

Introduction and summary

This submission concerns the proposals to “refocus reliefs towards innovation in the UK”. The majority of R&D funded by UK biotech and life sciences SMEs takes place in the UK. However, some activity, including expensive clinical trials, must be conducted overseas for legitimate and unavoidable reasons. It is vital for the continued growth of the UK’s biotech and life sciences SME community that these companies continue to be able to claim for overseas R&D through the tax reliefs regime. These SMEs will not be able to onshore this activity and will therefore see a reduction in their tax relief claims, which will undermine their competitiveness and slow the development of new medicines for patients. An exemption to the new restrictions for R&D activities that must by necessity be undertaken overseas could help avoid this unintended consequence.

The BIA is grateful for the opportunity to respond to the proposals in this submission and through meetings with HM Treasury officials. We are also grateful for the exemption for the payment of clinical trials participants noted in the report and the Government’s willingness to consider other overseas costs incurred through necessity. This paper focusses on the necessity of life sciences R&D conducted overseas and the negative impacts the current proposals would have. Potential exemptions to avoid these consequences are still being developed by the BIA, which we would like to share in further stakeholder meetings.

Why do biotech companies and SMEs outsource R&D overseas?

Where possible, UK biotech and life science SMEs conduct and outsource their R&D within the UK ecosystem. This is because it is more convenient to be close to the R&D for purposes of managing it, and transport and customs can be expensive and disruptive for valuable and time-sensitive biological materials. Local R&D is therefore preferred by our members.

However, the need to contract out R&D to third parties, often overseas, in many circumstances is essential given:

- The complexity of regulated medical R&D in life sciences means they must access specialist skills (researchers and doctors) and facilities that may not be present in the UK at all or in sufficient numbers. Where these skills and facilities are located within the NHS, there is often very limited capacity to support research, as treating patients takes priority. The relatively small size of the UK and almost infinite scope of medical science means the UK will never be “self-sufficient” in this regard.

- Medical regulators have specific requirements for the evidence and data they will accept. In many cases there are insufficient available patient numbers in the UK that can be recruited within a reasonable timeframe to satisfy the regulators. Investors too will scrutinise companies’ data and R&D project design, also requiring specific conditions. Many life science SMEs are developing medicines for rare diseases where the patient population in the UK is not large enough to conduct
clinical trials solely here. Ethnicity also impacts the effect of medicines, so they must be tested in different populations around the world; regulators often require this.

- Life sciences is a **global industry with high levels of collaboration**. Intellectual property will often be licensed from global partners that may remain active in the R&D programme, meaning it is necessary to continue with the R&D in the collaborators’ location. New medicines often require the combination of multiple proprietary and patented technologies, which may often be owned by companies overseas. To remain competitive, UK companies must work with the best and most innovative companies around the world.

We have provided case studies from BIA members in Annex 1 to illustrate these points. [REMOVED FOR ONLINE VERSION]

**What will the impact of excluding overseas R&D from tax reliefs be?**

Data collected¹ by the BIA from our SME members suggests that the average overseas R&D spend is 25%. Looking at the SME sector’s combined R&D expenditure, approximately 33% is spent overseas. The necessity of overseas R&D means this spend cannot be on-shored to bring it back within the R&D tax relief schemes. Removing this expenditure from tax reliefs will therefore significantly reduce the amount of money these companies receive back from the scheme. This in turn will reduce their capacity to invest in R&D, innovate and develop new medicines. Their R&D programmes will be slowed down, meaning their international competitors could overtake them in the race to develop new medicines, diagnostics and other technologies.

The change, if enacted, will disproportionally impact the life sciences sector because it is the only sector that must conduct expensive clinical trials, which must often take place overseas. It will directly and severely impact the ability of the Government and industry to deliver on the aims of the Life Sciences Vision published by the Department for Business, Energy and Industrial Strategy in July 2021².

**Will the policy change onshore more R&D activity to the UK?**

For the reasons given above, we do not think this is very likely. This activity is conducted overseas though necessity not preference. Biotech and life science companies must conduct R&D where the patients, capabilities and expertise are, and to meet the requirements of the markets being sold into. BIA members tell us that, as British companies, they are keen to conduct as much of their outsourced R&D as possible in the UK but the breadth of requirements of the sector mean the UK will never be “self sufficient” in this regard.

**Data and cloud computing costs**

The proposals to expand eligible costs to include data and cloud computing are very welcome. Both of these areas of expenditure are integral to life sciences R&D in the 21st Century. Generally, we support the approach being taken.

However, we have concerns with the statement that companies will not be able to claim relief for the cost of datasets that can be resold or have a lasting value to the business beyond the duration of the project. Clearly, all datasets will have lasting value to a business in the form of the knowledge generated from them.

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¹ This has previously been shared with the HM Treasury team.
This is the purpose of R&D in any business – to generate commercial value. This is true for all R&D whether it uses datasets or other inputs and materials.

Moreover, many datasets are used as part of an R&D project that generates an end product of commercial value that is the combination of the dataset with new insights. Thus the commercial product is the result of the R&D rather than the dataset itself, but it must be sold with the dataset to be of value. For example, a dataset of human patient genomes and their health records can be acquired and R&D performed to identify new links between genes and disease. This new insight is very valuable commercially and for improving diagnosis. The commercial product would need to include the genomic dataset as a reference, against which new patients’ genomes are compared as part of the diagnostic process.

We believe the Treasury's intention is not to prevent claims in such a circumstance and would welcome clarity on how this extremely valuable R&D will be supported.

**Abuse and compliance**

The new measures to tackle abuse and improve compliance are also welcome; R&D tax reliefs are hugely important and it is right that they are reserved for companies that are conducting genuinely innovative R&D.

**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.

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