



UK BioIndustry Association

Influencing and shaping our sector

January -
April 2024

bioindustry.org

INTRODUCTION

The BioIndustry Association (BIA) continued to represent the innovative life science sector to Ministers and senior policymakers between January and April 2024. This quarterly report provides an overview of these engagements.

With a general election widely expected to be called later this year, the BIA's long-established relationships with senior parliamentarians have been of particular importance this quarter. From launching the Labour Party's Life Science Sector Strategy in Stevenage in January to hosting Science Minister Andrew Griffith MP at our Gala Dinner, we continue to represent the sector at the highest levels.

Outside of the pre-election political spotlight, but no less important, the BIA has continued to engage with senior civil servants to make the innovative life science and biotech sector heard. From the National Technology Adviser to the MHRA and the IPO, we have continued to strengthen our stakeholder relationships.

4 
**consultation
responses and
briefings submitted**

9 

**meetings with 16
Parliamentarians, incl.
4 Ministers and 5
Shadow Ministers**

We have also expanded our influencing remit into uncharted territory this quarter with the launch of our Deep Biotech group and accompanying report. The transformational potential of this community adds another innovative and forward-looking caucus to our membership.



**2 letters to
Ministers**

Read on for a complete rundown of how the BIA has influenced and shaped our growing sector over the past three months.

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Engagement with the Government and Parliament on life sciences policy

This year is likely to be dominated by two major elections: the UK general election and the US presidential election. Both will be very impactful on the BIA's work and our sector.

Election preparations got off to a fast start this year with the launch of the **Labour Party's Life Sciences Sector Strategy**, '[A Prescription for Growth](#)', on 30 January. Wes Streeting MP and Peter Kyle MP visited the Stevenage Bioscience Catalyst, arranged by the BIA, to launch the strategy, which also referenced the work of the BIA and [featured many of our policy priorities](#). As the respective Shadow Secretaries of State for Health and Science, Streeting and Kyle presented themselves as a team in lockstep, encapsulating the bond between health, innovation, and wealth. This connection was mirrored by Keir Starmer and Rachel Reeves at the party's **Business Conference** on 1 February, attended by the BIA.



Steve Bates meeting Wes Streeting (second from right) and Peter Kyle (far left) at the Stevenage Bioscience Catalyst, alongside SBC CEO Sally Ann Forsyth.

Science Minister Andrew Griffith MP delivered the keynote speech at the **BIA's Gala Dinner**, not only reinforcing the current government's commitment to the sector and appreciation for the BIA's collaboration with his department, but also welcoming our new work on Deep Biotech ([see below](#)). Professor Sir Mene Pangalos, outgoing Executive Vice-President of Biopharmaceuticals' R&D at AstraZeneca, was also awarded the prestigious BIA Lifetime Achievement Award at the dinner.

The Chancellor's **Spring Budget** on 6 March brought more BIA cheer as our long-running campaign to unlock pension funds for the sector began to deliver results with the announcement of the first partnership between a life science venture firm and a pension fund ([see below](#)).



Andrew Griffith MP, Minister for Science, Research and Innovation, delivering the keynote speech at BIA's Gala Dinner

In the first quarter of 2024, the BIA has also represented the sector at several key industry-government fora: the Biosecurity Leadership Council; National Genomics Board; Life Science Council Data Subgroup; Business Environment Board; and the Department for Business and Trade's One Health Think Tank.

On 1 February, we were delighted to be recognised by the **PRCA-PoliMonitor Public Affairs Awards** for the Best In-house Campaign of the Year – beating many far larger and better-funded organisations to the trophy. The award recognised the [successful campaign](#) last year to reverse cuts to R&D tax credits imposed in Autumn Statement 2022



The BIA team receiving their public affairs award for best in-house campaign.

Finance, tax and investment

Spring Budget delivers major step forward in BIA's pensions campaign

The [BIA's work to unlock pension funds](#) for investment into UK life sciences took a major step forward with the announcement that the life sciences team of Intermediate Capital Group (ICG), led by former BIA Board member Allan Marchington, has successfully partnered with Phoenix Group, the UK's largest pensions provider, with the support of the Government's Long-term Investment for Technology and Science (LIFTS) initiative. The announcement came as part of the Chancellor's Spring Budget which delivered large life science investment announcements alongside smaller tweaks to the tax system that should make the UK business environment friendlier for innovative businesses to start and scale.

The Budget was relatively quiet on R&D tax relief, which is welcome given the many changes our sector has been subjected to [over the past few years](#). However, it did include a new HMRC Industry Expert Panel to improve the administration of the regime following complaints by BIA and others that the agency lacks the expertise to assess complex R&D tax relief claims efficiently and effectively. The BIA has since met with HMRC to discuss the terms of the panel and who from our community will represent the sector. It will focus on life sciences, deep tech, and manufacturing sectors.

The Chancellor also announced that [AstraZeneca intends to invest a total of £650 million in the UK](#). This includes £450 million towards their manufacturing site in Speke, Liverpool, for the research, development, and manufacture of vaccines, building on the site's current role in supplying a world leading childhood vaccination programme. AstraZeneca will also expand its presence at Europe's largest life sciences cluster in Cambridge with an investment of £200 million. The facility will house around 1,000 employees and will be adjacent to its £1.1 billion global R&D Discovery Centre (DISC), which already hosts 2,300 researchers and scientists.

The BIA's CEO, Steve Bates OBE, [welcomed the announcements](#): 'I'm delighted that the UK Government continues to recognise start-ups and scale-ups are forging the innovative products and technologies underpinning the UK's economic future and improving all of our lives in the process. Today's Spring Budget delivers welcome progress on increasing private investment into these companies and improving the tax regime to support innovation'.

Read a full analysis of the Budget, including many other relevant announcements for life sciences, on the [BIA's website](#).

BIA discusses R&D tax reliefs with Treasury Minister

On 16 April, the BIA met the Financial Secretary to the Treasury, Nigel Huddleston MP, to discuss the importance of R&D tax relief to the continued growth and success of the UK's innovative life sciences and biotech sector.

BIA CEO Steve Bates and Chair of the Finance and Tax Advisory Committee ([FTAC](#)) Colin Hailey welcomed the new HMRC Expert Industry Panel announced at Spring Budget. They discussed with the Minister how it will help upskill and inform HMRC so that the administration of tax reliefs is quicker and simpler for innovative companies.

Both BIA and the Minister agreed that key to ensuring the UK remains a world-leading destination for investment in life sciences is a combination of an internationally competitive R&D tax relief rate *and* efficient administration of said regime. The BIA will continue to work collaboratively with government to make this a reality.



(From R-L): Nigel Huddleston MP, Steve Bates, Colin Hailey, and Martin Turner, meeting at HM Treasury.

BIA report shows resilient UK biotech sector landed £1.8 billion investment in 2023

The UK's innovative life sciences and biotech sector showed resilience in 2023, securing £1.8 billion in equity investment despite a challenging global economic climate, according to the [latest financing report](#) by the BIA published on 24 January.

Key findings from the report included:

- UK biotechs secured £1.8 billion in equity financings, down only 9% from 2022.
- UK retains top spot in Europe receiving 41% of total venture capital invested into biotechs across the region.
- £1.25 billion was raised in venture capital, a 6% decrease year-on-year.
- The collective share price of London-quoted UK biotechs is up approximately 250% compared to pre-pandemic levels, showing the sector delivers long-term returns for investors.

Steve Bates said: 'Although 2023 was a tough year for companies across sectors, including the global biotech industry, the UK sector showed remarkable resilience and investment, and stock market performance continues to outpace pre-pandemic levels.'

Prime Minister's chief advisor meets BIA members in Cambridge

The BIA organised a Cambridge life sciences scale-up roundtable on 26 February for the Prime Minister's Investment and Business Advisor, Franck Petitgas. Members in attendance highlighted the lack of homes and infrastructure holding back growth in the region, and discussed how government is unlocking pension fund investments through the [Mansion House reforms](#). The meeting was kindly hosted by Cambridge Innovation Capital.



BIA members meeting the Prime Minister's Investment and Business Advisor, Franck Petitgas, in a meeting chaired by BIA CEO Steve Bates.

BIA Chair hosts lunch for UK life science investors with MHRA CEO

The BIA's Chair, Dan Mahony, hosted his second VC lunch as the Government's Life Sciences Investment Envoy on 11 March. These lunches are intended to bring together the UK's leading life science venture capital investors to keep them updated and linked into the Government's and the BIA's work to increase investment into the sector, including through the Mansion House Reforms to unlock pension funds.

This lunch provided the opportunity to hear from Dame June Raine, CEO of the MHRA, about how improvements to the regulation of clinical trials and product authorisations are improving the UK environment as a place to invest in life sciences innovation.

Genomics, data & AI

BIA collaborates with trade associations on the future of NHS SDEs

The BIA has issued a survey collecting members' views to inform the implementation of the NHS England Secure Data Environment (SDE) network in partnership with The Association of British HealthTech Industries (ABHI) and the Association of the British Pharmaceutical Industry (ABPI). The responses will help us understand members' technical, governance, and contracting requirements for the programme, which we will then feed into government.

With SDEs set to become the default route for accessing health data in future, the NHSE [Data for R&D Programme](#) has been developing a network of secure data environments to facilitate access to regional health data. Each of these subnational SDEs will cover a regional population ranging from 3 to 10 million people while complementing a national SDE. 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.

If you are interested in finding out more about the NHSE Data for R&D Programme, or would like to respond to the consultation, please contact Senior Policy and Public Affairs Manager [Dr Emma Lawrence](#).



Influence, Connect, Save

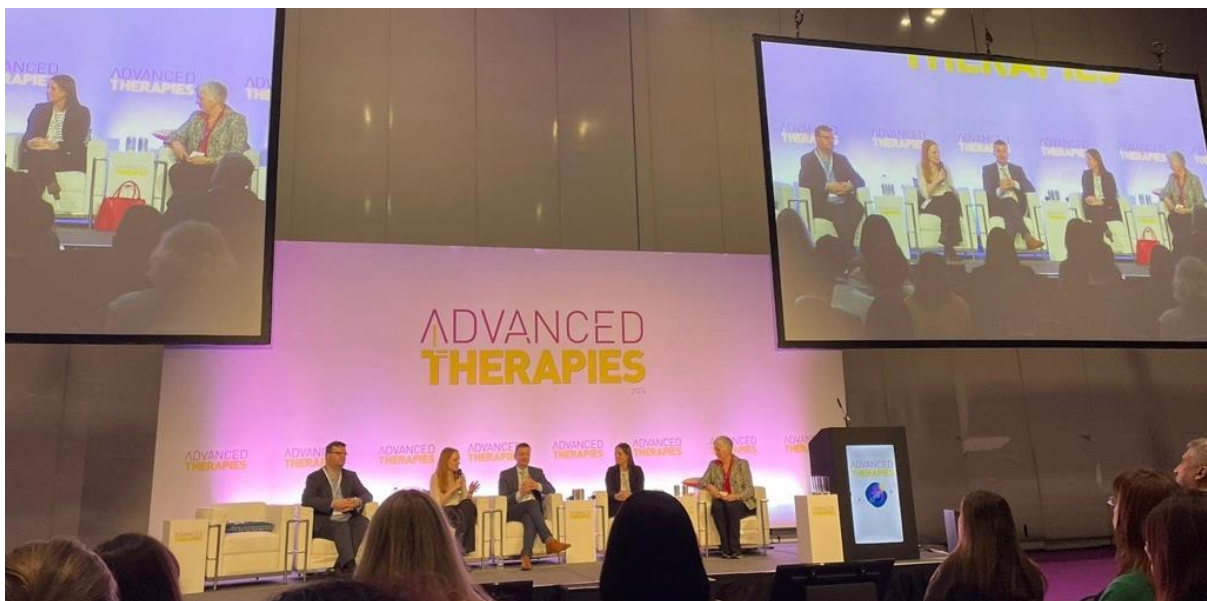
Cell & gene therapies

BIA engages in discussion on the UK environment for cell and gene therapies

On 19 March, the BIA joined a panel discussion on the UK environment for cell and gene therapies at the [Advanced Therapies Conference](#) at the ExCeL in London. Rosie Lindup, Policy and Public Affairs Manager, spoke alongside representatives from NHS England, MHRA and the Advanced Therapies Treatment Centre (ATTC) Network. The panel discussion was chaired by Nicola Redfern, former UK General Manager at bluebird bio, and covered topics including NHS adoption of advanced therapies and the [voluntary scheme for branded medicines](#), as well as findings from recent reports from the [BIA](#) and [ATTC Network](#).

The BIA looks forward to continuing to engage with members and stakeholders to ensure that the UK is able to maintain its leadership in the development and adoption of cell and gene therapies.

Please contact Policy and Public Affairs Manager [Rosie Lindup](#) with any further questions about the cell and gene therapy space.



Policy and Public Affairs Manager Rosie Lindup speaking on a panel at the Advanced Therapies Conference held at London's ExCeL.

Influence, Connect, Save

Engineering biology

First steps of expansion into Deep Biotech for BIA

The BIA has expanded its influencing activities to support Deep Biotech companies: innovative startups and SMEs applying modern biotechnologies such as engineering biology to humanity's most profound challenges beyond health, including climate change, pollution, and food security. On 7 February, the BIA made a significant move into the Deep Biotech space with the release of a new report entitled '[Deep Biotech: Disruptive innovation for global sustainability](#)'.

To mark the beginning of the BIA's activities in the non-health space, we held a [launch event](#) kindly hosted by Osborne Clarke. An insightful panel brought together investors, innovative companies, and government to discuss the potential of Deep Biotech and the policy, regulatory, and financial hurdles that will need to be overcome to enable a biorevolution.

Looking ahead, the BIA is developing a programme of influencing, events, and membership activities for the Deep Biotech space. This programme will include hosting member workshops to identify influencing needs, flying the flag for UK Deep Biotech at Synbiobeta 2024 in May, organising the [Synthetic and Engineering Biology British-Swiss Summit](#), and producing a series of case studies to showcase the achievements of Deep Biotech companies.

Biosecurity Leadership Council discusses DNA synthesis screening

On 18 March, BIA took part in the first Biosecurity Leadership Council ([BLC](#)) meeting of 2024. The BLC is a Department for Science, Innovation and Technology (DSIT) expert advisory group chaired by Minister for Science, Research and Innovation Andrew Griffith MP, and comprised of leading industry and academic experts from the biotech sector.

The council supports the Government's policy development for responsible innovation and biosecurity.

The next BLC meeting will take place in June. Should you be actively involved in or have an interest in this area, please get in touch with Senior Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA meet with National Technology Advisor to discuss engineering biology and Deep Biotech

On 10 April, BIA met with the Department for Science, Innovation and Technology (DSIT) National Technology Advisor ([NTA](#)), Dr Dave Smith. The NTA's role includes working closely with industry and academia to integrate their expertise with government and drive growth and innovation in the UK, including in the emerging engineering biology space.

At our meeting, we discussed the value of engineering biology and [Deep Biotech](#) companies to the UK, the importance of integrating engineering biology solutions into the Government's environmental and growth ambitions, and the key enablers and barriers to companies' success. This included the necessary regulatory, financial, and infrastructural levers that can aid companies' scale-up.

Intellectual property and technology transfer

BIA meet with IPO in bilateral to discuss SPC reform and data & AI in IP

On 27 March, the BIA's Intellectual Property Advisory Committee ([IPAC](#)) held a bilateral meeting with the Intellectual Property Office (IPO) to discuss supplementary protection certificate (SPC) reform and developments in Data & AI. EMA marketing authorisations for human medicines will cease to apply in Northern Ireland as of 1 January 2025, with the MHRA giving UK-wide authorisations (including Northern Ireland) going forward. This change affecting SPC law will be legislated through a Statutory instrument (SI) laid before Parliament this year.

While no changes will be made to how SPC term duration is calculated – a change BIA has been pushing for – the IPO reassured us that this will be reviewed in 2025, in line with a potentially broader-scope review of UK SPC law. The latter sees itself diverging from [EU SPC law](#) which is currently being reviewed as part of the EU's [pharma review](#). The BIA will continue to feed into this process.

The meeting also covered the [notice](#) that the IPO's [working group](#) of rights holders and AI developers convened to develop a code of practice on copyright and AI in the context of Text and Data Mining (TDM) was unsuccessful in agreeing a voluntary code. A consultation process may follow soon that the BIA will respond to.

Submission made to WHO pandemic accord Pathogen Access and Benefit Sharing Scheme

As international negotiations to agree a [WHO pandemic preparedness accord](#) continue, the BIA submitted comments to the Department for Health and Social Care (DHSC) on the proposed model for a Pathogen Access and Benefit Sharing (PABS) system in March. The PABS system is to be set up as part of the accord, which could be agreed at the upcoming World Health Assembly ([WHA](#)) in May.

Following on from our [September 2023 submission](#), we made clear that the system cannot become a tax on innovation which would disincentivise R&D and the production of diagnostics, therapeutics, or vaccines for infectious diseases, leading to PABS running counter to its very aim. We also commented on the voluntary and mandatory contributions to the system that may affect R&D-led SMEs, and warned of relying on untested models such as the [PIP Framework](#).

BIA co-host life sciences roundtable with WIPO Director General

On 19 March, BIA delivered a [life sciences roundtable](#) jointly with the ABPI and UKIPO for Director General Daren Tang of the World Intellectual Property Office (WIPO) and his delegation. Led by representatives from our IP Advisory Committee ([IPAC](#)), we highlighted how AI is changing our sector and its IP landscape, welcoming WIPO's forward-looking approach to AI and IP.

Most importantly, we shared our concerns about the upcoming [Diplomatic Conference on IP & Genetic Resources](#) in May, particularly around the draft treaty for a global patent disclosure requirement where inventions are based on genetic resources and/or traditional knowledge. The draft text still lacks clarity and would need substantial changes in order to be of any benefit to the patent system and its users. Following the WIPO roundtable, on 8 April the BIA discussed the draft

treaty with the UK IPO to reiterate industry concerns over the scope and legal uncertainty of the treaty.

BIA join FCDO workshop to discuss access and benefit sharing of marine genetic resources

In February, the BIA took part in an expert stakeholder workshop to discuss the details of the UK implementation of the Biodiversity of Areas Beyond National Jurisdiction ([BBNJ](#)) Agreement, an international treaty on the conservation and sustainable use of marine genetic resources (mGRs).

Joined by Lord Benyon, Minister of State for Climate, Environment and Energy, the meeting covered ‘commercialisation’ as a trigger point for benefit sharing, learnings from related access and benefit sharing mechanisms such as the Nagoya Protocol, and the scope of the agreement.

The implementation of the treaty may influence the future implementation of a treaty on benefit sharing over the use of Digital Sequence Information (DSI) currently discussed at the Convention of Biological Diversity ([CBD](#)). The BIA is part of Defra’s DSI business advisory group to help shape any future mechanism for DSI.

People, skills and talent

Life science apprentices celebrate National Apprenticeship Week 2024

National Apprenticeship Week (5-11 February) brings together businesses and apprentices from across the country to shine a light on the positive impact that apprenticeships make to individuals, businesses, and the wider economy. This year, the BIA hosted Secretary of State for Education, Gillian Keegan MP, at the National Horizon Centre at Teesside University, showcasing the Advanced Therapies Apprenticeship Community ([ATAC](#)). Business leaders and apprentices from Pharmaron Biologics, CPI, NHS Blood and Transplant, and the Cell and Gene Therapy Catapult discussed the opportunities and challenges presenting employers and learners through apprenticeships across life science and digital career pathways.



Education Secretary Gillian Keegan MP at Teesside University's National Horizon Centre.

Further announcements regarding apprenticeships came out in the Chancellor's Spring Budget, including a [£60 million package of reforms](#) to reduce red tape and boost apprenticeship uptake by increasing apprenticeship levy transfer to 50% and reducing SME co-investment to 100% for early talent apprentices.

Momentum behind BIA's Diversity in Biotech report builds

This quarter, the BIA's sector-leading [Diversity in Biotech](#) report continued to garner interest from a wide variety of stakeholders engaged in changing the diversity landscape for innovative life sciences.

For example, the British Science Association (BSA) hosted a [panel discussion](#) on diversity & inclusion in the life sciences at Newcastle's [Life Sciences Centre](#) chaired by local MP Chi Onwurah, Shadow Minister for Science, Research and Innovation. Dr Kate Barclay attended on behalf of the BIA, advocating for the value of apprenticeships in increasing diversity in the life science sector.



Dr

Kate Barclay, BIA's Skills Strategy Consultant, speaking alongside Shadow Science Minister Chi Onwurah MP on a panel hosted by the British Science Association.

On 29 February, the BIA hosted an interactive workshop in partnership with Eversheds Sutherland on '[Navigating the UK's Immigration System for Biotech SMEs](#)'. The workshop informed companies of their roles and responsibilities, legal pitfalls, and policy challenges, as well as offering them the chance to gain valuable feedback on their current processes.

The BIA's Dr Kate Barclay also joined a panel discussion on Diversity, Equity & Inclusion in Advanced Therapies at the Advanced Therapies Conference at London's ExCel alongside CGT Circle, LifeArc, Microfluidx, and Assurea. Panellists considered how to improve representation at all levels in an organisation, including attracting diverse talent, supporting professionals throughout their careers, and the role of diversity & inclusion in delivering innovative therapies to patients.

Women in Biotech mentoring programme begins

The second cohort of the BIA's Women in Biotech mentoring programme kicked off in January 2024 with 53 pairs of mentees and mentors taking part. The programme is intended to support career development and leadership growth opportunities within the sector, whether applicants are in early stages of their career or operating at C-suite level.

In a special extended [Women in Biotech event](#) hosted at Hinxton Hall in Cambridge on 12 March, mentees and mentors were well supported with by a number of sessions spanning influence, power & presence, work-life balance & wellbeing, authentic leadership, and strategic thinking.



A panel at WiB Cambridge featuring (L-R) Paula Holland (Cooley), Fiona Marston (Erebagen), Kirsty McCarthy (M:M Bio), and Rippon Ubhi (Sanofi).

Influence, Connect, Save

Manufacturing

BIA supports development of Life Sciences Manufacturing Fund

After lobbying for several years for larger, longer term capital grants, the BIA welcomed the government's reaffirmed commitment at Spring Budget to investing [£520 million in life sciences manufacturing](#) to build resilience for future health emergencies and capitalise on the UK's world-leading research and development. The funding will be available from 2025 for five years, providing industry with greater certainty which will encourage investment.

To ensure the scope and application process is suitable for companies of all sizes and stages of investment, OLS have embarked on pre-market engagement with the sector and joined the BIA's Manufacturing Advisory Committee (MAC) meeting in February, at the Annual Committee Summit, where strategy and plans were shared and members fed back from experiences with previous incentives schemes (including the of [Life Sciences Innovative Manufacturing Fund \(LSIMF\) grants](#) where Ipsen, Pharmaron and Touchlight were amongst the recipients), to support OLS in developing their approach.

The BIA will continue to work closely with OLS as the fund is rolled out, ensuring that members remain aware and engaged.

140 LeaPers leaping: latest cohort of MAC LeaP unveiled

Following the January 2024 intake, the BIA Manufacturing Advisory Committee (MAC) Leadership Programme ([LeaP](#)) has now engaged 140 next generation leaders from nearly 50 BIA member companies.



The January 2024 MAC LeaP cohort pictured at the BIA's offices.

Established in 2017 to support the development and training of these future leaders in the biomedicines and deep biotech industries through cross-sector learning, site visits and peer networks, LeaP has gone from strength to strength. The alumni network has evolved and the monthly lunch and learns remain popular, with the most recent featuring career stories and advice from Brendan Fish of CPI and Sharon Brownlow of Cytomos, in addition to a workshop on strategy and innovation from Dr Kate Barclay, BIA's Skills Strategy consultant, on

To find out more about this burgeoning programme, which is free to join and suitable for all BIA members who have a biomanufacturing footprint in the UK, please take a look at this short [video](#), visit the [webpage](#), or reach out to [Netty England](#).



Influence, Connect, Save

Regulatory affairs

BIA advises Business Environment Board on regulatory priorities

On 21 March, the BIA took part in a meeting of the Business Environment Board (BEB), whose purpose is to create an outstanding environment in the UK for life science businesses to start and grow. We highlighted to Roz Campion, Director of the Office for Life Sciences and co-chair of BEB, that prioritisation of new legislation for clinical trials was important to retain the UK's global attractiveness for clinical research. However, one year on from the government [response](#) to a public consultation on an ambitious legislative reform of the UK clinical trials regulatory framework to which the BIA responded, there is still no clear timeline for when the legislation will be updated. The BIA advised that pushing back to the next Parliament would create more uncertainty for our member companies. Additionally, we noted that the Medicines and Healthcare products Regulatory Agency (MHRA) introduced initiatives and procedures which need to be more joined up between regulatory approval and prompt access to new, innovative medicines.

On 28 March, the BIA co-signed a letter to Andrew Stephenson MP, Minister of State for Health & Secondary Care, asking the Minister to provide a timeline for when the government might expect to lay the required statutory instrument before Parliament. Later, on 23 April, the BIA participated in a MHRA workshop on the forthcoming clinical trial regulations. To find out more about the BIA's work in the clinical trials space, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

BIA working hard to progress ILAP

Since February, the BIA has been invited to join a series of meetings with the MHRA and their partners in the healthcare ecosystem to discuss on how to tackle the current delays and to help shape their plans for the future of the Innovative Licensing and Access Pathway (ILAP) under the Trusted Advisor Principles. This initiative takes into consideration the recommendations outlined in the [Pro-innovation Regulation of Technologies Review \(Life Sciences\)](#), conducted by Government Chief Scientific Adviser Prof Dame Angela McLean and published in May 2023.

Members will recall the [ILAP](#) was launched in January 2021 to accelerate the time to market and patient access to innovative medicines. In the last three years there has been huge interest from companies wishing to have their products considered as part of the ILAP; the total number of applications received was 229 as of March 2024, which is overwhelming regulator capacity and leading to slow processing of applications.

We provided members feedback from the BIA Regulatory Affairs Advisory Committee on the proposed changes including entry criteria and scope with optimised processes to provide certainty on timeframes. For further information on the BIA's work in this area, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

BIA takes part in MHRA Data Strategy Engagement Workshop

On 25 March, the BIA was invited by the MHRA to attend an engagement workshop on its Data Strategy which will define the agency's vision for data, digital technologies, and real-world evidence

(RWE) over the next three years. This workshop provided the opportunity to give industry feedback on the proposed five key priorities: data-driven innovation and early access; timely and proportionate regulatory decisions through RWE; capabilities in data and digital technologies; collaboration across the data ecosystem; and harness the potential of AI and advanced analytics.

The MHRA aims to publish the finalised Data Strategy in the summer together with its Regulatory Science Strategy, within which data science is one of five core themes.

International Recognition Framework for medical devices welcomed by BIA

On 26 January, the BIA was invited to an MHRA stakeholder meeting which brought together industry associations, approved bodies and company representatives to discuss the proposed routes for international recognition of medical devices and in vitro diagnostics (IVDs) under the Trusted Advisor Principles. Reducing duplication of assessments conducted by comparable regulators from Australia, Canada, the EU, and USA will enable regulatory resource, and manufacturer resource, to be focused on more innovative products for the benefit of patients.

The MHRA aims to publish an outline of the International Recognition Framework ahead of the Life Sciences Council meeting in May, subject to necessary approvals. Overall, the BIA supports the proposed framework, which is going to be a vital part of the MedTech regulatory reform in accordance with the MHRA [Roadmap](#) published in January 2024.

BIA continues engagement on the Windsor Framework implementation

The BIA has continued engagement via monthly meetings involving the MHRA, DHSC, and industry associations on the [Windsor Framework](#) implementation. The latest engagement meetings provided the opportunity to learn more about guidance under development, as well as to discuss plans for communication to encourage marketing authorisation holders to start making their labelling submissions ahead of the final quarter of 2024.

The Windsor Framework makes changes in relation to medicine licensing and the application of the Falsified Medicines Directive ([FMD](#)). The EU Acquis continues to apply for Northern Ireland in all other areas post 1 January 2025, and needs to be followed for manufacturing and distribution of products. The pharmacovigilance guidance updates, which are expected in May, will not depart significantly from the current position for industry, but will ensure clarity and reduction of burden. The EU Acquis will continue to apply for key pharmacovigilance activities where it does now, and the UK will continue to align with EU outcomes where appropriate. The [UK Parallel Import Licences guidance](#) published on 5 April provides information relating to parallel imports following agreement of the Windsor Framework.

For further information, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#)

Access to medicines

BIA rare disease parliamentary event emphasises the need for continued collaboration

On 20 February, the BIA held a lunch reception in the House of Commons to discuss patient access to medicines for rare diseases, ahead of Rare Disease Day 2024 (29 February). The event was hosted by Liz Twist MP, Chair of the APPG on Rare, Genetic and Undiagnosed Conditions and provided an important opportunity for representatives from across the UK rare disease community to connect with stakeholders and policymakers, including Shadow Science Minister Chi Onwurah MP, Health and Social Care Committee member Paul Bristow MP, and former health ministers Lord Bethell and Will Quince MP.

The panel discussion was informed by the Rare Disease Industry Group's ([RDIG's](#)) latest [report](#), which assessed the progress that has been made in securing broader and faster access to rare disease treatments in the UK. Chaired by Steve Bates, CEO of BIA, the panellists included Sam Roberts, CEO of NICE, Emily Reuben, CEO and Co-Founder of Duchenne UK, Sean Richardson, General Manager UK & Ireland at Alexion and Alastair Kent, Chair of the UK Rare Disease Forum.

The discussion highlighted that whilst great progress has been achieved in recent years to facilitate access to innovative treatments, including the implementation of the [UK Rare Disease Framework](#) and corresponding national [action plans](#), continued collaboration between system stakeholders is needed to overcome remaining challenges and improve the lives of people living with rare diseases in the UK.



Panel at the BIA's rare disease event featuring (L-R): Steve Bates (BIA), Emily Reuben (Duchenne UK), Alastair Kent (Rare Disease Forum), Sean Richardson (Alexion), and Sam Roberts (NICE).

As we head towards a general election, the BIA will endeavour to keep rare diseases on the political agenda through engagement with policymakers and key stakeholders on the challenges and future opportunities for improving access to innovative treatments.

New Rare Disease Action Plan commits to further engagement on access schemes

On 29 February, the Department for Health and Social Care (DHSC) published the [third Rare Disease Action Plan for England](#) to coincide with Rare Disease Day. This 2024 Action Plan evaluates progress on the 29 commitments in the 2023 and 2022 Action Plans and commits to seven new actions to continue addressing the priorities set out in the [UK Rare Diseases Framework](#).

The BIA welcomed the decision to continue working on Action 25 of the plan, which committed to a review the effectiveness of EAMS, ILAP and the IMF in supporting access to treatments for people living with rare disease. Early drafts of the third Rare Disease Action Plan didn't include further work on Action 25 but the final version did following the submission of a joint BIA and ABPI member survey showing industry concerns about the access schemes. NHSE, MHRA and NICE have committed to analyse the results of the survey in more detail and meet with the BIA and ABPI to discuss the survey before providing a written response, with further progress being reported in the 2025 action plan.

Minister Andrew Stephenson spoke about the new action plan at Genetic Alliance's annual Rare Disease Day Westminster reception, alongside Liz Twist MP, Genetic Alliance CEO Louise Fish, and patient advocate Grant Finney. The BIA is committed to [continued collaboration on rare diseases](#), building on the momentum created through Rare Disease Day.

BIA responds to two NICE consultations on TA and integrated topic prioritisation

The BIA responded to two consultations from the National Institute for Health and Care Excellence (NICE) in April. In our [response](#) to a [consultation](#) on NICE technology appraisal (TA) recommendations, we welcomed NICE's proposals for the incorporation of NICE TA recommendations into the guideline topic area, which we believe will fulfil NICE's aim to bring together and make it easier for users to find all its guidance about a condition.

However, the BIA has opposed proposals for integration of TA recommendations into guidelines. As set out in our response, we are concerned that the proposals could lead to a number of unintended negative consequences, including reducing clinician and patient choice and risk significantly damaging the attractiveness of the UK as an early launch market for new medicines. The BIA has therefore urged NICE not to proceed with the pilots for integration and to instead focus efforts on the incorporation of TA recommendations into guidelines. We look forward to engaging with NICE on the proposals for incorporation over the coming months.

Secondly, the BIA [responded](#) to a NICE [consultation](#) on its proposals for integrated topic prioritisation and strategic principles. The proposals include establishing a new integrated prioritisation board, a prioritisation framework, and a set of strategic principles, including for rare diseases. Our response supported NICE's intention to establish a new overarching integrated approach to prioritisation and topic selection.

However, the BIA recommended that NICE provide greater clarity and detail on a number of areas within the consultations proposals, including those that could unintentionally impact and limit patient access to rare disease treatments. As part of the consultation, NICE has committed to reviewing the application of the highly specialised technology (HST) routing criteria later in the year. Through RDIG, the BIA has repeatedly expressed concerns with the criteria being too selective and acting as a significant barrier to the number of rare disease products being routed through HST. In our response we have therefore called on NICE to urgently bring forward the review. We also recommend that industry experience and feedback should be considered as part of the review.

The BIA will continue to engage with NICE on this crucial review of the HST routing criteria and as its new prioritisation approach and strategic principles for rare diseases are introduced. Please contact Policy and Public Affairs Manager [Rosie Lindup](#) with any further questions.



Influence, Connect, Save

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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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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