BIA submission: Response to R&D Tax Reliefs Consultation

May 2021

UK BioIndustry Association

Summary

We welcome the Government's commitment to ensure that the UK's R&D incentives remain up-to-date, competitive, and well-targeted, and support the consultation to this end. Overall, we believe the SME and large company R&D tax relief regimes work very well and are a highly effective policy leaver through which the Government can incentivise private sector investment in R&D.

Any significant curtailment of the regimes and, particularly, support given to SMEs is likely to be harmful to the Government's ambition to make the UK a global life sciences hub. Instead, this consultation is a timely opportunity to fine-tune the schemes, and the key measures that we support or recommend are:

- Maintaining the current structure of the SME and RDEC regimes with the introduction of additional incentives for data, cloud computing and capital to encourage new investment aligned with government policy priorities.
- Maintaining the alignment of the SME regime to the Life Sciences business model where essential aspects of R&D need to be contracted out.
- The inclusion of data and cloud hosting now seen as an increasingly essential input to R&D.
- The inclusion of capital expenditure in both regimes.
- For R&D incentives to be better targeted to innovation in new products and services and restricted or eliminated for internal software platforms.
- Actions to stem the proliferation of tenuous claims which divert potential support from genuine R&D by addressing agent behaviour, results-based fees and better quality standards for claims.

Introduction

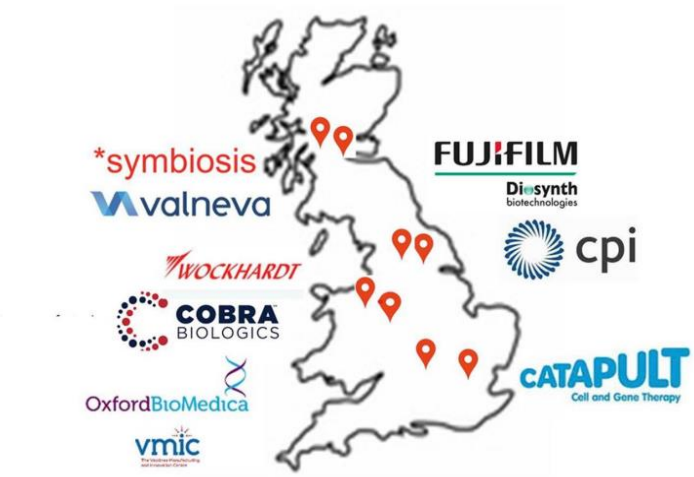
The UK's R&D-intensive life sciences sector is universally recognised as world-leading, and it delivers great benefits to the economy, the health of the nation, and it is key to the Government's net-zero agenda. From improving patients' lives through new treatments and digital healthcare, to the development of environmentally-sustainable technologies, such as biological fossil fuel substitutes and biodegradable bioplastics, our deep understanding of biology is helping to address humankind's greatest challenges.

The pandemic has highlighted the strategic importance of the life sciences industry to the UK's resilience. It is as a result of having a vibrant UK life sciences 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 Oxford/AstraZeneca vaccine encapsulates this: the science came from one of our many world-leading universities, the technology was further developed by Oxford spin-out Vaccitech, the regulatory and global distribution capability was provided by the UK-based multinational giant AZ, and Oxford Biomedica and Cobra Biologics provided their existing UK-based manufacturing capabilities to

rapidly scale up domestic production. This has been achieved through a public-private partnership that demonstrates the uniqueness of the UK life sciences ecosystem.

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.[1] High-value medicines manufacture is spread across the UK, a fact illustrated by the sites of COVID-19 vaccine production[2] (figure 1). There are over 6,300 life sciences businesses in the UK, 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[3] and the sector consistently invests more in R&D than any other (£4.8bn in 2019).[4] The sector is also attracting record levels of investment and overseas investors, who are in large part attracted to an ecosystem enjoying strong Government support.[5]

Figure 1: UK sites of COVID-19 vaccine manufacture



Companies within the life sciences sector benefit from a complementary set of government support schemes. R&D tax relief is widely seen as the most important and effective mechanism to promote innovation. R&D grants are also very valuable and offer a more targeted way for the government to support specific R&D projects and policy objectives (such as levelling up and addressing public health challenges) to complement tax credits. These schemes underpin all other government initiatives to support and grow the UK life sciences sector by providing a solid and productive bedrock of business-led innovation.

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 grow their life sciences sectors. This review is therefore a timely and crucial opportunity to take stock and update the R&D tax relief regime to ensure it puts the UK and its businesses in the most competitive position possible within a global economy based on technological innovation.

---

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

[2] BEIS (2020), *UK Vaccine Taskforce 2020 Achievements and Future Strategy*: https://www.gov.uk/government/publications/uk-government-vaccines-taskforce-vtf-2020-achievements-and-future-strategy

[3] 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

[4] ONS (2020), *Business enterprise research and development, UK: 2019:* https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2019

[5] Radnor Capital Partners, commissioned by BIA (2021), *UK quoted biotech performance and investor base in 2020:* https://www.bioindustry.org/resource-listing/rcp-bia-2020-review-january-2021-final-pdf.html

Responses to Consultation Questions

Structure and administration of reliefs

Question 1 Do you consider yourself to be a research-intensive firm? How does your business benefit from the R&D reliefs (e.g. cashflow, reduced tax liability)? If your company is an SME that claims under both the SME tax relief and RDEC, what is your experience of using each scheme and how do they compare?

Life sciences is the most research-intensive sector in the UK; it invested £4.8bn in R&D 2019, more than any other sector.[6] It is also attracting increasing (but still not sufficient) levels of private investment and numbers of overseas investors.[7] Our members tell us that R&D tax credits are the most important form of innovation support provided by the UK Government to help companies grow and a strong incentive to maintain headquarters, R&D operations and intellectual property in the UK. They claim under the SME scheme, the RDEC or commonly both, and report that they find the schemes straightforward to use notwithstanding the fact that they typically seek professional advice to be able to successfully navigate the BEIS Guidelines and related tax legislation. Many companies claim both particularly where projects are grant funded but where possible life science SMEs seek to claim through the SME scheme. A majority investor structure of some companies also means SMEs must claim through RDEC (for example, see the RedX Pharma case study). The few differences between the schemes are well understood.

GW Pharmaceuticals: a British success story in building a pharmaceutical company

GW Pharmaceuticals (GW), a Jazz company, is a global biopharmaceutical company that has established a world-leading position in cannabinoid science and medicine. GW's mission is to unlock the potential of the cannabis plant through rigorous scientific investigations and extensive clinical trials to improve the lives of seriously ill patients. GW is proud of our longstanding commitment to the UK, which was recently recognised with the 2021 Queen's Award for Enterprise in Innovation, regarded as the highest official UK award for British business, due to GW's ground-breaking work to harness cannabinoid science to create regulatory approved, world-first cannabis-based medicines.

In 1998, GW's founders, Dr Geoffrey Guy and Dr Brian Whittle took up the challenge of creating a tried and tested, regulatory approved modern medicine from the cannabis plant. Along with its physician-investigators, collaborating scientists, and patients, GW embarked on an ambitious and pioneering programme to investigate the therapeutic potential of cannabis, at a time when cannabis still carried a significant stigma and barriers to research were formidable. In the period between 2000 to 2017, GW was eligible for the UK Government's SME R&D tax relief scheme and took advantage of this to support investment into its world class research and development programmes, as well as state of the art

[6] ONS (2020), *Business enterprise research and development, UK: 2019:* https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/businessenterpriseresearchanddevelopment/2019

[7] Radnor Capital Partners, commissioned by BIA (2021), *UK quoted biotech performance and investor base in 2020:* https://www.bioindustry.org/resource-listing/rcp-bia-2020-review-january-2021-final-pdf.html

manufacturing sites and research facilities. This support also allowed the company to focus on its product and corporate development.

To date, our continued dedication and investment into R&D and the facilities needed to bring cannabis-based medicines to the patients who need them, has resulted in the regulatory approval of two, world-first, and potentially life-changing treatments in a new frontier of medicine. This investment has enabled GW to conduct over 100 clinical trials involving over 8,000 patients globally. These trials have allowed GW to achieve regulatory approvals in over 40 countries around the world, including in the US and EU, by demonstrating that complex botanically extracted cannabis-based medicines can be successfully routed through the pharmaceutical regulatory approval pathway.

More recently, GW has invested approximately £470 million in R&D and £114 million in manufacturing facilities in the UK in the last five years. GW continues to invest in its future, once complete, the new building at our site in Kent is expected to be the largest GMP facility in the extraction of cannabis compounds anywhere in the world. This continuous investment in our manufacturing facilities provides us with the scale to supply regulatory approved medicines to meet the growing needs of the patients for novel treatment options.

Question 2 Is there a case for consolidating the two schemes into one? What do you value about the design of the current schemes that might be lost if they were unified?

The BIA would not support this on the basis that the two regimes are targeted at different types of company at different stages of the lifecycle and the two interact well together. Whilst both schemes have the policy intention to increase R&D activity, they seek to achieve this in different ways as a result of the different challenges faced by SMEs and large companies.

Beyond the rate of relief (see Q3), the principal design difference between the two regimes is the inclusion of sub-contract R&D for SMEs.

The SME regime is designed such that it is focused on the creation of new IP in UK companies. Much of this work needs to be contracted out (reasons for this are covered in detail in Q15). This allows companies to accelerate the discovery of new ideas and development of products without the need to establish a significant fixed cost base, which in many cases may render the R&D project/investment unfeasible. The inclusion of outsourcing costs, including overseas activity, in the SME regime therefore acts as a strong incentive for R&D investment that would not occur otherwise.

The support given by the SME scheme is essential in allowing these companies to be agile, to accelerate new projects and explore new applications that may not otherwise be considered with much more restricted budgets. The ability for SMEs to be able to contract out R&D is essential, and the R&D regime should be aligned to support this. However, we understand and share the Government's desire to ensure the scheme effectively stimulates innovation and commercialisation in UK-based companies. This could be reinforced by the re-introduction of the IP condition provided that the definition of IP was drawn sufficiently broadly to include other intangible assets where companies choose not to or cannot register rights.

In contrast, by excluding sub-contract R&D, the RDEC is focused much more on employment of specialist personnel in the UK to support R&D undertaken by larger, more established enterprises.

The two regimes provide a coherent and complementary incentive structure with no double counting.

RedX Pharma: creating high value jobs in the North West of England

Redx Pharma is an AIM-quoted biotech focused on the discovery and development of novel targeted medicines for the treatment of cancer and fibrotic disease, aiming to progress them to clinical proof of concept. Redx recently signed an exclusive licencing deal with AstraZeneca to develop RXC006 its treatment for fibrotic diseases and, in addition, has entered into two separate oncology partnering deals with US-based Jazz Pharmaceuticals, also evidencing the quality of the company's science and its attractiveness on the global stage. The company is based at Alderley Park near Manchester, and in the past 18 months has trebled its headcount from 25 to 75 scientists with world-class medicinal chemistry, biology and clinical skills.

Throughout its development, the company has been supported by R&D tax credits, typically providing c.£1m in cash per annum, which is reinvested directly into R&D activity and helps increase the competitiveness of the company compared to its international peers. Historically, it has claimed through the SME scheme but following the majority of company shares being acquired by Redmile Group, a US-based specialist life science investor, it has only been able to claim through RDEC. This is despite no material change to the company size, structure, assets or heavily UK-centric footprint.

For scientific studies that cannot be done in-house, the company tries to use UK-based clinical research organisations but sometimes it must look overseas for reasons relating to specialism in certain scientific expertise or cost. The IP generated through these clinical trials is owned by the UK company and drives the growth of its UK operations and attracts further investment.

Question 3 What do you think explains the difference in additionality between the two schemes? How could the schemes be improved to incentivise the R&D your business does or might consider doing? Can you give evidence to support your suggestions?

We would question whether additionality accurately takes into account:

- The effectiveness of the SME regime to attract new investment and the establishment and financing of new start-up companies.
- The impact of the most successful SMEs transitioning, who are likely to have the highest levels of R&D expenditure, from the SME regime to RDEC either through growth or acquisition.
- The fact that most SMEs claim through both schemes, meaning activity and outputs cannot be attributed to the influence of one scheme or the other.
- Sub-contracted R&D activity that could not be performed in-house by SMEs and therefore would not happen (as described in Q2).

Ensuring the schemes remain relevant to how R&D is conducted in the 21st Century is crucial to its ongoing ability to incentivise investment. Potential improvements would include:

i. The inclusion of data and cloud hosting, which is now seen as an essential input to R&D. This has been covered in the recent consultation process and we welcome the Government's conclusion that there is a compelling case for its inclusion.
ii. The inclusion of capital expenditure in both regimes (see the response below in Qs 13 and 14).
iii. To the extent possible, remove the limitation (lower relief rate and no outsourcing costs) for SMEs on governmental grant funded R&D as this will allow companies to understand the true economic benefit of grant incentives. The UK's new freedom outside the EU to set its own subsidy control regime allows this.
iv. The removal of the €7.5m state aid cap under the SME regime as this imposes an artificial limit on valid R&D expenditure. Again, the UK's new freedom outside the EU to set its own subsidy control regime allows this.

Question 4 To what extent do the rates of relief available to you impact your investment decisions and/or your choice of location? Is the balance of relief between the two schemes appropriate? Is there any evidence of significant deadweight where investment decisions would proceed without relief?

The increased rate of relief to SMEs is justifiably higher given that there is a greater risk of market failure for small companies due to greater challenges in accessing finance.

R&D tax reliefs are a crucial part of any company's consideration for where to locate themselves internationally, and therefore invest in R&D and IP creation in the UK. Our members have reported that current rates of relief are such that the UK is still seen as competitive but there is increasing appeal in the regimes offered by other territories including France, Ireland and Australia. Furthermore, Ireland has increased the rate from 25% to 30% for SMEs, subject to approval from Ministerial Order. Australia has also increased the amount of depreciation for capital assets used in R&D that can be included as eligible expenditure. In the past the UK has been successful in attracting inward investment from the US and Europe although this may now be impacted by the rise in the rate of corporation tax.

Members have highlighted that planned investment in R&D is often influenced with the knowledge and certainty around the subsequent receipts of R&D credits. The ability to forecast the receipt of R&D credits is critical to loss-making biotech companies for the purposes of financial planning leading to continued support from investors and job creation. The ability to anticipate R&D credit support, in contrast to grant funding, is essential. Credits are modelled by investors to support fundraising commitments where grants cannot be relied upon in the same way.

We believe that R&D incentives should be better directed to creation of innovative products and services where R&D is much easier to validate. There is increasing evidence of claims being made on internal software platforms (Enterprise Resource Planning, financial and other operating systems) where it is much more difficult to assess whether there is an advance in technology and the true level of technological uncertainty. This is fueling the ever-expanding industry of poorly supported R&D claims which is an

increasing drain on HMRC resource and is misdirecting R&D incentives away from more productive innovation.

In the majority of cases this is likely to be deadweight cost as the R&D incentives would not have been modelled as part of the investment decision and internal software platforms are not the intended policy target of the R&D tax credit system. Other regimes such as the US and South Africa give lower or no incentives on internal software platforms. In the US, a higher degree of innovation is needed for software developed primarily for internal use to be included in the claim in contrast to other R&D activities[8]. In South Africa, the development of internal or management business processes is explicitly excluded as qualifying R&D, and this includes accounting / human resources software and management reporting software[9].

These systems are distinct from software platforms developed and used expressly for use in R&D projects within a company, such as artificial intelligence programmes, which are clearly both innovative and core to R&D activity within life science businesses and other sectors (as described in detail in our response to the R&D tax relief scope consultation).[10]

Supporting scale-up: Oxford Biomedica

Oxford Biomedica was founded in 1996 as a spin-out from the University of Oxford to develop gene therapy technology for diseases such as Parkinson's. Gene therapy offers potential solutions to wide variety of diseases by targeting genetic causes, but getting the treatment to where it is needed is challenging. Oxford Biomedica has perfected a technique for engineering viruses into vectors that can safely deliver gene therapy into target cells. More recently, this expertise and its advanced biomanufacturing facilities have been used to produce the Oxford-AstraZeneca COVID-19 vaccine.

During the Group's time as an SME, R&D tax credit payments accounted for approximately 20% of the Group's R&D investment. As a loss-making Group dependent on successive capital raises from investors, the payments provided valuable cash flow and contributed to a core R&D budget that the Group could use at its discretion to explore strategically important R&D projects that investors may be unwilling to fund the full costs of. Kristoff Rademan, Group Financial Controller at Oxford Biomedica, said: "It's integral to allowing you to grow unless you are well capitalised".

As a UK Group, Oxford Biomedica aims to run clinical trials in the UK where possible, and it is listed on the London Stock Exchange and committed to growing its UK manufacturing base. However, due to the small patient populations of some of the diseases it is developing treatments for, it must sometimes look overseas to run clinical trials. For example, whilst it was able to do its Parkinson's trials in the UK and France, it had to go to America for its trials for severe wet Age-related Macular Degeneration (AMD), a rare eye disease.

[8] https://www.thetaxadviser.com/issues/2017/apr/reasonable-internal-use-software-regulations-research-tax-credit.html

[9] https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Tax/dttl-tax-survey-of-global-investment-and-innovation-incentives-southafrica-2020.pdf

[10] https://www.bioindustry.org/resource-listing/bia-submission-to-the-hmt-consultation-on-the-scope-of-r-d-tax-credits-pdf.html

By 2012, Oxford Biomedica had invested in a production facility and was licensed for manufacturing. The following year, the Group signed its first deal with global pharma group Novartis to help produce a cutting-edge CAR-T therapy, a treatment where patients' immune cells are reprogrammed to help them fight cancer. In a subsequent deal, Oxford Biomedica became Novartis's approved vector manufacturer for its blood cancer product, Kymriah®.

This led to a period of significant growth for Oxford Biomedica, and in 2020 the Group exceeded the 500 employee limit for the SME scheme and now exclusively claims through RDEC. This has resulted in a reduction in cash flow of approximately 50% (the Group remains loss-making due to its heavy R&D investment) but the Group is now in a strong financial position following the past years of growth supported by the SME R&D tax credits scheme. As a result, the UK has a globally-leading gene therapy Group and a vital biomanufacturing capability that has helped it fight the COVID-19 pandemic.

Question 5 Would a departure from the ordinary Corporation Tax self-assessment system be justified? Should more information and assurance be required from companies at the point of claiming? Should a company providing more information upfront be treated differently?

If R&D claims were to be treated separately from the Corporation Tax self-assessment system, and thereby allow claims to be made earlier, this would be particularly beneficial to SMEs from a cashflow perspective.

We acknowledge that safeguards would need to be implemented to ensure that claims received the same level of scrutiny and HMRC retained the right to enquire into claims. This could be linked to a minimum standard of evidence/support. The principle of being able to claim repayable credits closer to the time in which the cost was incurred, and the R&D activities carried, is however one we would support.

We would also support a more general minimum information standard in order to address the increasing prevalence of spurious claims. Mandatory minimum information requirements could be imposed by project, with no exclusion based on materiality.

In terms of compliance, we believe that an SME making a claim for a £20,000 project should have the same compliance burden as a larger company claiming a project for the same economic benefit who are currently able to agree sampling methodologies with their Customer Compliance Manager.

Question 6 When did you first claim, and what prompted you to do so? Do you use an agent? If so, why? What is your experience of how agents' fees are structured? How could the expertise and specialist knowledge of agents assisting with R&D claims be improved?

We hold the view that experienced and suitably qualified agents play a valuable role in helping companies understand the regime, adopt best practice and encourage greater consistency.

Our principal concern regarding agents is the use of results-based fees as:

i. They provide an incentive for inflated claims and compromise objectivity in validating qualifying expenditure and cut-off.
ii. Companies are paying fees that are disproportionate to the level of advice/support received resulting in a significant proportion of the incentive being channeled to the agent.
iii. The business model underpinned by success fees is being adopted by an increasing number of agents who lack sufficient experience and professional integrity to conduct the work.

Evidence for this is that early stage biotechnology companies are being approached to engage on this basis where there is very little doubt that the activities would qualify under the BEIS guidelines.

We would recommend that these fee structures are prohibited or, if this was not possible, ensure that disclosure was made by the claimant and/or the agent if a results-based fee was being charged against the credit.

It may also be helpful for HMRC to publish guidance, similar to the one on the Australian Tax Office's website[11], highlighting red flags of risky behaviour from agents.

Question 7 How can the responsibilities of HMRC, agents and the company be better reflected in the claims process?

As mentioned previously, we are in favour of mandatory minimum information requirements to be provided when submitting a claim. This would raise the minimum standards of claims and help HMRC conduct a more accurate risk assessment.

There should be greater regulation on advisers. The market for R&D tax advice is largely unregulated, yet this is unbeknown to many businesses seeking the advice. This can result in spurious tax advice being given, and the large numbers of R&D claims filed lead to many of these incorrect claims escaping the attention of HMRC. Claims should include a declaration of which agent has been employed to make it and if result-based fees are involved. We are aware that there is a broader programme being run by HM Revenue & Customs in respect of the raising of standards in the tax advice market.

We welcome the recent expansion of HMRC's R&D team; however, we recognise that it would be more appropriate to implement preventative as opposed to detective measures. Greater regulation on R&D tax advisors would prevent claims containing incorrect qualifying expenditure being filed, as well as protect the companies that the claim is being filed on behalf of.

Question 8 What other changes might help claims to be dealt with more smoothly, while ensuring better compliance? Is there a way HMRC and advisers can work more effectively to improve the quality of external advice available to companies? If you claim R&D tax reliefs in other countries, how does the claim process differ and what are your views on this?

Please see our previous answers.

[11] https://www.ato.gov.au/business/research-and-development-tax-incentive/checklist-for-claiming-the-r-d-tax-incentive/

The BIA has in the past spoken at HMRC conferences to help inspectors' understanding of the life sciences sector. We would be happy to do this again.

Qualifying expenditures and R&D definition

Question 9 Is there evidence to suggest areas of activity other than those currently covered by the R&D definition drive positive externalities which should be recognised by the tax system?

The definition of R&D set out in the BEIS Guidelines issued 5 March 2004, updated 6 December 2010 effectively addresses innovation. The concept is widely understood and the conclusion from previous consultations have been to maintain the definition. This does not include areas such as pure mathematics, the creative industries or social sciences, however, this is largely in line with most international competitors, such as the US.

We are not aware of other areas of activity driving positive externalities that are not already covered by the BEIS guidelines. We are concerned that a further widening of this definition could result in deadweight claims.

Question 10 Do you think R&D tax reliefs could better incentivise R&D with specific social value, for example developing green technology? Could R&D tax reliefs be used to disincentivise R&D in certain fields?

The development of new medicines and other technologies that help improve health and address disease is R&D with clear social value. There are many other applications of bioscience that have other social value, such as replacements for fossil fuels. As described elsewhere in this response, we believe R&D tax reliefs incentivise this R&D extremely well, and the proposed improvements we make in answer to Q3 could even better incentivise it. Conversely, reducing SME benefits would disincentivise investment in this socially-valuable activity.

We believe incentives outside the R&D tax relief regime, such as grants, offer the Government a more agile and flexible lever to direct R&D to achieve specific social value objectives determined by Government priorities, which can change from one year to the next. It is our view is that there would be benefits in maintaining the RDEC and SME regimes under their current structure rather than adding in features that would need to be dynamic. This will deliver greater certainty and avoid additional complexity.

Please see Q4 for comments on internal software platforms.

Question 11 What is your experience of conducting R&D in different regions across the UK? How do R&D tax reliefs benefit these activities, and how could the offer be improved to better support these activities?

Different regions of the UK have different scientific and engineering strengths, which are reflected in their academic institutions and are even more pronounced in the concentration of industry. The Midlands is well known for its automotive industry, Scotland for its marine geology expertise, and the South East for its life sciences. This has built up for a range of reasons over decades. However, BIA members flourish across the UK in the locations best suited to them, helped by a level playing field of R&D tax reliefs, as illustrated in Figure 1 and the bioscience and health technology sector statistics published by the Office for Life

Sciences.[12] In HMRC statistics, R&D tax claims are assigned to headquarters, not necessarily where R&D activity is taking place, this should be remembered when assessing regional policy interventions (this is also true for ONS analyses).

Clusters have agglomeration effects that are important to the success of businesses. The US has two major biotech hubs based around the cities of San Francisco and Boston, Massachusetts and these account for the lion's share of investment in US biotech. In 2020, the West and East Coast hubs accounted for 27% (£4.55bn) and 33% (£5.65bn), respectively, of the US total of £16.88bn.

Given the highly specialist nature of R&D in Life Sciences companies may not have a choice around where activity is located; they will likely be close to the skills and expertise that they need to access in the labour market and academic/medical institutions. The Government should be mindful not to create distortions that would be detrimental to the long-term success of a particular sector and create deadweight by giving beneficial treatment to companies that would naturally locate in a given region anyway.

We believe incentives outside the R&D tax relief regime, such as grants, offer the Government and devolved/local governments a more agile and flexible lever to target and incentivise regional economic activity. It is our view is that there would be benefits in maintaining the RDEC and SME regimes under their current structure rather than adding in features that would need to be dynamic. This will deliver greater certainty and avoid additional complexity.

Question 12 Are there any other areas of qualifying expenditure that should be included within the reliefs? How would this influence your investment decisions?

We continue to support the inclusion of data and cloud computing costs, and capital expenditure, and hope to see these costs being included in the scope of relief as soon as possible.

Question 13 What proportion of your R&D expenditure is treated as capital for the purposes of corporation tax? What would be the impact on your R&D activities of increased relief for capital expenditure?

We would welcome the inclusion of capital expenditure in both the R&D tax regimes as the UK has historically offered the lowest incentives for R&D capital expenditure out of all of the G7 countries[13]. A selected example of countries that allow capital expenditure to be claimed within its R&D tax credit system or inclusion of depreciation include: France, Ireland, Japan, the Netherlands, Australia, Belgium and Austria.

Under the current regime, capital expenditure incurred for the purpose of R&D is only eligible for the Research and Development Allowance ("RDA"), therefore companies can claim 100% tax relief at the year of acquisition of the asset. As many UK research-intensive SMEs are loss-making already, accelerated tax relief

[12] Office for Life Sciences (2020), *Bioscience and health technology sector statistics 2019*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2019

[13] ABPI, June 2020, Technical report: raising UK productivity by including capex in R&D tax credits

is of little benefit. The inclusion of capital expenditure would likely provide an incentive for more companies to undertake capital intensive R&D in the UK.

The depreciation of the assets could be included as qualifying expenditure as is the case in many territories. Alternatively, the relief can be provided in the form of an upfront incentive for SMEs, similar to costs capitalised as intangible assets whereby the company needs to make a section 1308 CTA 2009 claim in their tax computation for a current year deduction.

Where there is mixed use of R&D and non-R&D, an apportionment for the part used directly in R&D could be determined on a just and reasonable basis. There could be an avoidance opportunity where companies used facilities for R&D on a temporary basis with the long-term use being intended for different purposes. This could be addressed through a targeted anti-avoidance measure (TAAR) or by including a claw back if the use changed within a limited period somewhere between 2-5 years.

The inclusion of capital costs as a qualifying expenditure would also address the uncertainty around projects taken to capital on the balance sheet under CTA09/Ss 53; 1044(5), 1063(4), 1068(4) & 1074(7) (see CIRD81700).

Question 14 Do you currently claim RDAs? If not, why not? What do you like and/or dislike about RDAs?

See above.

Question 15 How much of the activity in respect of which you claim R&D in the UK is undertaken outside of the company, and how much of that is not undertaken in the UK? What are the benefits and drawbacks of subcontracting, whether overseas or domestically? What are your commercial/other reasons for carrying out work overseas rather than in the UK?

Modern Life Sciences R&D is complex and highly specialised. The facilities and equipment required present very high setup costs, and the expert staff required to conduct R&D are few and far between. Furthermore, the research is risky and may fail at any time, rendering the capital investment and staff redundant. SMEs therefore outsource to companies and universities that have the ability to make those capital investments and long-term commitments to facilities and staff.

This business model has enabled a community of innovative SMEs to form in the UK, attracting direct foreign investment and leveraging private venture capital investment crucial to the Government's ambition for the UK to be a global life sciences hub. The model allows entrepreneurs to start-up R&D-intensive companies at a lower cost, which means more discoveries get tested for scientific and commercial viability – supporting such activity is at the
heart of the Government's Industrial Strategy. This "many shots on goal" approach also holds the key to developing treatments for the wide range of currently incurable diseases that impact the population. Outsourcing is not just important at the early stages of a life science company's development when it is involved in discovery science.

At the heart of the UK sector are around 300 companies that own intellectual property for new drugs that they are developing.[14] 80% of these have 10 or fewer employees and largely operate on an outsourcing model whereby they rely on universities and other companies to conduct R&D on their behalf. Furthermore, clinical trials which are the most expensive stage of drug R&D are conducted in hospitals whereby the company pays for use of NHS staff and infrastructure, often via a Contract Research Organisation (CRO).

The need to contract out R&D to third parties is essential given:

i. The complexity of regulated R&D in life sciences and the need to access specialist skills and patient populations
ii. The high risk of failure is such that early stage firms need to minimise fixed costs and keep headcount to a minimum
iii. The challenges in raising sufficient finance to undertake this in-house and so the inclusion of sub-contract R&D is critical to the effectiveness of the regime.

It is important to allow SMEs to subcontract as they do not have access to sufficient capital to build the facilities or hire the required individuals in the short term. Even if they did, many of the skills they require are in short supply in the UK and often globally, so not every company could recruit who they need. Moreover, skills and indeed equipment, is often only needed for a small component of an R&D project, so it is not economically viable to build in-house capability.

The process for testing medicines on patients or volunteers is highly regulated and needs to be undertaken through specifically designed clinical trials. The universal model is for the management of these trials to be undertaken by an enterprise with specific skills and resource, namely Contract Research Organisations (CROs). This is an essential and significant activity in life sciences R&D. Both regimes need to be structured such that clinical trials undertaken by CROs are eligible either as sub-contract expenditure.

Much of this outsourced R&D will be conducted in the UK due to the expertise and world-class facilities and hospitals here. There are pockets of highly-specialised CROs and CMOs across the UK, and clinical trials will often be spread across multiple hospitals throughout the UK to obtain sufficient patient numbers or access medical expertise; in this way, the new model of R&D contributes to regional development rather than concentrating activity in a few large institutions (see the Novabiotics case study below as an example).

UK companies will also utilise a global network of CROs and CMOs to develop their products at the necessary pace and standard to be internationally competitive. However, crucially, the IP and therefore the value-creation, remains in the UK. Given the outsized UK life sciences sector in comparison to its population, the ability of SMEs to be based in the UK but conduct R&D overseas, supported by R&D tax credits, is a distinct advantage for the domestic sector. There are various factors that determine whether R&D activities are undertaken domestically in the UK or overseas. For example, small patient populations for rare diseases mean drug developers must conduct clinical trials in multiple countries. Clinical trials may also be needed for specific local markets due to the differences in profiling of patients and the prevalence

[14] This figure does not include cell and gene therapy companies, of which there are about 70 more. Medicine Discovery Catapult and BIA (2019), *State of the Discovery Nation 2019*: https://md.catapult.org.uk/resources/state-of-the-discovery-nation-2019/

of the disease in the area. Ethnicity can have profound impacts on people's reaction to medicines, so it is vital diverse populations are involved in clinical trials.

Furthermore, certain clinical trials often need to be conducted overseas to receive approval from the relevant local authorities and investors. An example of this includes the FDA preferring US-sourced data and this can be very important for investors, given the size of the US healthcare market. Under the current structure of the SME regime, a UK company could take a new drug through clinical development (including expensive US trials) and retain all of its principal activities in the UK. When the product is taken to market, the majority of the resulting revenues and profits will be generated in the UK. The UK tax system, including the SME R&D regime and patent box, needs to be structured and aligned to support and promote this business model. A very compelling recent example of this has been the success of Oxford Nanopore Technologies which has retained the majority of its activities in the UK. The reintroduction of an IP condition, as outlined in our response to Q2, would help ensure UK tax payer support via R&D tax credits leads to long-term benefit to the UK and its tax payers.

Novabiotics: accessing outside expertise to build a successful science business

Novabiotics is a leading clinical-stage biotechnology company focused on the design and development of first-in-class antibiotics for difficult to treat, medically-unmet infectious diseases. It was founded in 2004 and is based in Aberdeen, where it employs 16. The company's drug development platforms are based on research at The University of Aberdeen, which retains legacy shares in exchange for the original patents.

NovaBiotics claims under both the SME and the RDEC scheme. R&D tax credits payments of approximately £3m have helped the company develop in Aberdeen since 2004, funding approximately 12% of the £25m total it has invested in the research and development of its strong pipeline of treatments, including Novexatin® , which is due for commercial launch in 2022 to treat fungal infections affecting 12% of the world population.

The majority of the company's R&D expenditure is in-house but Novabiotics must utilize a wide range of specialists for the many different aspects of drug development. For example, Upperton Pharma Solutions, based near Nottingham, was contracted for its expertise in the development of spray dried powder dosage formulation of drugs. This is a highly specialized capability required at only one step of the drug development process, meaning a small company couldn't invest to build itself. No UK university has the capacity either, meaning there were no HMRC qualifying bodies available to Novabiotics to employ and subsequently the company could not claim for this aspect of its R&D project through RDEC when the project was also supported by a grant. Similar examples occur with services sub-contracted to Alderley Analytical based at Alderley Park, Cheshire, Covance CRS, Harrogate, and Evotec, Germany.

Question 16 How could the government distinguish between work that needs to take place abroad and which benefits the UK, and that which doesn't?

For the SME scheme, there is now a control over the level of R&D conducted outside the UK following the introduction of the R&D cap for SMEs with the claim limited to a multiple of UK PAYE/NI. Only those

companies where the management activities relating to the development and exploitation of the IP are undertaken by the claimant are eligible for the exemption from the cap.

Under RDEC the exclusion of sub-contract expenditure and the PAYE/NI cap naturally limit the extent of activities that can be undertaken overseas.

We believe that any additional measure would add complexity and an additional compliance burden, whilst also undermining the policy objective of supporting SME to exploit R&D to generate economic growth. However, the reintroduction of an IP condition, as outlined in our response to Q2, would help ensure UK tax payer support via R&D tax credits leads to long-term benefit to the UK and its tax payers.

Question 17 How can we identify the supporting activities which are most valuable for R&D, while providing a clear boundary to assist companies in claiming and HMRC in administering?

The definition of qualifying indirect activities ("QIAs") set out in the BEIS guidelines does not provide a clear boundary to identify supporting activities which are most valuable for R&D. This lack of clarity can give rise to inconsistency and deadweight R&D.

We would support the following test based on the BEIS guidelines to help claimants to understand what can qualify as a qualifying indirect activity:

A QIA is an activity that is undertaken as part of a project but may not necessarily directly contribute to the resolution of the scientific or technological uncertainty. However, the activity should be both:

i. *one that was essential to the undertaking of R&D such that, had it not been undertaken, the likelihood of the R&D being carried out in an effective manner would have been compromised, and*
ii. *an activity that was influenced by the project itself (i.e. while it may have been an activity that would have been undertaken by the company it was undertaken because of or adapted for the project).*

This would also resolve a long-standing area of contention being the extent to which regulatory activities can be included as eligible expenditure. This would help distinguish activities between those addressing scientific uncertainty which should be eligible and those limited to addressing regulatory uncertainty, which we accept should be excluded.

For further information on this submission, please contact Martin Turner, Head of Policy and Public Affairs, on 07850 518 075 or mturner@bioindustry.org.