# BIA submission:
# R&D tax reliefs review consultation on a single scheme

## March 2023

UK BioIndustry Association

## Key points

- The UK has a truly world-leading life sciences industry that is growing in size and impact as a result of long-term support from successive governments, most crucially via the R&D tax relief scheme.
- We welcome the intention to create a new simplified regime to ensure taxpayers' money is spent as effectively as possible to support innovation and improve international competitiveness while reducing fraud and misuse of public funds.
- This can be achieved if the following four requirements are met:
    - Provide an additional rate of credit for R&D-intensive SMEs
    - Exclude soft innovation
    - Include sub-contract R&D as eligible expenditure
    - Support specialist R&D service providers
- Our proposals for the structure of a merged are shown in the table below

**Proposals for the structure of a merged R&D Regime**

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|---|---|
| Eligibility | All claimants must meet the following to receive the standard relief rate (currently 20%):<br><br>1. £100,000 of qualifying expenditure (see Threshold below);<br><br>**AND**<br><br>2. R&D expenditure is equal to or greater than 15% of operating costs in one of the last 3 years or, on average, greater than 10% over the last three years; or<br>2. Annual R&D expenditure is equal or greater than £1 million; or<br>3. R&D activities are responsible for at least 80% of the company's revenue |
| Threshold | As above, £100,000 of qualifying expenditure with an exception for companies above a defined intensity threshold of R&D costs as a percentage of operating costs. |
| Rates | A standard rate (currently 20%) with a higher rate for research intensive companies.<br><br>To qualify for the higher relief rate, claimants must meet the following, with no qualifying expenditure threshold: |

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|---|---|
| | • 500 staff, and either: A turnover of no more than €100 million; or. Gross assets of no more than €86 million[1]<br>• R&D expenditure is equal to or greater than [e.g. 40]% of operating costs in one of the last 3 years or, on average, greater than [e.g. 35]% over the last three years |
| Qualifying Expenditure | As currently included under RDEC with inclusion of sub-contracted work that is undertaken in the UK, or eligible as Qualifying Overseas Expenditure.<br><br>Include capital expenditure to be globally competitive. |
| Qualifying Indirect Expenditure | Restricted to expenditure satisfying the conditions set out in the response to Q16 |
| PAYE/NI Cap | Adoption of the RDEC cap with the current SME exception for companies actively managing IP, with less than 15% connected party subcontracting |
| UK connected parties | New rules should not put UK connected parties who disaggregate activities and/or employment at a disadvantage[2] |
| Simplification measures | - No restriction for subsidised R&D<br>- Removal of the State Aid cap<br>- Removal of reimbursed expenses as qualifying staff expenditure<br>- Removal of Gripple restriction for Externally Provided Workers |

## Introduction and objectives of R&D tax reliefs

The consultation is right to state that there is a strong correlation between innovation, productivity gains and economic growth, and that the driving force of innovation – R&D – has great spill-over benefits for the public. It is also right to identify the UK's strengths in science and innovation.

Life sciences is responsible for much of this strength, in both academic and private sectors. As a result, the UK benefits from a truly world-leading life sciences industry that is growing in size and impact. Government figures show there are over 6,548 businesses in the UK life sciences industry, the vast majority of which are SMEs. These businesses employ over 282,000 people and generated £94.2 billion of turnover in 2021.[3] The number of businesses and the number of sites operated by these businesses have both seen an upward trend since 2009, with 23% more businesses and 32% more sites operating in 2021 compared to 2009. Consultants PwC estimates that pharmaceuticals – the largest part of the UK's life sciences industry – contributes £36.9 billion in GVA (Gross Value Added) to GDP.[4] The UK's pharmaceutical sector also invests more in R&D than any other[5] and the UK has the highest intensity of pharmaceutical patenting activity of all leading economies globally.[6]

Small and medium-sized life science companies are the driving force of innovation in this sector, with the majority of new medicines in the global pipeline discovered and developed by these emerging companies. In

[1] This is the current SME definition used in the R&D tax relief legislation. We would support a conversion into British currency but the 500 headcount must be remained.
[2] Previous EU non-discrimination concepts should no longer apply to intra-UK
[3] https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021/bioscience-and-health-technology-sector-statistics-2021
[4] https://www.abpi.org.uk/publications/life-sciences-superpower-growing-the-leading-hub-in-the-uk-key-messages/
[5] Office for National Statistics. Data not available due to recent ONS methodology changes and reclassifications.
[6] https://biotechfinance.org/#randd

many cases, multinational pharmaceutical companies play the crucial but often supporting role in the later stages of the development process, although an increasing number of smaller companies are succeeding in independently taking a medicine all the way from discovery to market, such as Oxford-based Immunocore.[7] As a result, emerging life science and biotech companies represent 65% of the global drug development pipeline with an additional 7% being developed by them in partnership with larger firms.[8]

> ***"Emerging life science and biotech companies represent 65% of the global drug development pipeline with an additional 7% being developed by them in partnership with larger firms."***

Equity investment into such emerging companies in the UK has risen dramatically over the past decade, creating new companies and jobs, and accelerating innovation. In 2012, life science spin-outs, start-ups and SMEs raised £286 million in equity finance. This rose to £4.5 billion by 2021, but as fallen back to £1.7 billion in 2022 as a result of the global economic uncertainty hitting investment in all sectors.[9] As a result of this increase in venture capital investment, the UK accounts for 35% of all life science start-ups created in Europe since 2012.[10] This growth is in large part the result of support received from successive governments over decades through well-targeted policy and regulation, including R&D tax relief.

> ***"The UK accounts for 35% of all life science start-ups created in Europe since 2012, in large part thanks to R&D tax relief"***

Given the central importance of R&D tax relief to the success of our sector, we welcome the intention to create a new simplified regime to ensure taxpayers' money is spent as effectively as possible to support innovation and improve international competitiveness. Furthermore, we welcome the commitment to supporting R&D-intensive SMEs. This presents an opportunity to reshape UK R&D incentives to put innovation at the heart of our economy, as the Prime Minister recently set out in his speech on building a better future.[11]

The objectives of a new single R&D tax relief regime should be to support the growth of the most highly innovative businesses that are investing heavily in R&D to create the products and sectors of the future that will ensure Britain remains a science and economic superpower.

To do so, R&D tax reliefs need to focus on genuine high risk and ground-breaking research and reduce deadweight cost resulting from soft innovation that would be undertaken regardless of whether there was an incentive in place or not. This is where the boundaries are being pushed and it is fuelled by an industry of "no win, no fee" advisors that have distorted the regime and its effectiveness for meeting its original policy objectives.

Given that HM Treasury is not prepared to outlaw no win, no fee claims, which we have lobbied for, we believe that there is a straight-forward way of addressing this, which is by limiting the regime to companies that satisfy a minimum R&D investment threshold and intensity. This will create significant savings in stopping misdirected credits and relieve the consequential pressure from HMRC.

Before responding to the specific questions we set out some essential requirements of a new merged regime to meet the objective described above.

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[7] https://ir.immunocore.com/news-releases/news-release-details/uk-medicines-and-healthcare-products-regulatory-agency-mhra
[8] https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharma-contribution-to-innovation
[9] https://biotechfinance.org/
[10] https://www.mckinsey.com/industries/life-sciences/our-insights/biotech-in-europe-a-strong-foundation-for-growth-and-innovation
[11] https://www.gov.uk/government/speeches/pm-speech-on-making-2023-the-first-year-of-a-new-and-better-future-4-january-2023

**Requirement 1**: **Provide an additional rate of credit for R&D-intensive SMEs**

Enhanced incentives should be retained for R&D-intensive SMEs creating IP in the UK. The UK could also go further by creating a new super-high rate of relief for hyper-R&D intensive companies to demonstrate its commitment and ambition to be a science superpower.

The cut to the SME rate announced at Autumn Statement has already caused significant damage to the sector (see Annex 1 for case studies already provided to HMT). Such companies suffer from the greatest risk of R&D investment market failure, but also exhibit exponential business and R&D investment growth (i.e. even higher future R&D) resulting from the R&D expenditure when successful. Furthermore, companies which retain the IP arising from their R&D work in the UK will recognise higher profits on success and therefore pay more corporation tax. Current HMRC analysis of SME scheme effectiveness does not provide a full assessment of these benefits, nor a sector-specific breakdown, which is needed (see below). We have offered to work with HM Treasury and HMRC to produce the required evidence to inform policy development.

**Requirement 2: Exclude soft innovation**

Soft innovation is where there are minor and low risk technical enhancements to existing products or internal platforms that businesses would undertake regardless of the availability of incentives and is therefore a deadweight cost. In many cases, eligibility for these activities under the BEIS guidelines is questionable but this is very difficult for HMRC to disprove. This consultation presents the opportunity to refocus the regime on genuine high-risk R&D which was the original purpose when the regimes were introduced. In recent years there has been increased prevalence of abuse and boundary pushing, resulting in significant misdirection of taxpayer money. This long-tail of non-R&D intensive and un-innovative companies is also the reason analysis commissioned by HMRC and referenced in the consultation document suggests the SME R&D tax relief scheme is less effective than RDEC (discussed further below). This cannot be addressed through the guidelines but can through limiting eligible claimants to:

i. Companies that pass a certain threshold of percentage of qualifying R&D spend to operating costs;

ii. large fully integrated enterprises where the R&D intensity may be lower but who, nevertheless, have recognised R&D teams and meet a minimum R&D spend threshold; and

iii. companies whose trade is to provide R&D services.

We believe that this would result in significant cost savings allowing other changes to be implemented without impacting the cost envelope.

**Requirement 3: Include sub-contract R&D as eligible expenditure**

The retention of sub-contract R&D as a category of qualifying cost is particularly critical for SMEs operating in life sciences who must outsource significant elements of pre-clinical and clinical R&D to specialist service providers, universities and hospitals. However, the introduction of new measures to refocus R&D to the UK and limitations on qualifying overseas R&D should allow sub-contract expenditure to be claimed by the IP owner (i.e. the customer) for all participants in a merged scheme.

Plans to restrict claims for overseas activity should be delayed so that they can be implemented as part of a new single scheme to avoid piecemeal changes and the disruption they cause. The draft HMRC guidance published 20 December 2022 rightly reflects a non-exhaustive set of reasons why R&D must be undertaken by necessity overseas. Other reasons exist and HMRC should work with industry to identify these within the guidance to provide clarity and assurance to claimants. If it goes ahead, greater clarity on the evidence requirements for qualifying overseas expenditure is also required.

**Requirement 4: Support specialist R&D service providers**

In life sciences, a significant proportion of R&D needs to be outsourced to specialist R&D service providers, which are a vital part of the UK's life sciences ecosystem employing highly skilled professionals, creating spill-over benefits and generating valuable service exports. Companies, whose trade is to provide R&D services should be eligible to claim where they are performing R&D for non-UK tax paying clients.

## Limitations of current analysis on the effectiveness of R&D tax reliefs

The consultation makes reference to the econometric study produced by London Economics, commissioned by HMRC. It is suggested that the SME R&D tax relief is less effective at leveraging additional R&D than the RDEC.

The study estimates the 'user cost elasticity' (UCE) for SMEs. The UCE measures the percentage change in R&D spending in response to a 1 percent change in the user cost of R&D. The study finds this elasticity to be too low, indicating that the response of R&D spending to changes in the user cost (caused by R&D tax incentives) is less than what it should be from a government policy (and spending) perspective.

Using UCE to evaluate policy is standard in the academic literature. However, the study has several limitations that impact its value for assessing the effectiveness of the SME R&D tax relief scheme in comparison to RDEC.

1. **The LE study considers all sectors together**. The estimated UCE is an average across all sectors and types of companies. However, different sectors have very different characteristics, and the biotech sector and other high-R&D intensity sectors will respond very differently to incentives, and deliver very different benefits, than less R&D intensive companies. R&D intensive companies also tend to be venture capital backed, meaning there are different types of decision makers being influenced by R&D incentives in these sectors (i.e. the policy's mode of action is different, meaning its assessment may need to be different also).
2. **The LE study includes fraudulent and boundary-pushing companies.** There is a long tail of low R&D-intensity companies that should not be using the R&D tax relief scheme and will not be responding to it as an investment incentive, either because they are fraudulent or because they are not setup to conduct or take advantage of R&D and its products. These companies will show a low UCE and drag down the average. This is not a fundamental flaw of the SME R&D tax relief as a policy lever, but does demonstrate the need for more rigorous eligibility criteria (as discussed elsewhere in this document) and policing of the regime by HMRC (as BIA has strongly advocated).
3. **The LE study only produces short run UCE estimates**. The study ignores the step-wise nature of R&D spending, especially in life sciences where funding rounds are a long term necessity in order to allow R&D expansion to occur, progressively larger clinical trials are standard, and the fact that all elasticities are larger in the long run.
4. **The LE study ignores the spillover effects from R&D**. This is another serious shortfall, as spillover effects from R&D are large and well understood. They magnify the return of R&D to society and the economy, which should be the aim of government policy.

BIA is keen to work with HM Treasury and HMRC on new analysis that more accurately and fully assesses the effectiveness of R&D tax reliefs for innovative and R&D intensive sectors of the economy.

## Responses to consultation questions

**1. Do you agree a new scheme should be an above the line RDEC like credit? If not, what alternative would you propose?**

The reasons cited for merging the regimes are i) simplicity, ii) greater visibility and iii) the fact that SMEs that make small profits cannot always monetise the benefit. In the life sciences sector, the SME regime is generally well understood and having the credit above the line is less important for small entities as the accounting is unlikely to influence decision making. The third point on small profits can easily be addressed, if needed, by amending the surrenderable loss rules such that the credit is always payable at the company's election. This would reduce the lack of certainty over the potential benefit referred to in the consultation document (para 2.9). Therefore, whilst we do not necessarily oppose an above the line credit, if it or the overall merged scheme came at the cost of reducing the effective rate of credit or excluding sub-contract, we would be strongly against this change.

**2. Does the taxability and subsequent different post tax net benefits impact your decision making when allocating R&D budgets?**

Generally not, although the frequency of changes to the rules over the last five years has been very unhelpful. It can be an issue when a company is profitable but not paying tax because of shelter through tax losses. This can be easily addressed by amending the surrenderable loss rules such that a cash credit can made regardless of the tax position at the company's election.

**3. If you use RDEC now, is there anything in your view that should be changed?**

We continue to call for the inclusion of capital expenditure (or related amortisation or depreciation) in the eligible costs for R&D tax relief. Whilst we appreciate the limited fiscal envelope, the regime currently lacks an incentive for "sticky" capital investments to anchor businesses' activity in the UK, ensuring both the R&D and downstream benefits are more likely to remain here as the company scales up to commercial manufacture and the UK economy will accumulate more of the value arising from the tax reliefs UK businesses receive throughout their life cycle. Addressing this would ensure the scheme is truly internationally competitive.

Capital R&D investments, such as bricks and mortar facilities, large equipment and other assets are hard to move overseas and anchor the business and its activities in the UK. Scale-up development research and early-stage manufacturing are part of this, as they often form part of the overall R&D process; in life sciences, experimental medicinal products must be manufactured for use in clinical trials (R&D) and there is also significant R&D involved in perfecting the manufacturing process of any given medicine and health technology.

Moreover, R&D spending on operating and capital assets are complementary, suggesting that tax incentives should treat both spends similarly, allowing firms to make investment decisions based on their individual needs without the tax system favouring any one kind of R&D investment. Including capital spend within the R&D tax credit regime would put it on an equal footing with revenue spend, with the same level of visibility for stakeholders, ensuring the incentive covers all types of R&D investment.

Depending on any changes in the merged regime, all requirements and exemptions need to cater for groups who disaggregate R&D between connected parties in the UK.

## Subcontracting

The following three questions are answered together:

**4. Do you agree the same treatment of subcontracting should apply to all claimants in the merged scheme?**

**5. If so, where R&D activity is subcontracted, do you think that the customer should claim the tax relief, as in the SME scheme, or the subcontractor, the person carrying on the R&D, as in the RDEC?**

**6. Can you see any positive or negative impacts on your business or sector from the Government adopting either approach?**

It is critical that the ability to claim for R&D sub-contracted to other parties is retained for R&D-intensive SMEs in life sciences. Companies in our sector must outsource significant elements of their work to specialist providers, hospitals and universities. We would strongly oppose merging the regimes if sub-contract expenditure was removed as an eligible cost category as this would be significantly damaging and is likely to result in many companies failing in their development with insufficient support or simply not being established in the UK.

## Why subcontracting is critical for R&D-intensive SMEs in life sciences

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. Innovative life science SMEs therefore outsource to other companies and universities that have the ability to make those capital investments and long-term commitments to facilities and expert staff. Put simply, it is uneconomic for an SME to build all of the facilities to run a drug development program all the way through to commercialisation.

This "virtual biotech" business model has enabled a community of innovative SMEs to form in the UK, attracting direct foreign investment and leveraging private venture capital investment. The model allows entrepreneurs to start and build R&D-intensive companies at a lower cost, which means more discoveries get tested for scientific and commercial viability. 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.

As companies grow and develop, they continue to require external expertise and infrastructure that it is not feasible to have in-house. The process for testing medicines on patients or volunteers through clinical trials is highly regulated and needs to be undertaken by expert scientists, doctors and nurses at specially-designed facilities or medical settings. The universal model is for the management of these trials to be undertaken by an enterprise with specific skills and resource, known as a Clinical Research Organisation (CRO). Amongst other things, the CROs will work with the company to plan the trial, identify hospitals or other sites where the trials can take place, recruit patients, oversee the trials, provide advice, analyse the data and interpret the results. This is an essential and significant activity in life sciences R&D, and even large multinational companies use CROs for their expertise[12].

For experimental medicines to be tested in clinical trials they must be first manufactured; this too is a highly specialist and regulated activity that it is rarely feasible to do in-house. Clinical manufacture, as it is called, forms part of the overall R&D process; in life sciences, experimental medicinal products must be manufactured for use in clinical trials (R&D) and there is also significant R&D involved in perfecting the manufacturing process of any given medicine and health technology, especially when that specific material has never been made before or improvements are required. Quality control testing, supply chain

[12] For example, London-based hVIVO (formally known as Open Orphan) has multiple global pharmaceutical clients: https://polaris.brighterir.com/public/hvivo/news/rns/story/wkoej1x

management and medically safe packaging must also be perfected at this stage. Manufacture must be done in a facility approved by the regulatory agency – the MHRA in the UK. These activities are therefore regularly outsourced to contract development and manufacturing organisations (CDMOs) that have the expertise and advanced equipment required.

There are pockets of highly-specialised CROs and CDMOs 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 companies and the economic precariousness that brings.

**7. Do you have an alternative model you think could apply to all claimants in the new scheme? Please provide qualitative and quantitative evidence with your proposal.**

The regime should be structured such that R&D activity remains eligible either as sub-contract expenditure claimed by the client, or the service provider itself when the client is not a UK taxpayer.

To overcome the difficulties around the risk of double counting and boundary pushing identified in 2011 consultation, the scheme should only allow contracted out R&D to be claimed by the service provider (e.g. CRO/CDMO) where the other party (the client) is outside the UK and cannot claim themselves. Furthermore, the ability to claim under this basis should be restricted to companies whose principal activity is the provision of R&D services. This will support the growth of a valuable service export industry, create high-value jobs and attract additional investment and R&D activity – with associated spillover benefits – to the UK because UK service providers would be able to provide more competitive fees to foreign (non-UK tax paying) clients. However, this group of claimants should not be able to claim sub-contract expenditure (i.e. activities they contract out to another party) as these costs would simply be passed through to their customer.

The right to claim under the above conditions should be self-elected by the taxpayer with a declaration. We do not believe joint elections would be a workable way to determine which party should claim for sub-contracted R&D. The joint election concept was previously considered and ruled out, by both industry and HM Treasury, on the above grounds in the 10-year review on R&D tax credits. It would create a considerable compliance burden on businesses in negotiating the elections and pricing of contracts and could create opportunities for abuse. It also creates an inherent gateway for double counting, which can only be verified by positive verification of an election unless appropriate infrastructure is created. In most cases the customers are SMEs who are outsourcing to larger parties. They will have a weaker negotiating position and are likely to lose out. Furthermore, service providers outside the UK may be unwilling to sign an election unless there is a mechanism for the customer to be able to claim where the service provider is not subject to corporation tax.

## PAYE/NI Cap

The following four questions are answered together:

**8. What are your experiences of the PAYE / NICs cap?**

**9. Are there any ways the Government could simplify the PAYE / NICs cap whilst ensuring there is protection against abuse?**

**10. Which of the SME and RDEC PAYE & NICs cap should the Government implement in the new scheme?**

**11. Should the Government change the way either cap is calculated if is taken forwards? And if so, how?**

Whilst we understand and support the Government's motivation for using a PAYE / NICs cap to prevent fraud and anti-tax avoidance, it is important that it is compatible with how the life sciences and other cutting-edge industries operate, notably through small but highly specialised in-house teams managing R&D programmes sub-contracted to other organisations (as described above). When the original PAYE cap was removed in 2012 – in large part due to BIA highlighting the problems it was causing – investment in life science SMEs rose dramatically. In 2012, life science SMEs raised £286 million in equity finance. This rose to £4.5 billion by 2021, an increase of 1600%.[13] As a result of this increase in venture capital investment, aided by the more generous (uncapped) R&D tax relief, the UK accounts for 35% of all life science start-ups created in Europe since 2012.[14] Any cap design in the new scheme should be designed to avoid putting unnecessary brakes on this success story.

As an anti-fraud/avoidance measure, we propose that the current RDEC PAYE / NICs cap should be used. This should limit claims (whether as relief from corporation tax, or as payable cash credits) to the amount of PAYE/NI paid by the claimant in respect of R&D workers.

Given the need to subcontract R&D, it is essential that an exception for the creation and active management of IP, as used currently within the SME PAYE / NIC cap, be retained.

A current failure in this exception is that it is only tested at the claimant level. This has been highly problematic for companies who separate R&D programmes into single asset companies to manage the risk of individual drug development programmes and to facilitate licensing and collaborations with partner companies. The PAYE / NIC cap exceptions should be assessed by reference to all UK connected parties within an economic group. We believe this can be introduced as part of a new merged scheme, given that EU non-discrimination concepts no longer need to be adopted in an intra-UK context.

## Additional support for different types of R&D or R&D intensive companies

The following two questions are answered together:

**12. Do you consider the government should provide more generous support for different types of R&D or more R&D intensive companies relative to less R&D intensive companies?**

**13. In the event this were to be done, how might this best be achieved within an overall cost envelope?**

With the widely-accepted role of innovation in driving productivity gains and therefore economic growth, the UK should be prioritising R&D intensive companies for support, including and especially in the R&D tax relief scheme, which is the form of innovation support most favoured by innovators, entrepreneurs and investors. Moreover, start-ups, spin-outs and scaling companies have high growth potential, meaning they are able to deliver disproportionate benefits for the taxpayer through job creation, increased R&D and innovation leading to productivity gains and economic growth.

[13] https://biotechfinance.org/
[14] https://www.mckinsey.com/industries/life-sciences/our-insights/biotech-in-europe-a-strong-foundation-for-growth-and-innovation

However, due to their early-stage, the inherent risks of scientific failure and their funding model (typically venture capital), such companies also face more significant market failures than more established companies or those operating in less innovative parts of the economy. There is therefore a greater need for more generous support to ensure these companies start and scale in the UK rather than elsewhere. A higher relief rate should therefore be set for SMEs with a higher level of R&D intensity. The exact R&D intensity threshold should be carefully modelled and set with reference to economic analysis yet to be undertaken on the characteristics of the sectors and companies that deliver greatest long-term return on investment for the taxpayer. For simplicity, all other elements of the scheme would be the same regardless of tier.

### Differentiated relief rate criteria example

All claimants must meet the following to receive the standard relief rate (currently 20%):

1. £100,000 of qualifying expenditure;

   **AND**

2. R&D expenditure is equal to or greater than 15% of operating costs in one of the last 3 years or, on average, greater than 10% over the last three years; or
3. Annual R&D expenditure is equal or greater than £1 million; or
4. R&D activities are responsible for at least 80% of the company's revenue

To qualify for the higher relief rate, claimants must meet the following:

5. 500 staff, and either: A turnover of no more than €100 million; or. Gross assets of no more than €86 million[15]
6. R&D expenditure is equal to or greater than [e.g. 40]% of operating costs in one of the last 3 years or, on average, greater than [e.g. 35]% over the last three years

Moreover, we believe the UK could demonstrate its commitment and ambition to be a science superpower and send a global signal that the UK is *the* place to start and grow highly innovative businesses by creating a new super-high rate of relief for hyper-R&D intensive companies.

Eliminating R&D on soft innovation will reduce the cost, better target the incentive, significantly eliminate boundary pushing and help prevent abuse, allowing for more generous support to R&D intensive SMEs. Soft innovation is where there are minor and low risk technical enhancements to existing products or internal platforms that businesses would undertake regardless of the availability of incentives and is therefore a deadweight cost. In many cases, eligibility for these activities under the BEIS guidelines is questionable but this is very difficult for HMRC to disprove. This consultation presents the opportunity to refocus the regime on genuine high-risk R&D which was the original purpose when the regimes were introduced. In recent years there has been increased prevalence of abuse and boundary pushing, resulting in significant misdirection of taxpayer money. This long-tail of non-R&D intensive and un-innovative companies is also the reason analysis commissioned by HMRC and referenced in the consultation document suggests the SME R&D tax relief scheme is

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less effective than RDEC. This cannot be addressed through the guidelines but can through limiting eligible claimants to:

i. R&D-intensive companies based on a threshold percentage of qualifying R&D spend to operating costs (see suggested definition in box above);

ii. large fully integrated enterprises where the R&D intensity may be lower but who, nevertheless, have qualified R&D teams and meet a minimum R&D spend threshold; and

iii. companies whose trade is to provide R&D services.

We believe that this would result in significant cost savings allowing more generous support to be provided to R&D-intensive SMEs without impacting the cost envelope. As an alternative, R&D-intensive companies could be defined without requiring them to be SMEs, but the law would need to contain strong anti-avoidance measures to prevent artificial ring-fencing of R&D-intensive activity in a UK claimant company.

## Guidance and transition

**14. If the schemes are merged do you agree the Government should implement the merged scheme for accounting periods starting on or after 1 April 2024?**

We would welcome long term stability in the regime and clear guidance over the application of any changes. SMEs are experiencing half a decade of instability and uncertainty due to constant changes to the R&D tax relief regime. As an example, a company with a 31 December year end must navigate the changes as follows:

Year ended 31 December 2021 – old rules apply
Year ended 31 December 2022 – PAYE cap applies
Year ended 31 December 2023 – PAYE cap applies for the whole year. SME rate cut applies to spend from 1 April 2023
Year ended 31 December 2024 - PAYE cap, SME rate cut and overseas activity restriction applies for the whole year

We believe that implementing these changes by 1 April 2024 is too ambitious and will not allow sufficient time to plan with the benefit of final legislation and an appropriate level of published guidance. Consequently, we would recommend an implementation date of accounting periods starting on or after 1 April 2025.

**15. How can Government ensure SMEs are supported in the transfer into a new scheme?**

It is essential that R&D-intensive SMEs receive further support from 1 April 2023 when the SME rate cut is expected to apply and that this further support or better is effectively maintained going forward under the merged scheme or otherwise.

Aligning the regime under RDEC principles should importantly allow the credit to be monetised regardless of the claimant's tax loss position and therefore provide greater certainty. If the regimes were not merged then this could be addressed by modification of the surrenderable loss rules.

Recent changes, such as restrictions on claims for overseas activity, have been rushed through in legislation and guidance from HMRC has been slow to be produced, increasing uncertainty for all businesses. Given their

resources, the impact on SMEs is arguably greater. All businesses need certainty and clarity as soon as possible to make their investment plans. It is therefore vital that the transition to a new scheme is done to a sensible timescale and reliable guidance is published as soon as possible for any changes, with time given for companies to plan and adapt.

## Other design features

**16. Does claiming for expenditure on qualifying indirect activities influence your decision to undertake R&D?**

The definition of qualifying indirect activities under the BEIS Guidelines has always been difficult to apply and also results in boundary pushing. This review allows an opportunity for this to be addressed to allow essential supporting activities that are not explicitly included within the definition of 'direct activities' be included that satisfy the following hallmarks:

- activities that are essential to the undertaking of R&D such that, had they not been undertaken, the likelihood of the R&D being carried out in an effective manner would have been compromised, and
- activities that are influenced by the project itself (i.e. activities undertaken because of or adapted for the project).

**17. Do you think a threshold should be implemented? If one was implemented what at what level should it be introduced?**

We would support a threshold of £100,000 of qualifying expenditure. This could disadvantage early stage research intensive companies and so this could be relaxed for companies above a defined intensity threshold of R&D costs as a percentage of operating costs, as described above.

**18. What is the average amount of R&D expenditure per year per firm in your business or sector?**

The life sciences sector is extremely diverse, but it is characterised by a high R&D intensity as defined by R&D expenditure as a proportion of total expenditure.

Life science companies are typically focused almost solely on R&D for the first 10 to 15 years of their life, as this is the time it takes to develop a new medicine or other highly regulated product. During this time R&D expenditure will gradually ramp up, with progression to clinical trials a particularly significant inflection point.

The average (mean) expenditure eligible for R&D tax relief in a survey of 90 of our members was £7.2 million, but the maximum in the sample (which did not include any established "large pharma" companies) was £72 million, and the minimum was £25,000.

## 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.

Our members include: start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR

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

**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**

## Annex 1: BIA member case studies of impact of SME R&D tax relief rate cut

**1. Early-stage precision medicine development company**

We were in the process of preparing for our first full Board meeting with our new investors following our successful Series A fundraise in October 2022 when the disappointing news of the Autumn Statement changes hit. **Our plans and funding for the next three years to end 2025 require us to meet certain R&D milestones both to secure a second tranche of the announced fundraise and to put us in a position to be able to raise a further round (Series B) in late 2025.** To ensure that we have sufficient funding leeway (runway) to cover the uncertainty of R&D results, we have had to look very carefully at our hiring plans, facilities, and R&D plans.

To provide a specific example of an item delayed due to the significant reduction in R&D tax credit for SMEs, **we originally planned to seek expansion laboratory space in the Oxford area ahead of the Series B funding (sometime mid 2024 to end 2025). This has now been put back to after Series B (likely 2026) due to the reduced runway and uncertainty.** This of course comes with the possibility of reduced employment expansion and R&D capability if we are constrained for space at that time.

**2. UK-headquartered public biotech company**

About half of our 500 heads are in the UK predominantly undertaking R&D. We manufacture in the US and conduct clinical trails in the US, UK and Europe

About two years ago we were making an investment decision as to where to set up our research facility. **Ultimately this involved a $20m investment in a state of the art cleanroom facility for allogeneic manufacture plus approx. 20 highly skilled research heads and associated support staff. As we made that business decision the SME R&D tax credit was a significant element in choosing the UK over the US.**

**We are now in the middle of a restructuring given the well know biotech funding environment – the announcement of the change to the R&D tax credit regime came right in the middle of this and has created a $10m whole in our cash projections over the next two years.** We are working through as we speak how we will be able to plug this gap but the answer will have to be, at least partly, through further headcount cuts and programmes put on the shelf.

As a US listed and UK domiciled company one of the primary reasons we have remained UK domiciled has been the access to a supportive R&D tax credit regime – as we look out unto the medium term and compare the support given to companies like ours in the UK v US the **UK is becoming less attractive for us.**

**3. Early-stage precision medicine development company**

We have been in a few rounds of internal budget-updating meetings since the announced cut, we have lost say £100k of R&D credit based the announcement, it will significantly impact the scope of our ongoing Phase Ib clinical trial, facing a **potential early termination of the trial, slowing the overall development**

**of the product and leaving us with very little wriggle room**. Being a small start-up, we are working to a very tight budget and things like this make a material difference.

In addition, we would like to point out that Drug Development is a medium/long-term business and plans/budgets are made several years ahead – so although this change seems like it gives us lots of warning to absorb/change plans, our plans are budgeted several years into the future.

**4. Medical device development company**

When I factor in the likely impact to our organisation, we're likely to see a cash decrease of approximately £1.5 million per year. In terms of timing of cash reimbursement, the credit for the year ended 31 December 2023, which I'd normally expect in June 2024, will be down about £1.1 million given the new regime kicks in from April 2023. This has come at the worst time for us whilst we've been finalising our annual budget and has been one of the reasons why we have looked to scale back some of our expenditure for 2023. **We've now been forced to prioritise between our lead programmes to mitigate the shortfall.** One of our secondary R&D areas has been subject to a reduction in c.£0.9 million of UK-based work on development of a new medical device (multi-disciplinary) and taken out approximately 10 heads from our budget. These will now no longer be filled, and the product will take longer to get to market.

**5. Early-stage brain cancer drug discovery company**

R&D tax credits are a critical part of the start-up ecosystem in the UK and are fundamental to high-growth, high-tech industries. We are using the R&D tax credits to fund critical drug development for Brain Cancers. We claim R&D credits on reagents and consumables used for novel AI-driven drug development and costs for R&D staff. We have found that these refunds are highly focused on UK R&D and spending. For example, our consumables costs are spent in the UK, with over 90% of our spending in pounds; these consumables are high-grade research items which are typically manufactured in the UK.

Our R&D credit refund is also highly critical for recruiting and training our team in cell biology, genomics, drug discovery, quantum computing and AI (70% of our team are PhD qualified). These team members contribute to the high-tech industries in the UK and ensure that the UK maintains its global competitiveness. The new changes have reduced the R&D tax credit by over 50% for companies like ours. We have raised over £6.5M in venture funding, and due to these reductions, we will now have £500,000 less to spend on R&D. **This has meant that we will scale back our growth plans and will recruit fewer team members.**

I have worked for companies that have actively set-up R&D centres in the UK due to these incentives; for example, Boston (MA) offers an approx. 17% R&D claim equivalent. The UK was refunding 33% of qualifying R&D spend and it is now just over 15%. These rules actively inhibit investment in the high-tech industries in the UK, stifle growth for R&D-intensive start-ups, and they will ultimately make the UK less competitive.

**6. Early-stage liver disease drug discovery company**

We are currently fundraising and have circa 15 months' cash left in the bank. Our runway projections have been predicated on a significant R&D Tax Credit for this year. With the proposed change, our calculations

suggest that we should only anticipate just over half of the expected amount, which would bring forward the date **we will run out of money to less than 12 months from now**. This shortening of our cash runway makes a significant difference for our ability to raise funds now, as it now puts us in a much higher risk category of investment, and as such could put the brakes on our current fundraise and potentially **spiral the business.** An unforeseen change like this, with little warning, will have a dramatic effect on the early-stage growth companies and innovators the current government intends to support.

**7. Scaling cell and gene therapy company**

We are a genuine R&D start-up conducting ground breaking clinical trials of personalised cellular therapies for late stage cancer patients. At short notice it feels like the rug has been pulled out from under us in this blunt and crude approach to tackling the abuse of the SME scheme. We welcome reform to the R&D tax credit SME scheme to tackle fraud, but not in the manner proposed.

The changes detailed in the Autumn Statement will have a material impact on our current spending plans in the near term with an annualized £5M increase in net operating cash out flows from April 2023. **Given the current market environment and depressed equity valuations, fund raising is extremely challenging and uncertain**. We do not anticipate being able to raise money in 2023. In order to maintain our cash runway projections, following the announcement, we would need to reduce our R&D spending plans through **staff reductions (current or planned hires) and the halting of R&D programmes. ~50 jobs would meet the reduction in R&D tax credit over the next 2.5 years**.

We would also need to evaluate the costs of taking forward additional R&D activity in the future as we scale and raise additional funds. We have long terms plans to expand our GMP manufacturing capacity in the UK including investment of up to £100M into a GMP facility to support our registrational clinical trials and commercial manufacturing in the UK. This facility would potentially generate up to **250 direct jobs as well as many other indirect jobs in the supply chain and wider ecosystem**. **We may decide to focus this longer term investment in other jurisdictions which are more receptive to R&D spending through the tax incentives they provide and scale back or stop the planned investment in the UK.**

**8. Early-stage biotech developing therapies for eye diseases - established and headquartered in the UK**

Our company was founded by a highly successful US CEO. He was willing to headquarter the company and build a management and R&D team in the UK in large part because of the R&D tax credit, which in our case amounts to £12m of credits over two years. Our CEO was able to attract £55m Series A into a UK headquartered company in February 2022, a time of limited investment in the industry, in particular in the UK. I think it is fair to say that one of the largest biotech start up investments in the UK in recent years happened **as a direct result of the R&D tax credit, that would not have happened in this country otherwise.**

In light of this change, at a critical phase in hiring our team, I will not receive support for hiring or contracting in the UK and will be pushed to hire in the US where biotech development talent is far easier to come by and existing networks can be used. It will result directly in less investment in talent in the UK, reducing rare opportunities for trans Atlantic cross-pollination in this field that is of huge value to individuals in the industry, and the industry as a whole.

This change will materially effect our business plans and **I anticipate that some £17m of investment in R&D staff is now at risk of leaving the UK.**

**9. Early-stage immune-oncology company - established and headquartered in the UK**

I have quantified the impact to the business of the changes to the rates – it will be about £1.1m for the 2023 claim and £1.7m to the 2024 claim. We are not currently forecasting beyond 2024 but as we will be running at least two clinical trials by 2025 our costs will continue to increase and the detrimental impact will only grow.

The most obvious impact is that more funds will need to be raised from investors. So far we have received a high proportion of our funding from private investors but that is already constrained by EIS limits. **Needing to spend more time raising funds is likely to lengthen the research timescale and therefore the route to making taxable profits.**

Our employees are highly skilled and in international demand. Several have relocated to the UK to take up employment with our company (both UK and non-UK citizens). The tax regime for R&D companies and individuals is becoming more and more hostile so we would expect recruitment to become more difficult. Given the type of work and the make-up of the team, there is no intrinsic reason to base the research in the UK. **The positive tax and regulatory environment are the big draws so if this becomes less advantageous it will have an impact on where future businesses set up.**

**10. Pre-clinical company in cancers and autoimmune diseases**

As a small pre-commercialisation biotech, it will severely adversely impact our R&D budget and our ability to create new jobs. Having budgeted carefully for the next 5 years we will have to look at short term, medium term and long term mitigations. If these changes do come in **we will need to run a significantly paired down R&D programme and could result in us losing the market opportunity to overseas competitors.** A paired down R&D programme would also impact on our collaborators which include a number of UK Universities. We are currently waiting to kick off work with UK suppliers and we are waiting on our R&D tax credit coming in before signing contracts. This funding is a lifeline for small companies.