www.bioindustry.org/resource-listing/leading-innovation.html>

finance grants programme to achieve this target. This would align us with our key competitors (Ireland, Singapore, Belgium, US and France), which offer capital incentives to secure investments.

Grants would increase the international competitiveness of the UK to leverage private capital investments. Without it, them, commercial-scale manufacturing investments will continue to go to Ireland and other countries that provide these incentives. The programme would support 10-15% of the total capital investment, meaning £300-450m could achieve the high-ambition range of ten £250m and ten £50m investments. The grants should be available to domestic and foreign companies looking to invest in the UK and, crucially, designed to ensure state aid rules do not prevent participation for loss-making businesses or those that are investing in growth.

### **Establish manufacturing centres of excellence to provide infrastructure for SMEs to scale up and deploy their innovations into manufacturing**

Due to the complexity of production of many medical innovations, such as cell and gene therapies, manufacturing decisions need to happen much earlier in the product development cycles, for instance through modular, continuous and agile manufacturing. The UK is a scientific leader in these fields now, but our leading SMEs operate in a global sector and we must ensure the UK remains an attractive place for them to maintain operations as they scale.

Access to state-provided expertise and infrastructure is a key part of companies' decision making, as these can be too expensive to build purely in-house at the early stages of a company's development. The establishment of manufacturing centres of excellence would support companies at this critical point, and in doing so anchor "sticky" manufacturing operations in the UK, leading to larger commercial scale investments down the line. These centres will provide smaller companies in targeted regions with the expertise and infrastructure to scale up and deploy their innovations into manufacturing.

### **Continue to fund R&D to transform medicines manufacturing through challenge-led programmes**

Funding deployed since 2017 through the Industrial Strategy Challenge fund to support collaborative R&D to improve medicines manufacturing processes has boosted innovation in this high-value manufacturing sector, and, although not envisaged at the time, allowed the UK life sciences base to respond quickly to the challenge of scaling up vaccines manufacture for COVID-19.

These time-limited investments must be followed with further funding to maintain momentum and ensure the initial investments lead to long-term benefits and leverage private investment. The UK's competitive advantage in cell and gene therapies could be cemented through improvements to the efficiency of their manufacture, for example, and a range of therapy modes could be improved through better delivery to target tissues and cells. Collaborations between industry, academia, and the NHS can unlock these advances through targeted challenge-led funding support and infrastructure.

### **Promote life sciences manufacturing careers, expand apprenticeship schemes, and deliver a programme of training for existing workers**

As the UK life science sector grows, and with it more investments in manufacturing are made by UK companies and attracted from overseas, there will be a substantial increase in job opportunities and demand for the right skills. The UK does not currently have enough trained and skilled people to adequately fill the roles anticipated, and there are structural problems that need to be addressed. Without vision, energy and investment, this situation will continue. The UK is currently perceived to lag behind

European competitors in some areas of critical skills and the skills gap could widen, risking both new investments and future growth.

Life sciences manufacturing covers a broad base of products, technologies and innovations and involves a broad range of occupations. The key areas of shortages are around engineering, digital and data. A significant challenge is that manufacturing in Life Sciences necessitates a multidisciplinary approach. Generally, 65% of roles in manufacturing are specialist roles meaning they will require unique skills.<sup>17</sup> Furthermore, around 60% of roles will require qualification to degree level or above. The proposed solutions of the Science Industry Partnership, of which the BIA is a part, centre on a small number of key activities:

**Attraction and perception** – Attract and retain a diverse workforce, positioning life sciences manufacturing as a modern, technologically advanced industry and focussing on highlighting the requirement for the range of STEM skills, including data, digital, engineering and science. Promoting the range of opportunities available through a series of virtual events and social media campaign.

**Apprenticeships** – Expand apprenticeship opportunities, ensuring all businesses are supported to adopt apprenticeships such that they become the benchmark for international training. Remove the barriers to apprenticeships of geographic availability, SME challenges and industry lack of familiarity and ensure parity of esteem with academic routes.

**Integrated skills** – Aligned with the technical education reforms and building a central resource to identify and highlight available life sciences manufacturing programmes. To support the greater tailoring of provider content to meet employer needs in new and emerging subjects, such as data analytics. Developing new provision virtually and physically for advanced therapies. Ensuring that businesses have the skills to translate innovation into commercial products and to encourage lifelong learning in a fast-moving environment.

## Making the UK a world-leading drug development and launch market

### Transform the MHRA into a truly innovative, patient centred, global regulatory leader

The UK is in a position to lead the world into a new age of medical advances, from genomics to digital and AI-enabled treatments. This requires an innovative, patient centred, and global regulatory leader. The Medicines and Healthcare Regulatory Agency (MHRA) has developed a spending review bid which would transform the agency into a world-leading regulator.

The BIA supports the MHRA bid which would drive the adoption of a world leading regulatory system, driving innovation in healthcare and ensuring the UK is the number one destination for investment in innovative products. This would also lead to the growth of UK SMEs developing cutting-edge technologies.

The MHRA's expertise is seen as a major draw for global life sciences businesses as well as crucial for supporting the domestic industry and the agency faces systemic change to its business model as it takes on new roles as the transition period ends. MHRA funding from industry fees does not allow the agency to offer advice services to SMEs on the same terms as the European Medicines Agency's SME Office does currently; additional funding should therefore be made available in this spending review to enable this so that UK-based SMEs can continue to access high-quality scientific advice.

---

<sup>17</sup> Science Industry Partnership (2019), *Life Sciences 2030 Skills Strategy*: <https://www.scienceindustrypartnership.com/skills-issues/sip-2030-skills-strategy/>

Further funding should be provided to:

- Support the MHRA's Innovation Office and expand its scope to cover a horizon scanning function and an SME advice service. Early access to expert scientific advice from the UK regulators is essential to the early planning and development of clinical research, novel product development, and manufacturing
- Retain the MHRA's capacity to support researchers and businesses to innovate and develop new treatments and vaccines for the benefits of patients; and
- Recruit regulatory experts in emerging technology areas; for example, cell and gene therapies, AI and algorithms, and combination products.

### **Deliver on the commitment to the Innovative Medicines Fund, making medicines for rare diseases a priority**

The BIA welcomed the announcement in the 2019 Conservative Manifesto that the £340 million Cancer Drugs Fund (CDF) will be extended into a £500 million Innovative Medicines Fund (IMF). The IMF is further referenced in the Government's July 2020 R&D Roadmap which commits to using the fund to leverage "NHS England as one of the world's largest single procurers of technology and health innovation to take a greater role in seeding and adopting innovation."<sup>18</sup> The Government's emphasis on supporting end market access for innovative medicines is welcome, and the BIA is keen to ensure that the IMF receives the announced funding.

Funding market access is a crucial part of generating and attracting investment into R&D. The UK's excellent research ecosystem and the NHS's position as a large single procurer make the UK a potentially attractive place to invest in R&D operations, run clinical trials, and launch products. However, limited and delayed access to reimbursement in the NHS is seen as a stumbling block, particularly for orphan and ultra-orphan medicines. Indeed, The American Pharmaceutical Group, which represents a number of US research-based bio-pharmaceutical companies with a presence in the UK who collectively invest more than £1.2 billion annually in the country<sup>19</sup>, has identified the IMF as a key opportunity to improve US boardroom sentiment for England's end market access landscape<sup>20</sup>.

To ensure the IMF supports innovative medicines beyond oncology, the fund should include a ring-fence for orphan and ultra-orphan medicines. Due to a variety of issues (e.g. small patient populations, data limitations, and less well understood epidemiology), orphan and ultra-orphan medicines struggle to show value within NICE's strictly cost-effectiveness centred appraisal system. This obstructs and delays these medicines' access for NHS patients and consequently disincentivises foreign direct investment. Currently, England is lacking behind several other European countries in terms of speed of access to orphan medicines<sup>21</sup>. Orphan medicines are forecast to comprise over 20% of worldwide prescription medicine market by 2024, with a compound annual growth rate between 2018-24 of 12.3%, approximately double that of the non-orphan drug market<sup>22</sup>. The IMF is a welcome opportunity to ensure the UK's excellent life sciences research eco-system is supported by a fit for purpose end market that can continue to facilitate

<sup>18</sup> HM Government (2020), *UK Research and Development Roadmap*: <https://www.gov.uk/government/publications/uk-research-and-development-roadmap>

<sup>19</sup> American Pharmaceutical Group, Key Facts, available online: <https://apg.uk.com/key-facts/>

<sup>20</sup> Hilary Hutton-Squire, UK and Ireland operations lead, Gilead, *Making the UK attractive to investing US/multinationals and market access opportunities for the UK in the US*, speaking at the APPG on Access to Medicines & Medical Devices, September 2020

<sup>21</sup> EFPIA (2020), *Patients W.A.I.T. Indicator 2019 Survey*: <https://www.efpia.eu/media/554526/patients-wait-indicator-2019.pdf>

<sup>22</sup> Evaluate Pharma (2019), *Orphan Drug Report 2019*: <https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma%20Orphan%20Drug%20Report%202019.pdf>

investment in innovative orphan and ultra-orphan medicines and deliver the best possible patient care in the NHS.

The fund should be complemented by broader programmes to help companies deliver their innovations into the NHS, allowing them to prove the efficacy of their products in a real world setting and get wide uptake of the most innovative products in the UK. This will help UK companies establish their products and lead to exports and global distribution.

## About the BIA

The 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. We are full members of the UK Life Science Council and ensure our members participate fully in UK government consultations and partnership working. In 20220 we are working particularly closely with the UK Government Covid -19 Vaccines Taskforce.

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, IR agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

**For any further information on the contents of this submission please contact Dr Martin Turner, Head of Policy and Public Affairs, by emailing [mturner@bioindustry.org](mailto:mturner@bioindustry.org)**

## Prokarium

London

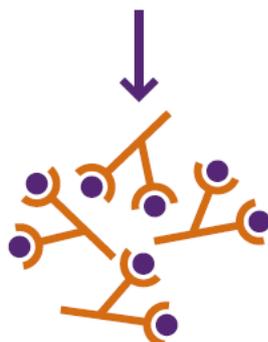
**Innovation support:**

Innovate UK

**Sub-sector:** Health



Bacterial factories produce a vaccine inside the body



Immune system responds

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

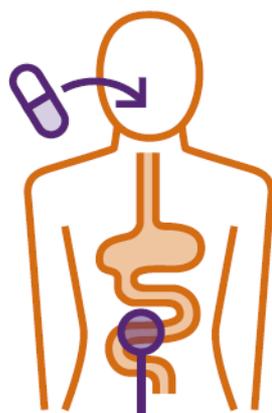
**Sub-sector:** Health

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

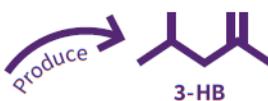
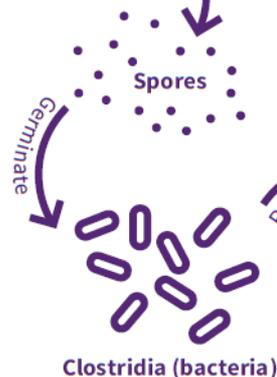
CHAIN develops a disruptive technology for the production and delivery of therapeutic molecules to relevant targets in the human gut. Its lead product produces a potent anti-inflammatory targeting ulcerative colitis.

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 life.



Bacteria produce  
beta hydroxybutyrate



Reduces inflammation in the gut

“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 Officer, BioAscent

