



UK BioIndustry Association

# Influencing and shaping our sector

April -  
June 2024

[bioindustry.org](https://bioindustry.org)

# INTRODUCTION

The BioIndustry Association (BIA) continued to represent the innovative life science sector to Ministers and senior policymakers between April and June 2024. This quarterly report provides a summary of those engagements.

With the Prime Minister calling a snap election set for 4 July, the BIA's attention has turned to preparing for the next government. Meanwhile, Parliament Day, our flagship day of parliamentary engagement, has been postponed to the autumn. Official engagements with civil servants have also been restricted in accordance with the pre-election period of sensitivity.

However, there has been no shortage of engagements in the second quarter of 2024. Highlights have included hosting a bilateral UK-Swiss summit on the potential for collaboration on engineering biology, meeting the Lord Mayor of London to discuss future skills for our sector, and follow-up meetings with parliamentarians on improving access to innovative treatments for rare disease patients.



**meetings with  
parliamentarians,  
incl. 1 minister and  
2 shadow ministers**

Less glitzy, but no less important, have been our submissions and engagements with civil servants. The BIA has worked with London Economics to develop a stronger approach to assessing R&D tax credits, fed into the future of vital secure data environments (SDEs) within the NHS, and harnessed our relationship with the MHRA to shape forthcoming UK clinical trials regulation.



**2 letters to  
Ministers**

Read on for an overview of the BIA's influencing work over the past quarter as we look ahead to a brand new parliament in the next.



**consultation  
responses  
submitted**

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## Engagement with the Government and parliament on life sciences policy

The Prime Minister's 22 May announcement of a general election put a halt to the BIA's formal engagement with the Government and parliament. The Life Sciences Council due to take place on 22 June was cancelled, and the BIA's 24<sup>th</sup> annual Parliament Day has been rescheduled for November. A Business Environment Board and Life Science Council Data Subgroup meetings were also cancelled.

The **pre-election period of sensitivity**, as it is known, prevents government communications that could influence the election, and restricts discussions on policy. Nonetheless, some civil servants have taken the opportunity of this quiet period for government activity to reach out to BIA for informal meetings to hear of our priorities for the next government, including No10 officials and those in the Office for Life Sciences. All in "listening mode".

Prior to the election announcement, the BIA met with a range of Parliamentarians, including Shadow Health Secretary Wes Streeting MP and Shadow Science Minister Chi Onwurah MP. BIA also gave oral evidence on engineering biology to the House of Lords Science and Technology Select Committee and represented the sector at a parliamentary breakfast on scale-up finance arranged organised by the British Business Bank.



*Dr Martin Turner, Associate Director at the BIA, speaking at the UK Reception at the BIO Convention in San Diego.*

In early June, the BIA also partnered with the Department for Business and Trade to deliver the UK Reception at the **BIO Convention** in San Diego as well as a large UK pavilion in the convention's exhibition hall, featuring all four nations of the UK, leading academic institutions and BIA members.

**Election manifestoes** were being published as this report went to press. Increases to R&D investment, as well as many other life science policy priorities, such as improving access to health data, have featured in all so far, demonstrating the effectiveness of BIA's and the wider sector's campaigning over the course of this parliament.

The BIA team stands ready to engage with the new Government and new parliament as soon as they are formed following the result expected on 5 July. You can reach us [here](#).

## Finance, tax and investment

### **A new approach to the assessment of R&D tax relief impact developed by BIA**

The BIA met with HM Treasury on 22 May, encouraging them to improve the evidence base for research and development (R&D) tax relief policy to deliver greater value for the taxpayer through increased innovation and economic growth. This built upon previous meetings with HMRC to deliver the same message.

Despite the fundamental role they play in the positioning of the UK as a leader of innovation, R&D tax relief schemes have been undervalued by government and subject to disruptive changes in recent years.

A robust evidence base is crucial to securing political support for the continuation and enhancement of the schemes under a new government, and it is likely that current evidence significantly underestimates their impact.

Working with London Economics (LE), the BIA has produced a proposal, and corresponding explainer, outlining how to improve current evidence and take sector-specific differences into account, the lack of which is currently a significant flaw in existing studies. This work will ensure that R&D tax reliefs remain appropriately valued and will allow the government to make more informed policy decisions and the best use of taxpayer money when public finances are under pressure.

The Labour Party has already demonstrated its commitment to UK life sciences in their plan for the sector, '[A Prescription for Growth](#)', confirming their intention to conduct a review of the impact of R&D tax reliefs on life sciences.

*For further information on the BIA's work on finance, tax, and investment, please contact [Lewis Miles](#), Policy and Public Affairs Manager.*

## Genomics, data & AI

### **BIA and members set out industry requirements from NHS data environments**

The BIA contributed to a workshop on optimal data research environments run by NHS England in May. Members in attendance shared the minimum product requirements they would expect from a single cloud-architecture research workspace for data analysis. Their key requirements included cohort discovery, data ingress and egress airlock, and the ability to use specific tools in a single, multi-user collaboration workspace.

The workshop was led by the NHS England Data for R&D Programme team, who are developing a network of secure data environments (SDEs) to facilitate access to NHS data. SDEs will become the default route for accessing NHS data in future. This is an important agenda which the [BIA has fed into](#) previously.

The BIA is a member of the NHS Data for R&D Programme's Strategic Advisory Group and the Life Science Council Data Subgroup, both of which are important forums for shaping these key pillars of UK health data infrastructure.

### **BIA launches important health data survey to identify the sector's needs**

The BIA is currently surveying members to map the use of health data in the life science sector. Data is a key priority for both Labour and the Conservatives, and with a spending review expected soon after a new government forms, this is an important moment to highlight how critical data access is and to ensure it is prioritised in future public investment decisions. The BIA will use the results to demonstrate the breadth of sources and uses of health data, as well as outline our priorities from future government spending on health data.

This survey will build on the work the BIA has done in recent years to engage with data custodians, including NHS England, Genomics England, and Health Data Research UK (HDRUK). If you are a health data user, please do feed into the project by [taking the survey now](#).

*If you are interested in finding out more about the BIA's work on genomics, data, and AI, including the NHSE Data for R&D Programme please contact Senior Policy and Public Affairs Manager [Dr Emma Lawrence](#).*

## Engineering biology

### **BIA give evidence to House of Lords inquiry into engineering biology**

On 7 May, the BIA responded to the House of Lords Science and Technology Committee's [inquiry](#) into engineering biology. In our response, we focused on the innovative work of UK engineering biology companies and their impact across a range of sectors, as well as the progress that needs to be made across infrastructure, finance, and regulation to help them succeed. In addition to our written submission, our Associate Director Dr Martin Turner provided oral evidence to the Committee on 23 April.

The BIA's evidence highlighted the need for more cost-accessible pilot and scale-up facilities. Secondly, the submission raised the importance of appropriate resourcing for regulators and the need for regulators to adopt a pro-innovation, collaborative mindset to improve horizon scanning and deliver effective regulation. Thirdly, the Mansion House Reforms need to be implemented to unlock capital that is key to delivering long-term strength in the UK venture financing ecosystem that most engineering biology companies rely on.

Significant progress must be made in these three areas in the first half of the Government's 10-year [National Vision for Engineering Biology](#) in order to ensure innovative companies can continue to grow in the UK.



*Dr Martin Turner giving evidence on engineering biology to the House of Lords Science and Technology Committee on 7 May.*

### **Swiss-UK Engineering Biology Summit hosted by the BIA**

On 22 May, the BIA held the inaugural [Synthetic & Engineering Biology British-Swiss Summit](#) in collaboration with the Swiss Business Hub UK & Ireland, Lucideon, and the University of Bristol. The two-day event brought together industry leaders, policymakers, and academic experts to explore avenues for advancing collaboration between Switzerland and the UK, with a focus on healthcare and environmental sustainability. Attendees included key officials from the UK Government's newly appointed Engineering Biology Steering Committee, specialist start-up incubators such as Science

Creates (Bristol) and BaseLaunch (Basel) and sector-specific investment firms. Discussions centred on identifying bilateral opportunities for commercialisation through innovation, policy, and diplomacy in science and innovation.

On the second day, a series of roundtables were held at the Swiss Embassy, with discussions chaired by Government Chief Scientific Advisor, Dame Angela McLean. The outcomes of the discussions are being distilled down into policy asks which will feed into our [Deep Biotech](#) influencing activities after the general election.

The conference finished with a dinner at the Swiss Ambassador's residence, where select invitees from the two days were invited to share insights from the conference, network further, and solidify plans for future collaborations, reinforcing the bonds forged during the summit.

*Please contact Senior Policy and Public Affairs Manager [Linda Bedenik](#) to find out more about the BIA's influencing work on engineering biology.*



## Intellectual property and technology transfer

### **BIA respond to EPO consultation on Substantive Patent Law Harmonisation**

On 25 May, the BIA responded to the European Patent Office's (EPO's) second stakeholder survey on Substantive Patent Law Harmonisation (SPLH), an effort led globally by the [Group B+](#) to harmonise hitherto fragmented national and regional patent systems. The survey follows on from an EPO consultation on SPLH in 2022, and an initial survey in 2023.

International discussions through the working group continue to focus on three areas of SPLH: grace periods, conflicting applications, and prior user rights. The survey probed stakeholders' flexibilities in these areas in order to close in on a position of consensus. The BIA's Intellectual Property Advisory Committee ([IPAC](#)) led the BIA's response.

Whilst the BIA supports global patent law harmonisation, we continue to insist that all users of the patent system are considered when agreeing on a harmonisation package, particularly smaller companies that have limited capability to navigate complex systems.

### **BIA send letter to HRA on concerns over IP & Data provisions in new draft Investigator Initiated Study Agreement**

On 31 May, the BIA sent a letter to the NHS Health Research Authority (HRA) in response to their call for comments on a new study agreement template. The [draft Investigator Initiated Study \(IIS\) Agreement](#) is intended for use between non-commercial sponsors and commercial organisations providing support for investigator-initiated trials.

While we welcome the availability of a new model template agreement for IIS which would improve the setup of trials, we are concerned that the IP and data provisions laid out in the draft agreement will render it difficult, if not impossible, for biotech companies to enter into such an agreement, leading to fewer commercially supported investigator-initiated trials in the NHS. This would be undesirable to both commercial and non-commercial partners, and the NHS as an innovation partner. The current provisions run the risk of setting an unfavourable precedent that could have a chilling effect on wider clinical trials research in the UK, running counter to the UK Government's strategic goals for the life sciences sector.

*To find out more about the BIA's ongoing work on IP and tech transfer, please contact Senior Policy and Public Affairs Manager [Linda Bedenik](#).*

## People, skills and talent

### **BIA supports Lord Mayor's 'Thrive in Life Sciences' event**

The BIA attended an event co-hosted by MedCity entitled 'Thrive in Life Sciences: Empowering London's Next Generation', presenting our views and leading workshop discussions on the challenges and opportunities for life sciences to thrive across London.

Led by the Lord Mayor of London, Michael Mainelli, a scientist by background and supporter of the UK's life sciences sector, the event brought together thought leaders from across industry and academia to demonstrate the City's growing life science prestige.

Interactive workshops generated great discussion among stakeholders from industry, education, real estate, and local government. Action plans were developed which take forward collaboration on topics including industry input to further education colleges' curricula, promoting exciting apprenticeship opportunities, and supporting university internships.



*(L-R): Paul Singh (City of London Corporation), Kate Barclay (BIA), Michael Mainelli (Lord Mayor of London), and Phillipa Clarke (SRG) at the 'Thrive in Life Sciences' event*

### **Women in Biotech take White City**

In May, the BIA held another sell-out Women in Biotech networking event at Scale Space in West London's White City, in collaboration with Imperial College's Enterprise Labs [WE Innovate programme](#). Sessions included an informative panel discussion on 'Female Founders in STEM: the Role of Universities in Challenging Underrepresentation' and a thought-provoking panel chaired by Alchemab Therapeutics. This saw representatives from Albion VC, Matrix Health & Care, Dama Health, and Resting Reef share advice on fundraising, pitching to investors, types of funding available, and other personal reflections to inspire the audience of women from across the biotech sector. The BIA also welcomed a cohort of future talent and aspiring leaders from UCL's Global Business School for Health postgraduate course in Biotech and Pharmaceutical Management.

### Insightful skills panel at BIA Start-up Festival

The BIA's annual Start-up Festival brings together the best of rising talent in the sector for a day of informative sessions designed to build on early-stage companies' existing knowledge and encourage learning from peers and established industry experts alike. This year's festival included a specific skills and talent panel sharing insights on building a team, developing skills, and attracting talent. Panellists from industry, catapults, and funders presented their experiences, leaving the audience informed and with tangible opportunities to develop their growing teams.



(L-R): Ioanna Mylonaki (Sixfold Bioscience), Martin McGurk (Innovate UK), Marc Daigneault (Medicines Discovery Catapult), and Kate Barclay (BIA) speaking at the BIA's Start-Up Festival

### STEM ambassadors' breakfast during National Volunteers' Week

The BIA represented the views of our membership during engaging discussions on 'Challenging the Stereotypes in STEM' hosted by STEM Learning and ABPI during National Volunteers' Week (3-9 June). Celebrating the scientists who are STEM ambassadors within schools and colleges, discussions included challenging existing understanding of career pathways into life sciences, the many motivations for a career in UK biotech, and the role of teachers can play in igniting passion for STEM. A stimulating panel discussion included representatives from The Elephant Group, STEM Learning, ABPI, and GSK. Employers across our sector play a significant part in engaging early and recognising the valuable role of volunteer STEM ambassadors in inspiring the next generation to ensure a healthy pipeline of talent for the industry.

Please contact the BIA's Skills Strategy Consultant [Dr Kate Barclay](#) to learn more about the BIA's work on people, skills, and talent.

## Manufacturing

### BIA holds fore-sighting workshop in Darlington to tackle RNA skills shortages

As part of BIA's strategic focus on mRNA vaccines and therapeutics manufacturing, in April we held a morning workshop at CPI in Darlington to bring industry together to input into a workforce foresighting report. Developed by CPI and FUJIFILM Diosynth Biotechnologies in partnership with the Innovate UK Workforce Foresighting Hub programme, the report highlights the future capabilities and skills required to intensify the manufacturing of RNA therapeutics.

Post COVID-19 pandemic, RNA therapies have risen to be a promising new technology to address life-threatening and contagious diseases. The bioprocessing industry must be able to adapt to produce these new types of technologies, which require different skillsets. Without being proactive in the face of change, the UK will not be able to onshore therapy manufacturing and retain a competitive advantage.

The [report resulting from the workshop](#) identified additional short courses for staff within the sector as a quick solution to existing skills shortages. Employees could also be reskilled from transferable backgrounds, such as brewing, and given additional RNA-specific training. Educators should work directly with industry employers to tailor course-specific content focused on the upskilling of medicine manufacturing using existing educational standards such as apprenticeships.

To support the mRNA manufacturing work further, the BIA has partnered with CPI and Imperial College London to deliver an RNA Vaccine & Therapeutics Conference on 2-3 October at the Royal College of Physicians. [Registration is open](#) and sponsorship and speaker opportunities are available.



Andy Kerr (Innovate UK) speaking at the foresighting workshop held in Darlington.

## Regulatory affairs

### **BIA informs UK's forthcoming clinical trials regulations**

In late April, the BIA participated in a stakeholder workshop held by the Medicines and Healthcare products Regulatory Agency (MHRA) in conjunction with the NHS Health Research Authority (HRA) on the UK's [forthcoming clinical trials regulations](#). The BIA highlighted at the March Business Environment Board meeting that prioritisation of new legislation for clinical trials was important to ensure the UK remains an attractive destination for international trials, enabling patient access to innovative medicines sooner.

The MHRA is working at pace to bring the required statutory instrument to parliament for approval between the general election and summer recess. The new clinical trials regulations will then come into force in October 2025 following a transition period of 12 months. Additionally, the HRA gave an update on the new transparency requirements for clinical trials and new guidance being developed to support implementation of the legislation which will require further input from stakeholders. BIA members will be invited to an HRA webinar when the guidance on diversity and inclusion of study participants is issued for consultation.

### **BIA provides input to the value proposition for ILAP 2.0**

Since February 2024, the BIA has been engaging with the MHRA and their partners in the healthcare ecosystem to help shape plans for the future of the Innovative Licensing and Access Pathway ([ILAP](#)). We provided members' feedback from the BIA Regulatory Affairs Advisory Committee ([RAAC](#)) on a high-level vision and the benefits that developers can expect from the refreshed ILAP, which will be launched later this year.

Overall, the proposals are aligned with what the BIA has been calling for. There are now some tangible offerings and prioritised access to key services that could make ILAP a more viable process. The early dialogue with the MHRA, Health Technology Assessment (HTA) bodies, and the NHS is a key draw that other comparable schemes such as the EU PRIME and the US FDA breakthrough therapy designation do not offer. Predictable timelines remain crucial if industry is to engage; this is particularly important for start-up biotechs which need to meet key milestones for their investors.

### **BIA welcomes MHRA AI-Airlock, a new regulatory sandbox for AI medical devices**

On 9 May, the [MHRA launched the AI Airlock](#) which will help the agency to identify and address the challenges for regulating AI medical devices (AIaMD). The MHRA has seen a marked increase in innovative devices entering the UK market, particularly AIaMD and digital technologies incorporating AI, which may be on the borderline of the scope of existing medical device regulations. Such products have the potential to revolutionise the healthcare landscape, maintain the UK as a hub of cutting-edge research, and provide improved ways to address patient and public needs.

The AI Airlock will require collaboration and expertise from within the MHRA and key partners, including approved bodies and the NHS. The MHRA will be holding a [webinar for innovators and](#)

[developers on 23 July](#) to provide further information and answer questions. This will be followed by a call for applications to the pilot project.

### **BIA contribute to MHRA framework for international recognition of medical devices**

On 21 May, the MHRA [announced](#) a proposed framework for international recognition of medical devices. The MHRA's [statement of policy intent](#) describes how the UK Government intends to recognise medical devices and in vitro diagnostics (IVDs) that have been approved in Australia, Canada, the European Union, and the USA, according to type, class, and prior approval of the device. The MHRA continues to review the list of comparable regulator countries and is exploring the recognition of medical device approvals from Japan.

The BIA provided feedback on the draft statement following the stakeholder meeting which was held earlier this year, bringing together trade associations, companies, and approved bodies under trusted advisor principles. Overall, the BIA supports the proposed regulatory framework for medical devices in Great Britain. Reducing the duplication of assessments conducted by comparable regulators will enable resources to be focused on more innovative products for the benefit of patients. The statement of policy intent is a draft and the final legal text will be integral with the future core regulations.

*For further information on the BIA's work in this area, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).*

## Access to medicines

### **BIA in Parliament to discuss patient access to rare disease treatments**

Throughout April and May, the BIA's Rare Disease Industry Group ([RDIG](#)) continued its engagement with parliamentarians on improving patient access to rare disease treatments. Building on the [parliamentary reception](#) held in February, the BIA has met with former health minister Lord Hunt of Kings Heath and Chair of the APPG for MND, Andrew Lewer MP. During the meetings, we discussed the importance of ensuring that the UK system is able to provide timely patient access to innovative new treatments for rare diseases, including the growing pipeline of cell and gene therapies and precision medicines.

The new Chair of RDIG, Kylie Bromley, General Manager UK&I at Biogen, has also been engaging with key stakeholders and system partners, including introductory meetings with representatives from NICE, NHS England, and MHRA to discuss shared priorities and key opportunities for driving improvements for patients with rare diseases.

Following the general election announcement, meetings with parliamentarians have been postponed until after 4 July. We look forward to continuing engaging with parliamentarians and policymakers after the election to ensure the UK delivers equitable access to rare disease medicines.

### **BIA welcomes publication of new UK national action plan on AMR**

In May, the Department of Health and Social Care (DHSC) published a [new 5-year plan](#) to combat antimicrobial resistance (AMR). The plan supports the [UK's 20-year vision](#) to contain and control AMR by 2040, and builds on the progress made in the previous 5-year national action plan.

The BIA [responded](#) to the [consultation](#) on the new plan which was held last year, and we were particularly pleased to see that the pilot world-first 'subscription model' for antimicrobials will be expanded. NHS England and NICE have published [updated guidance](#) on the subscription model, which will help to incentivise increased investment in antimicrobial drugs by enabling companies to be paid a fixed annual fee for antimicrobials based primarily on their value to the NHS, as opposed to the volumes used.

The BIA welcomed the publication of the new plan in a [webinar](#) on 9 May, which discussed solutions to the threat of AMR. The webinar also marked the launch of the [WHO's new campaign](#) sharing real-life stories to encourage global action against AMR. Sue Charles, former BIA Board member and a founding member of the [WHO Task Force of AMR Survivors](#), chaired the panel discussion, with panellists from the AMR Action Fund, NICE, Medicines Discovery Catapult and NovaBiotics. The webinar recording is available [here](#).

*Please get in touch with Policy and Public Affairs Manager [Rosie Lindup](#) if you would like to learn more about the BIA's access to medicines work, including RDIG's work on rare diseases.*

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Martin Turner, Associate Director, Policy and Public Affairs and Investor Relations at [mturner@bioindustry.org](mailto:mturner@bioindustry.org).



## BIA Supporters



### Not a BIA member?

If you want to have a say on policy areas key to the life science sector, contact Michael McGivern, Associate Director, Membership and Business Development, on 079 2029 3171 or [mmcgivern@bioindustry.org](mailto:mmcgivern@bioindustry.org)

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