

Influencing and shaping our sector

July - September 2024

bioindustry.org

INTRODUCTION

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

Following the election in July, the BIA has been busy engaging with the new government, sending 104 letters to new Ministers and MPs over the summer. Since Parliament returned in September, we have had the opportunity to continue this dialogue with many parliamentarians in person.

Highlights have included hosting panel events at both the Labour and Conservative party conferences; featuring MPs and the Pensions Minister Emma Reynolds MP and attending a roundtable with new Science Minister Lord Vallance.

Just as important have been our submissions and engagements with civil servants. The BIA has engaged with the MHRA on the Windsor framework, clinical trials and ILAP.





The Pensions agenda continues within government with vital BIA support. Important work to champion R&D tax credits continues ahead of the first budget in October.

We have also launched a new advisory committee, to lead our important work in techbio including data, AI, genomics and precision medicine.



Read on for an overview of the BIA's influencing work over the past quarter as we prepare for the next.

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Influencing policy: Engagement with the Government and Parliament on life sciences & biotech policy

The third quarter of this year began with the landslide election ushering in new Labour government. BIA held webinars for members leading up to and after the election, discussing policy commitments and new ministers and MPs.

Early engagement with the new government and its ministers included BIA CEO Steve Bates attending Chancellor Rachel Reeve's first speech, where she outlined her desire for government and industry to work in partnership. Steve was among a small audience of about 40 business leaders, demonstrating both the standing of the sector and BIA with the new administration.

BIA wrote to new ministers in the early summer and has been busy meeting ministers, advisors and senior officials. However, the upcoming first Life Sciences Council, taking place on 22 October, will provide the first set-piece engagement opportunity between BIA, wider industry and the new Secretaries of State for Health and for Science, Wes Streeting MP and Peter Kyle MP. This key meeting will be an opportunity for sector and government leaders to build relationships and understanding, and it will also set the scene for the government's first Budget.

Taking place on 30 October, the Budget is when the sector will see whether pre-election commitments will be backed with investment. Labour's plan for the life sciences sector, called <u>A prescription for growth</u>, was published in February, before the election. The strategy was launched in collaboration with BIA and featured many of BIA's policy priorities, including maintaining R&D tax reliefs and unlocking pensions investment, alongside many other policies on expanding the remit of the Office for Life Sciences, launching the £520 million life sciences manufacturing grants fund and upholding strong IP rights globally.

The party conferences provided another opportunity for BIA to engage with new ministers and also the intake of new MPs, as well as those re-elected. <u>Our policy and public affairs team attended the conferences of the three major UK parties this year</u>. Through fringe panels, discussions with influential figures, and participation in key sessions, we worked to advance the conversation around life sciences at a packed Labour conference in Liverpool where all sectors were vying for attention, and at the Conservatives in Birmingham, where the four leadership hopefuls were vying for attention.

At Labour, the BIA hosted a panel on 'Unlocking pensions to deliver an innovative, high growth Britain', which explored how the mobilisation of pension funds can provide a much-needed investment boost to the life sciences, while also providing better returns for the UK saver.

Steve Bates chaired the panel featuring the Pensions Minister Emma Reynolds MP, the new Labour MP for Mansfield Steve Yemm (who has experience of biotech and pharma on both sides of the Atlantic), and Kristen Albright, CEO of BIA member Prokarium, along with experts from the pensions and VC industries. Our panellist Tim Fassam from Phoenix Group – the UK's largest pension provider – said the life science sector's potential is recognised and the pension industry is keen to engage further.

We also highlighted the full potential of biotechnology to revolutionise every sector of the economy during our second panel event, which explored how <u>Deep Biotech</u> can help address climate change. Chi Onwurah MP, the new Chair of the Commons Science, Innovation and Technology Select

Committee, joined our panel and talked about the UK's huge strengths in R&D and advanced manufacturing, as well as the need for the new government to continue supporting engineering biology. CyanoCapture, who are engineering algae to sequester carbon, were just one of the exciting businesses that showed what is possible if we support these young companies to scale up in the UK.

We also held a panel on unlocking pensions for investment at the Conservative Party conference. Former Science Minister George Freeman MP emphasised just how important this initiative is, stating that the only way for the UK to escape the structural issues and debt crisis it currently finds itself in is 'economic growth via innovation'.







BIA panel at the Labour Party Conference

Business Environment

Finance and tax

BIA activity ramps up ahead of first Budget for new government

The BIA has <u>submitted its representation</u> to HM Treasury for the Autumn Budget, which will be the new Labour government's first. The submission comes amid warnings from the Prime Minister and Chancellor that "tough decisions" must be made due to the perilous state of the public finances.

In our submission we called for stability and the retention of already established commitments and programmes including R&D tax relief, pensions reform, and various other funding mechanisms such as the UKRI and Innovate UK budgets.

The submission is just one small part of BIA's policy and public affairs work to influence the direction of the new government and the crucial tax and spending decisions it must make, as detailed in the rest of this section.

R&D tax fraud and value for money concerns countered by BIA

Amid the Prime Minister's warnings that the Budget will involve "tough decisions" and publicised concerns that companies are abusing R&D tax reliefs and the schemes do not represent good value for tax payers' money, BIA published a proposal for HM Treasury to conduct a robust economic study to understand how R&D tax relief can be targeted towards innovative growth sectors of the economy.

BIA secured a Labour commitment to undertake this study before the election and we have now urged the Chancellor to commission it as part of her promised business tax roadmap. Our report argues for an evidence-based approach to tax policy, and summarises a paper produced by London Economics for the BIA that identifies gaps in the evidence base relating to the impact of R&D tax relief on innovative sectors. The paper proposes a new methodology that will fill these evidence gaps to inform a key tax policy within Labour's industrial strategy, ensuring that reliefs remain upto-date, competitive, and well-targeted. It would also allow government to cut the fraudulent waste of taxpayers' money in ways that do not harm genuine, law-abiding companies that have been hit in the past by rushed policymaking from the previous government.

In a meeting with the Treasury and HMRC to discuss the report, officials said they share many of the same concerns as the BIA, particularly regarding the suitability of the current variables and impact methodology, and these concerns were only exacerbated having read our report.

BIA's Finance and Tax Advisory Committee also recently met with the tax campaigner Dan Neidle, who has been publishing abuse in the R&D tax relief scheme, regarding fraud and non-compliance.

The committee expressed its concerns that biotech will suffer in attempt to stamp out fraud, as well as reiterating just how important R&D tax reliefs are to the life science sector. Dan listened to these concerns, and conceded that very little non-compliance was present in our sector.

Following this meeting Dan wrote <u>an article for The Times</u>, discussing the issue of fraud within the scheme, and said "The shame of it is that there are biotech companies struggling to claim relief for really significant R&D, whilst invalid claims have cost the country billions of pounds."

It is hoped that these efforts will help ensure that there are no damaging R&D tax relief changes for the life sciences and biotech sector in the upcoming Budget. BIA will publish analysis on Budget day and host a webinar to help members understand any announcements shortly after.

BIA continues to champion R&D tax reliefs

The BIA continues its work to ensure the HMRC's operation of R&D tax reliefs remain fit for purpose, representing the needs of the sector and pushing for improvements.

We submitted evidence to HMRC of current issues being faced by our membership on:

- **HMRC inefficiency**: delays in payments, inefficient enquiries, or ineffective/excessive questioning.
- **R&D intensity criteria**. A number of case studies that showed examples of companies that we would expect to qualify as R&D intensive under the new scheme introduced last year following pressure from BIA with the accompanying higher level of relief but did not qualify as such, for a variety of reasons.

In addition, it was noticed by some of our more active members that a statement regarding the qualification of clinical trial activity as R&D had been removed from CIRD (Corporate Intangibles Research and Development) guidance by HMRC. This was a significant removal, as the presence of the statement greatly increased the likelihood of tax inspectors questioning claims, especially in cases where they are less familiar with the interrelation between R&D and clinical trials.

We contacted HMRC to explain the issue, and was able to get this corrected, and the statement is now back in the guidance.

BIA will continue to meet with HMT and HMRC officials to ensure that our members receive better levels of service when making claims.

New government continues pension reform with support from BIA

The BIA <u>submitted views and evidence</u> to the government's Pension Investment Review. The publication of the review so soon after the formation of the new government, alongside the appointment of a dedicated pensions minister in the Treasury, is an extremely welcome sign that Labour wish to urgently push ahead with the pensions reform agenda that BIA has championed since 2017. This was a commitment BIA secured in the Labour Party's pre-election <u>plan for life sciences</u>.

The main purpose of the review is to boost investment, increase saver returns and tackle waste in the pensions system. We have long been advocating for policy reforms to boost investment into the life sciences sector.

Our submission to the review demonstrated that UK life science represents a significant opportunity for economic growth, but it suffers from a substantial lack of domestic investment, and has to rely heavily on foreign capital. Mobilising pension funds to increase domestic investment is a key strategy to solving this problem, and while we believe there is appetite among progressive pension funds to invest into UK life sciences, there will be a longer tail of potentially interested but much less motivated pensions.

Our submission therefore urged the government to champion this agenda, and use its convening power to drive forward commitment through a combination of a specialised vehicle to enable investment, and both carrot and stick policies such as a supportive 'Life Science Charter', and mandates that a percentage of assets be allocated to UK life sciences.

Venture capital investment incentives renewed after calls from BIA

On 4 September, the new government <u>announced</u> that it had extended the Enterprise Investment Scheme (EIS) and the Venture Capital Trust (VCT) scheme by ten years to 5 April 2035. The schemes to encourage individuals to invest into early-stage companies were due to come to an end next year due to their EU state aid approvals expiring. BIA and others had called on the previous government, and <u>the Labour Party</u> ahead of them coming into power, to extend these valuable tax reliefs.

BIA urges caution regarding the treatment of carried interest

The BIA <u>responded</u> to the HM Treasury's consultation on the tax treatment of carried interest. The consultation sought to understand the impact that treating capital gains as income – and thus taxing it at a higher rate – would have.

We understand and support the principle of fairness in the tax system. Yet, there is a risk that changes to the tax treatment of carried interest could lead to a reduction in domestic venture capital activity. Our submission urged caution and careful consideration of the impacts on life sciences as the government determines how to move forward with the taxation of capital gains.

HM Treasury is expected to announce the outcome of the consultation at the Budget on 30 October.

BIA publishes positive finance data

We published our latest UK biotech financing report that documents the increase in investment the sector has seen during April-June 2024.

In the second quarter of 2024, the UK biotech sector saw a significant rise in investor interest and confidence, driven by a sharp increase in both public financing and venture capital (VC) funding. Following a slow start earlier in the year, VC funding surged by 159%, reaching £622 million, up from £240 million in the first quarter. This represents the largest quarterly funding since Q3 2021 and reflects the impact of several major deals. Additionally, there was a strong uptick in follow-on financings, further highlighting the sector's momentum. Public fundraising also grew, with £731 million secured outside of IPOs, though the IPO market remained inactive in the first half of 2024, indicating continued caution due to broader economic conditions.

The sector's outlook has been strengthened by the Labour government's focus on unlocking new capital from British pension funds, which has the potential to create a more supportive environment for biotech innovation and investment. With increased investor confidence, a strong pipeline of developments, and the UK's competitive edge against major biotech hubs in the US and Europe, the sector is poised for continued growth and success in the coming months.

For further information on the BIA's work on finance, tax, and investment, please contact <u>Lewis</u> <u>Miles</u>, Policy and Public Affairs Manager.

IP and tech transfer

UK Government urged to oppose proposal for global tax on biotech sector

The Parties to the Convention on Biological Diversity (CBD), including the UK, are working towards establishing a multilateral benefit sharing mechanism and global fund for the use of Digital Sequence Information (DSI) of genetic resources. The options for sharing of monetary benefits taken forward for negotiation at COP16 this October include a far-reaching tax directly targeting companies in the pharmaceutical and biotech sectors.

All options considered are based on a levy mechanism (i.e., tax) on revenue or profit that encompasses companies and/or products in the pharmaceutical and biotech sectors. Significant details and clarity are still lacking on all options, including (among many other) the scope and definition of DSI, the explicit exclusion of human DSI, and any endpoint or ceiling to monetary contributions to be made.

BIA has met with officials across government in the past weeks, and has written several briefings and an urgent letter to several Ministers and Secretaries of State to raise industry concerns over the proposed levy mechanism, asking the UK to oppose a mandatory levy at COP16. Significant engagement will continue towards and after COP16. BIA CEO Steve Bates was meeting with the responsible Defra minister to discuss our sector's concerns as this report went to press.

Cross-sector roundtable discusses future of UK IP policy

In September, BIA joined a cross-sector policy roundtable on the future of UK IP policy. Joined by the UK Intellectual Property Office and Department for Business and Trade, the roundtable brought together the UK's most innovative companies and associations to establish why the new government should prioritise strengthening IP rights and identify cross-sectoral IP positions for targeted future advocacy.

Attendees discussed the growing anti-IP narrative emerging in public and political domains, and identified potential cross-sector advocacy objectives that may benefit from future coordinated action. The BIA's Intellectual Property Advisory Committee (IPAC) continues to follow international IP developments that impact our sector, and drives our engagement where concerns arise.

To find out more about the BIA's ongoing work on IP and tech transfer, please contact Senior Policy and Public Affairs Manager <u>Linda Bedenik</u>.

Regulation and access

Clinical trials and international recognition among issues discussed at BIA-MHRA bilateral

In July, the BIA held its biannual bilateral meeting with the senior leadership of the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA gave an update on performance, noting that clinical trials applications continue to be assessed within statutory timescales, with ongoing process improvements to ensure the UK remains an attractive destination for clinical trials.

Discussion focused on several topics of interest to BIA member companies, including international recognition, refreshing the Innovative Licensing and Access Pathway (ILAP), the MHRA data strategy and the AI Airlock regulatory sandbox for AI medical devices. The meeting also covered the BIA Conference on the Future of UK Life Sciences Regulation, which takes place on 6 November in London and is supported by the MHRA.

MHRA responds to BIA asks regarding scientific advice meetings

At our bilateral meeting with the MHRA (see above), the BIA highlighted the need for the agency to communicate its plans to address the backlog of requests for MHRA scientific advice, given the impact these delays are having on clinical development programmes of both UK-based SMEs and global biopharmaceutical companies. Members are experiencing delays of more than 8 months to get a date for their scientific advice meetings (SAMs).

The MHRA followed up with communication to all companies affected by delays, offering various options to progress the request including providing written advice in a shorter timeframe or maintaining the request with the possibility of a videocall with an MHRA member of staff to consider options.

SAMs was discussed with MHRA Deputy Director for Innovation Accelerator and Regulatory Science at the BIA Regulatory Affairs Advisory Committee meeting in September. While the MHRA has strong feedback on the quality of advice given, the MHRA official acknowledged that there is dissatisfaction in the timelines to receive the advice and indicated that the agency is on track to clear the backlog by end of 2024 with additional assessor resources in place from September.

We are pleased to see the progress on the SAM backlog and encourage member companies to engage with the MHRA early and apply well in advance. The BIA continues to engage with the MHRA as it works to transform the Scientific Advice process into a timely, high-quality service in future.

BIA continues engagement on the Windsor Framework implementation

The BIA has continued engagement with the MHRA and the Department of Health and Social Care (DHSC) on the <u>Windsor Framework</u> implementation. The engagement meetings with industry associations provided the opportunity to influence the new arrangements for licensing of medicines in the UK and give members feedback on technical guidance regarding the requirements of the Windsor Framework. The <u>Windsor Framework guidance collection page</u> is regularly updated.

From 1 January 2025, the MHRA will be responsible for licensing all medicines on the market in Northern Ireland (NI) under a UK-wide licence. The new arrangements will make the supply of medicines to the UK market simpler and easier. Marketing authorisation holders need to be aware of three key areas of change and take action, where necessary:

- UK-wide licencing: a UK Product Licence (PL) will replace separate licences for Great Britain and NI and cover the whole UK.
- Medicines for the UK market will need to display a 'UK Only' label or sticker on the pack to show that they are only for sale within the UK. Companies must <u>submit</u> their updated artwork by 31 December 2024.
- The EU Falsified Medicines Directive (FMD) will no longer apply in NI, bringing NI in line with GB.

The MHRA developed communication plans to ensure companies are ready by 1 January 2025. The MHRA is holding Windsor Framework webinars for industry; the first webinar on 19 September covered technical guidance on UK-wide licencing, labelling requirements and pharmacovigilance, and a second webinar is planned for 23 October which will provide the opportunity for members to ask any questions they may have about the new arrangements.

In addition, the BIA gave feedback on a Windsor Framework explainer document to support industry in understanding more clearly the expectations and impact of the Windsor Framework, using a simpler narrative to explain and bring together what the MHRA has set out in technical guidance.

BIA provides input to proposals for the refreshed ILAP at engagement workshops

On 23 September, the BIA participated in workshops hosted by the ILAP Partners, including the MHRA, National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC) and NHS England as part of their engagement with key stakeholders ahead of the relaunch of the Innovative Licensing Access Pathway (ILAP). ILAP has undergone lessons learnt over the last six months, gathering stakeholder feedback including from the BIA on the three years of operation since 2021.

Our member company representatives appreciated the opportunity to input to the discussion on the proposals for an enhanced ILAP programme and help shape the formulation of guidance for companies seeking to use the pathway in future. 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. Building on industry feedback the ILAP partners are holding a further ILAP engagement event on 14 October.

BIA responds to two NHS England consultations on Commercial Framework and Budget Impact Test (BIT) threshold

The BIA responded to two consultations from the NHS England in September. Both of these consultations were commitments made in the 2024 <u>Voluntary Scheme for Pricing Access and Growth</u> (VPAG). In our <u>response</u> to the <u>consultation</u> on updating the NHS Commercial Framework for New Medicines, we welcomed the emphasis on indication-specific pricing (ISP) in supporting access to new indications for a given medicine and encouraged NHS England to make the most of the opportunity to increase commercial flexibilities.

However, the BIA is concerned that the proposed criteria for the circumstances in which NHSE will consider ISP remain unchanged from the previous arrangements, therefore limiting the increased

application of ISP. In particular, the requirement for products to represent value at or below the lower end of the standard NICE threshold could be especially punitive for patients' access to innovative treatments for rare diseases, where the inherent nature of the patient population and higher levels of uncertainty means that these medicines tend to sit at the higher end of the ICER threshold.

Secondly, the BIA responded to a NHSE <u>consultation</u> on its proposals to increase the Budget Impact Test (BIT) threshold. In our <u>response</u> we strongly supported the proposal to increase the BIT threshold as this will help to ensure timely patient access to innovative medicines. However, we have called for greater transparency on the rationale for the proposed new £40 million figure and have recommended the implementation of regular reviews of the BIT threshold to ensure it remains at an appropriate level, including metrics to monitor how the BIT is applied and its impact on patients access to new medicines.

NHS England has engaged closely with industry during the consultation period, including holding a workshop with the trade associations and industry representatives. We look forward to continuing this engagement as the final changes are determined.

For further information on the BIA's work on clinical trials, ILAP, and medicines licensing, please contact the BIA's Head of Regulatory Affairs, <u>Dr Christiane Abouzeid or Rosie Lindup on access</u>

Skills and talent

Biotech diversity data from BIA informs new report on women in manufacturing

Women in Manufacturing recently launched their report: *Women in UK Manufacturing 2024: Addressing labour shortages and bridging the gender gap* (WiM 2024) which presents an overview of progress and challenges encountered by women participating in UK manufacturing. BIA contributed sector evidence and meaningful case studies from the Diversity in Biotech report (DEI) as best practice of evidence-based action which feature prominently in the report. BIA also presented these at the Institute for Manufacturing (IfM) annual conference at the High Value Manufacturing Catapult Manufacturing Technology Centre in Coventry, which also included reports and workshops based on improving representation of women in the manufacturing workforce, inclusive innovation, gender bias in AI and access to funding.



BIA skills consultant Dr Kate Barclay presenting at the IfM Conference

Launch of new Medicines Manufacturing Skills Centre of Excellence

The government has announced a £6.5 million investment into skills and talent for the medicines manufacturing sector called <u>RESILIENCE</u>, which is to be hosted at the University of Birmingham. BIA was part of cross-industry efforts to secure the £6.5 million investment.

RESILIENCE is funded by the Office for Life Sciences through Innovate UK and is a partnership of core universities at the forefront of developing industry skills and a talent pipeline for the sector. Lord Patrick Vallance opened the event followed by speakers from across government, industry, funders and learners. RESILIENCE aims to provide teaching, outreach and coaching materials to attract, develop and retain much needed talent for the sector. BIA will continue to influence the delivery of RESLIENCE through member engagement and connection.

Please contact the BIA's Skills Strategy Consultant <u>Dr Kate Barclay</u> to learn more about the BIA's work on people, skills, and talent.

Manufacturing

Government urged to launch life sciences manufacturing grants programme

The BIA has urged government to launch the £520 million life science manufacturing programme in its Budget submission (see Finance and Tax section) and continues to emphasise its critical importance during ministerial discussions and communications. The programme was announced by the previous government but Labour committed to implement it prior to the election in response to requests from BIA and other industry representatives.

On behalf of, the BIA joined GSK and ABPI in writing a letter from MMIP chair Bill Dawson to Minister of State for Science, Research and Innovation, Lord Vallance. The letter highlighted the success of the manufacturing industry and its contribution to the UK economy. It was made clear that to obtain the highest growth in the G7, which is a Labour mission, there should be an immediate launch of the two critical programmes; the £520 million capital grants programme and another £78 million fund

for R&D into improving the sustainability of medicines manufacturing. The latter is financed through the Voluntary Scheme for Branded Medicine Pricing, Access and Growth (VPAG) Investment Programme and was launched on 28 August.

Input provided by the Manufacturing Advisory Committee to the OLS/IUK Future of UK Medicines Manufacturing Foresight Project

The Office for Life Sciences (OLS) and Innovate UK are developing a framework for understanding potential future medicines manufacturing needs, enabling a more proactive approach to supporting the industry and identifying areas of strategic advantage. The BIA's <u>Manufacturing Advisory Committee</u> identified emerging key modalities and themes within the industry. The findings were presented to the MMIP and subsequently contributed to shaping the government foresighting project.

Sustainable manufacturing put in spotlight by BIA as new funding call launched

The BIA hosted a medicines manufacturing sustainability event alongside Innovate UK and UCL's future Targeted Healthcare Manufacturing Hub aiming to share insights and strategies for integrating sustainable approaches into new manufacturing processes. Sustainability has been a key focus this quarter and will remain a top priority for manufacturers.

Innovate UK has launched a new <u>Sustainable Medicines Manufacturing Innovation Programme</u> worth up to £80 million in funding from the Department of Health and Social Care between 2024 and 2029. This grant funding will be directed toward fostering innovation in sustainable medicines manufacturing. It will be allocated through two key approaches: collaborative R&D projects and Grand Challenges. The funding supports all modalities but must align with one of the following areas: Green Chemistry, Circularity, or Productivity and Resource Efficiency. Additionally, projects must address regulation, measurement standards and data requirements.

Innovative medicines

Rare disease treatments

BIA continues engagement on Action 25 commitment in Rare Disease Action Plan

The 2023 England Rare Disease Action Plan committed to review the effectiveness of the Early Access to Medicines Scheme (EAMS), Innovative Licensing and Access Pathway (ILAP) and the International Monetary Fund (IMF) in supporting access to treatments for people living with rare diseases (Action 25). As part of this, the BIA and ABPI developed a detailed survey for members to understand companies experience of these schemes and wider factors that have the potential to influence future launch decisions of rare disease products in the UK. Responses were received from 20 companies and a detailed report was submitted to the Department of Health and Social Care and the England Rare Disease Delivery Board in December 2023.

The BIA and ABPI engaged with DHSC to ensure Action 25 was continued into the 2024 England Action Plan, which included a commitment for NHS England, NICE, and MHRA to meet with BIA and ABPI to further review the results of the member survey. The BIA attended this meeting on 31 July alongside representatives from ABPI, NHSE, NICE, MHRA as well as patient and clinical representatives, to discuss both challenges and opportunities in securing access to rare disease medicines and identifying potential solutions. This was a productive discussion, and it was particularly valuable to have so many of the key stakeholders in the rare disease medicines space represented at the meeting.

NHSE, NICE and MHRA have also committed to providing a written response following the meeting by Autumn 2024, with further progress being reported in the 2025 action plan. The BIA urges system partners to ensure that the written response reflects the discussions during the meeting and recognises the ongoing challenges within the wider rare disease access environment.

Please contact Policy and Public Affairs Manager <u>Rosie Lindup</u> to find out more about the BIA's work on Rare Disease.

Animal testing

Lord Vallance holds industry roundtable on animal research

On 5 September, BIA joined an industry roundtable to discuss animal research in the life sciences industry chaired by Lord Vallance, Minister for Science, Research and Innovation. Attendees from across the industry discussed the current status of alternative methods to the use of animals in science and future priorities. In particular, the roundtable looked at how to remove blockers to replacing the use of animals, including regulatory requirements, and how to drive a science-led approach to phasing in non-animal methods.

In addition, BIA raised the importance of reinstating the Ipsos Mori poll on public attitudes to animal research, as well as Government support needed to counteract animal rights activism that is increasingly impacting R&D in the UK. The BIA is a signatory to the Concordat on Openness on the Use of Animals in Research and supports the NC3Rs.

Please contact Senior Policy and Public Affairs Manager <u>Linda Bedenik</u> to find out more about the BIA's work on Animal testing.

Critical technologies

Engineering Biology

BIA publishes UK-Swiss engineering biology report to drive climate action

On 5 September, BIA, in partnership with the Swiss Business Hub UK & Ireland, Lucideon, and the Bristol BioDesign Institute, published a report: 'Synthetic & engineering biology: a joint opportunity for the UK and Switzerland'.

This report was based on insights from the <u>Synthetic & Engineering Biology British-Swiss Summit</u>, held on 23 May. The conference featured a series of roundtable discussions, focusing on engineering biology's role in climate and environmental solutions. Dame Angela McLean, Chief Scientific Adviser to the UK Government gave an opening speech to the day which brought together over 25 representatives from academia, industry, and government.

The report addresses key challenges and opportunities in the field, such as the need for supportive financial frameworks, clear regulatory pathways, and public engagement to scale engineering biology technologies.

To maximise the impact of the summit, BIA distributed the report to key stakeholders, including 64 UK parliamentarians. Additionally, the partners ensured the report reached key policymakers and leaders in Switzerland. By sharing these recommendations with decision-makers in both countries, BIA aims to drive the growth and commercialisation of engineering biology for climate and environmental benefit.

BIA meet with Embassy of Japan to discuss UK-Japan life science activities

On 8 July, BIA met with the Economic Minister for the Embassy of Japan and health attachés from the Health Ministry of Japan in London to discuss the UK and Japan's R&D ecosystem, as well as future opportunities for collaboration, including in emerging technology areas such as engineering biology.

The meeting followed after the Japanese Ministry of Economy, Trade and Industry (METI), the Embassy of Japan in the UK and UK Department of Science, Innovation and Technology (DSIT) held an open innovation event on Japan-UK tech collaboration in conjunction with London Tech Week. Japan and the UK have a long-standing science and technology agreement that was renewed in May 2024. BIA have <u>worked</u> with Japanese industry counterparts in the past to drive forward international collaboration on innovative biotechnologies, such as cell and gene therapies.

Please contact Senior Policy and Public Affairs Manager <u>Linda Bedenik</u> to find out more about the BIA's influencing work on engineering biology.

TechBio

New committee on data, AI and genomics launched by BIA

In September, BIA held the inaugural <u>Data, AI and Genomics Advisory Committee</u> meeting at Victoria House in London. Isomorphic labs, Jiva.ai and Relation Therapeutics join other innovative companies from across BIA membership to represent this important sector. The committee will focus on the key policy areas of health data access, artificial intelligence, multi-omics and precision medicine.

The committee was joined by Adam Lewandowski, Deputy Chief Scientist of UK Biobank. The group fed back on recent data access policy changes; providing an important opportunity for UK Biobank to hear the UK SME perspective.

This new committee is the consolidation of years of work from the BIA to build strong <u>genomics</u> and <u>techbio</u> communities. It will be the voice of the most cutting-edge technologies in the life sciences today, providing thought leadership and a sounding board to senior stakeholders.

BIA collaborates with NHS England on member workshop

BIA hosted a workshop for BIA members with NHS England. The workshop was run by the NHSE team leading key programmes such as the <u>Secure Data Environment (SDE)</u> network and <u>Digitrials</u>. It covered the various data assets and services that can be accessed through NHSE, with plenty of opportunity for discussion and feedback. Of particular interest was an update on the SDE network and the Digitrial's new <u>clinical trial feasibility service</u>. This service will support members with early clinical trial feasibility and cohort discovery.

The workshop was a unique opportunity for BIA members to share their perspectives with NHSE and support them in improving the research and development agenda. NHSE will use the feedback received during the workshop to improve their services.

BIA hosts new national initiative Our Future Health for an SME workshop

BIA hosted members of the techbio community for an engaging workshop with <u>Our Future Health</u> in July. Our Future Health is now the largest health research programme of its type in the world. This workshop allowed a two-way conversation between Our Future Health and the BIA's techbio community on the next phase of the programme. Key themes from the workshop included:

- Excitement for both the current data, plans and for potential future work;
- Optimism around recontact studies and clinical trials potential;
- The need to balance security with researcher usability;
- A plea for a predictable and transparent pricing model and researcher services.

Feedback received from members will help shape the programme and SME engagement going forwards. Our Future Health are investigating an 'SME early adopter programme' on the back of this workshop, specifically focussed on SME use of the resource.



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 <u>Dr Emma Lawrence</u>.

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.



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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

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