



# **INFLUENCING AND SHAPING OUR SECTOR**

**January – April 2022**

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

# INTRODUCTION

The BioIndustry Association (BIA)'s ongoing influencing and engagement continue to represent our members' voices at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued involvement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from January to April 2022.

This quarter saw some of the BIA's influencing work come to fruition within Government. The Chancellor's Spring Statement included an update on the R&D tax reliefs review, confirming that overseas clinical trials will be eligible for relief in line with BIA advice. Our annual report on biotech financing showed record investment in the sector in 2021 and was launched at a panel discussion with Science Minister George Freeman MP in January.



**13 consultation responses and briefings submitted**



**14 influence meetings with 10 MPs, Peers and MEPs, including two Ministers**

The BIA continued to foster government-industry collaboration through the Life Sciences Council and the All-Party Parliamentary Group (APPG) for Life Sciences, both of which had successful meetings this quarter.



**8 letters to Ministers**

The BIA has also represented members' and the sector's interests in numerous government reviews and consultations, covering shared commitments for boosting the genomics sector across the four nations, a new UK Biological Security Strategy, making the UK a 'science superpower', improving diversity in STEM, updating legislation on clinical trials in the UK, and the future of the Biomedical Catalyst.

Read on for further details on the BIA's work this quarter.

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

Although COVID-19 infection rates remained high, the first quarter of 2022 saw the return of more in-person meetings, including the BIA Gala Dinner and the launch of the BIA's [annual report on biotech financing in 2021](#) at a well-attended panel discussion in January. At both events, Science Minister George Freeman MP made his passionate commitment to the life sciences sector clear to a very engaged audience. The Gala dinner was also attended by Cambridge MP Daniel Zeichner, Dame Kate Bingham and former special adviser to the Prime Minister, Will Warr. The report launched at the *Harnessing the City's financial firepower for UK life sciences* event and the subsequent publication of the [Q1 update for 2022](#) gives the evidence to support our work with the Government's Scaleup Taskforce to unlock investment in UK biotech as part of the Life Sciences Vision.



*Science Minister George Freeman MP at the BIA Gala Dinner in January.*

The BIA had an introductory meeting in Parliament with Labour's new Shadow Health Secretary, Wes Streeting on 7 February at which we discussed the COVID-19 legacy and vaccines manufacturing, access to medicines policy and the importance of health data for biotech SMEs.

Returning to the normal cycle of set-piece Parliamentary events, on 23 March the Chancellor Rishi Sunak MP delivered his **Spring Statement** around which the BIA conducted a vigorous influencing campaign on R&D tax credits (read more on page 7).

### **Life Sciences Council and other government/industry engagement**

The BIA continues to support government-industry engagement through its membership of the **Life Sciences Council (LSC)** and the joint government-industry secretariat that coordinates the work of the Council and its sub-councils and expert groups.

There was an additional meeting of the LSC on 4 April to discuss **Net Zero and Sustainability**, co-chaired by Lord Kamall, Minister for Technology, Innovation and Life Sciences at the Department of Health and Social Care (DHSC), and Juliette White, Vice President of Global Safety, Health and Environment and Sustainability at AstraZeneca. The BIA was represented by CEO Steve Bates, Kit Erlebach, Chair of the BIA's

[Manufacturing Advisory Committee \(MAC\)](#) and Anthony Finbow, Vice Chair of the BIA's [Genomics Advisory Committee \(GAC\)](#), with the Minister having made it known that he was particularly keen to hear the SME voice. All three took that to heart and made the contribution of SMEs to finding sustainability solutions and the challenges for SMEs of getting these solutions to market clear to the meeting, with the Minister requesting to follow up in more detail. The meeting will be followed up by deep-dive working groups.

The **All-Party Parliamentary Group (APPG) for Life Sciences**, for which the BIA provides the secretariat jointly with the British In Vitro Diagnostics Association (BIVDA) and the Association of the British Pharmaceutical Industry (ABPI), held its Annual General Meeting in Parliament on 15 March followed by a discussion addressing the question: 'Can COVID-19 innovations be a springboard for future life sciences breakthroughs?'

The **Accelerated Access Collaborative (AAC)** held an Early-Stage Innovation Listening Event for Industry on 23 February.

The BIA's ability to influence policy across the whole range of issues that affect our industry draws heavily on the community of experts found in our Advisory Committees and expert groups. It was a great pleasure to gather that community for a successful **Committee Summit** on 24 February for a whole day of Committee and group meetings, plenary sessions and networking.

The pandemic has shown the great things that the UK life sciences ecosystem can achieve when it works together. To celebrate this and demonstrate to policymakers the unique contributions of industry, medical research charities and government research funders, the BIA partnered with the Association of Medical Research Charities (AMRC), the National Institute for Health and Care Research (NIHR), UK Research and Innovation (UKRI), the Medical Research Council (MRC) and the ABPI to produce [an animation illustrating the value of this rich ecosystem](#) which was launched at an event in Parliament on 14 March attended by Steve Bates.



*The BIA, in collaboration with partners across the research ecosystem, has launched a new animation explaining how, together, the charity, public and industry sectors help make research happen in the UK.*

The BIA has continued to **promote sector developments to the media**. In January, the BIA's annual finance report was published, which showed that 2021 was the best year on record for investments in UK biotech and life sciences companies, a story which was covered by the [Times](#), [Telegraph](#) and Politico as well as many trade publications. The BIA's reaction to key announcements by government also received

media attention including the Chancellor's Spring Statement, the acquisition of the Vaccine Manufacturing Innovation Centre (VMIC) by Catalent and the continued discussion of a possible IP Trips Waiver for COVID-19 vaccines.

*“Getting the right regulatory environment and investment in place for this sort of frontier science depends on a close and trusted relationship between Government and our industry on a complicated basket of interrelated policy issues. During these historic times, where Ministerial ‘bandwidth’ is limited, the role of the BIA has been invaluable most recently around the Life Sciences Vision, concerns around the National Security and Investment Act and settlements in last autumn’s Spending Review.”*

**Dr Mark Kotter, CEO and Founder of bit.bio**

## Finance, tax and investment

### Chancellor listens to BIA concerns on R&D tax relief changes in Spring Statement

On 23 March, Chancellor Rishi Sunak MP delivered his [Spring Statement](#), including an update on the R&D tax reliefs review that has been a key focus of the BIA's influence activity. The update provided some reassurance that the Treasury has heeded the BIA's concerns that clinical trials conducted overseas must remain eligible for R&D tax reliefs.

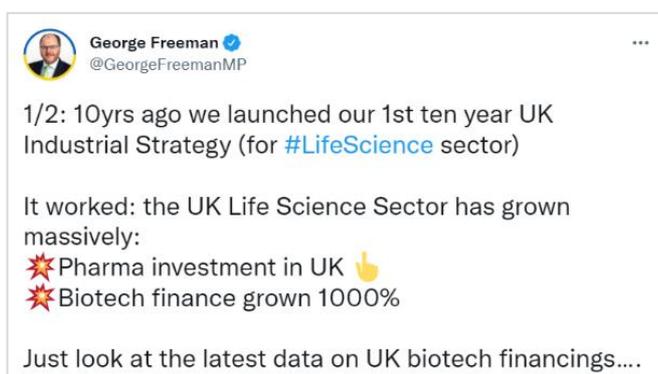
At the [Budget in September 2021](#), Sunak said he wanted to “more effectively capture the benefits of R&D funded by the reliefs through refocusing support towards innovation in the UK”, raising concerns in our sector that this could impact the many life science companies that conduct pre-clinical and clinical trials overseas through necessity.

The BIA's [Finance and Tax Advisory Committee \(FTAC\)](#) held several meetings with the Treasury following that announcement to help officials understand the nature of this activity. As a result, the Spring Statement committed the Government to legislate to permit R&D tax relief claims on overseas activity where “material factors” or “regulatory or other legal requirements” necessitate it taking place outside the UK, citing clinical trials as one of these reasons. However, it is not clear if all aspects of clinical trials will be exempt and how pre-clinical activity will be addressed. The BIA will continue to engage with the Treasury on these issues.

A full analysis of the Spring Statement and details of the next steps in the R&D tax reliefs review are available [on the BIA website](#).

### BIA data shows continuing success in UK biotech financing

In the first quarter of 2022, the BIA published its [annual report on biotech financing in 2021](#) followed by the [Q1 update for 2022](#) published in April. The sector broke previous records by raising £4.5 billion in 2021, 60% more than in 2020. Venture capital (VC) financings totaled £2,518 million, an increase of 81% from 2020, and Initial Public Offerings (IPOs) secured £1,304 million, an increase of 434% from 2020.



Science Minister George Freeman MP [tweeting](#) about the BIA's annual UK biotech financing report in January 2022.

The strong VC financing continued into 2022, with £453 million raised, but the public markets on both sides of the Atlantic faltered midway through 2021 and this continued into 2022, meaning only £28 million was raised from public sources in the first quarter of 2022 and the IPO window has closed for most companies.

In February, the BIA also published its [analysis of London-quoted biotech share price performance](#), showing continued outperformance of the FTSE All-Share in 2021 but, reflecting financings, a significant cooling of the market later in the year. However, [some investors see an opportunity](#) in the low valuations but strong fundamentals illustrated in the BIA's analysis and are exploring establishing a new fund to invest in smaller public biotech companies in London.

### **New efforts to encourage pensions investment in biotech announced**

The Government [has restated its commitment to change the rules governing pension funds](#) to enable greater investment in venture capital, but said that it will consult carefully on the proposals following concern from some stakeholders. The BIA has [previously urged the Government to change the rules](#) that we believe discourage pension fund managers from investing in venture capital funds due to the high costs. However, we also said that this change alone would not be enough to address the risk-averse approach of many in the City of London. The Government's commitment to consult further is therefore welcome but suggests a lack of urgency, which is disappointing.

Separately, the Government is consulting on new proposals to require some pension schemes to 'disclose and explain' their policies on illiquid investment, including venture capital, and for schemes with over £100 million in assets to disclose their current asset classes to members. This was previously [called for by the BIA](#) so that pension savers could choose funds that invest in biotech. The BIA will be responding to the consultation. To share any insights, please contact Head of Policy and Public Affairs [Martin Turner](#).

## Strategic technologies and areas of scientific focus

### **BIA contributes to shared commitments for Genome UK implementation**

The BIA has worked with government to develop shared priority actions for the genomics industry. The new shared commitments for England and the devolved nations set out priority actions to be taken across the UK for the first time and are part of wider plans to improve healthcare through genomics. The '[Genome UK: the future of healthcare](#)' strategy announced in 2020 is soon to get a three-year implementation plan, and these commitments are the first step in this process.

The 2020 strategy sets out the ambition of making the UK the best place globally to start and scale up new genomics companies. The shared commitments set out in this plan, including enabling industry access to clinical assets, expertise and partnerships are an important step in realising this ambition. The Government will also convene an industry engagement workshop with the BIA and the ABPI prior to the publication of the full implementation plan in June. The BIA is looking forward to working with the UK Government and devolved governments on the next phase of the Genome UK implementation planning. To find out more, please contact Senior Policy and Public Affairs Manager, [Emma Lawrence](#).

### **BIA invited to discuss future of BMC and MRC industry-academia collaboration processes**

In March, the BIA was invited by Innovate UK to provide feedback on the current and future structure of the [Biomedical Catalyst \(BMC\)](#) competition and future competition streams. The roundtable was attended by seven BIA members who discussed the accessibility of the grant, the risk-marking criteria for project applications and speed of decision making, as well as future investor partnerships.

The BIA was instrumental in securing the launch of the BMC in 2011/12 and campaigned for its expansion. We continue to ensure that this vital source of early-stage funding for UK bioscience companies will support the development of new life-changing medical treatments, diagnostics and devices, and underpin economic growth for the future.

In a similar vein, the BIA was invited by the Medical Research Council (MRC) to provide feedback on their [industry-academia collaboration processes](#) and related funding mechanisms. A roundtable held in February explored the challenges, needs and opportunities in life science SME/academic collaborations and was attended by six BIA members. Members highlighted challenges in IP sharing arrangements in collaborative projects, the role of Technology Transfer Offices (TTOs) and opportunities for better project management arrangements between SMEs and academia.

The BIA continues to work towards making funding available and accessible to innovative life science SMEs. [Read more about our decade-long BMC campaign](#).

### **BIA engages with OPSS and Defra on the Nagoya Protocol**

Throughout this quarter, the BIA has continued to engage with the Department for Environment, Food and Rural Affairs (Defra) on the forthcoming UK Guidance on Access and Benefits Sharing (ABS). Unfortunately,

the decision has been made by Defra not to share a draft of the guidance with stakeholders prior to publication. The BIA will be reviewing the new guidance once published and continue to inform members.

Legislation implementing the [Nagoya Protocol](#), which imposes obligations on users of non-human genetic resources and traditional knowledge associated with it, has been in force in the UK since 2015. The legislation requires the users of genetic resources to comply with due diligence obligations before ‘utilisation’ and carries penalties for failure to comply, which the BIA is concerned will create unreasonable bureaucracy for companies and is being implemented incorrectly.

The BIA raised concerns with the Office for Product Safety and Standards (OPSS) over its recent national enforcement activities of these [Nagoya Protocol \(Compliance\) Regulations 2015](#). Some BIA members received letters from the Government asking for information on their use of genetic materials and compliance with the Nagoya Protocol. In response, the BIA sent a letter to OPSS seeking clarification on the broad scope of the letter’s request for information and the intent behind it.

In parallel, the BIA conducted a survey of its corporate membership throughout March to understand their awareness and understanding of the legislation and regulation regarding Nagoya in the UK and abroad, to collate feedback on navigating the legislation and scope any concerns among our membership over the now likely inclusion of an ABS mechanism for Digital Sequence Information (DSI). The results will inform the BIA’s work to help its membership understand the obligations under the Nagoya Protocol and to improve regulation in the UK for the sector.

For questions or to share your views on this issue, please contact Policy and Public Affairs Manager [Linda Bedenik](#).

### **BIA inputs to reviews of the UK RDI landscape and delivering a UK science and technology strategy**

As announced in July 2021 in the [UK Innovation Strategy](#), Professor Sir Paul Nurse, Chief Executive and Director of the Francis Crick Institute, has led an [independent review](#) of the UK’s research, development and innovation (RDI) landscape. The BIA [responded to the review](#), highlighting the life sciences sector as one of the most research and innovation intensive sectors in the UK and emphasising the important role of life sciences companies.

Key points made in our submission covered the areas of most importance for life science SMEs to thrive. We emphasised the role of life science SMEs as a route through which the UK will realise the economic and social benefits of a strong RDI landscape, and the importance of creating the right policy environment for the RDI intensive life sciences sector and its innovative companies.

The review is one of several looking into the UK’s RDI landscape. The House of Lords Science and Technology Committee will examine the findings of these reviews to help answer the question as to whether the UK’s RDI institutions need reform to achieve the Government’s aims for UK science. The findings will feed into the Committee’s [consultation](#) on how to deliver an overall science and technology strategy for the UK.

The BIA has separately responded to the Select Committee's consultation. In our [submission](#), we highlight that the life sciences sector is universally recognised as world-leading, delivers great benefits to the economy and the health of the nation and is essential to making the UK a 'science superpower'. Ensuring the full implementation of the current [Life Sciences Vision](#) and its link to other science and technology strategies across Departments and sectors is vital for a successful joined-up UK science and technology strategy.

The BIA continues to promote the role of the life sciences sector in the RDI landscape and towards making the UK a 'science superpower'. To find out more, please contact Policy and Public Affairs Manager [Linda Bedenik](#).

### **BIA responds to call for evidence on the UK Biological Security Strategy**

In March, the BIA [responded](#) to the Cabinet Office [call for evidence](#) on the UK Biological Security Strategy. Our response set out the vital contribution of the life sciences sector to the UK's COVID-19 response, and its continued importance in the development of vaccines and other medical countermeasures. It also detailed the UK's role in tackling the global threat of AMR, including the development of novel antimicrobial drugs.

The BIA's submission also assessed future opportunities for the UK, including in the areas of genomics and engineering biology, which have the potential to address a range of biological threats. We recommended that, in order to deliver strategic capability on biological security, the Government should continue to provide support to the UK life sciences sector, including by linking the Biological Security Strategy to the strategy set out in the [Life Sciences Vision](#).

The call for evidence will inform a refresh of the [2018 Biological security strategy](#), which identified several significant biological security risks, including infectious diseases, antimicrobial resistance (AMR) and deliberate biological attacks. For more information, please contact Policy and Public Affairs Manager [Rosie Lindup](#).

### **BIA responds to inquiry on data privacy**

The BIA has responded to the House of Commons Science and Technology Committee's inquiry on '[The right to privacy: digital data](#)'. The inquiry examined the benefits, risks and barriers to data sharing and the extent to which these issues are addressed by recent government strategies, namely the Department for Digital, Culture, Media and Sport (DCMS) [National Data Strategy](#) and the Department of Health and Social Care (DHSC) draft strategy '[Data saves lives: reshaping health and social care with data](#)'.

The BIA set out the many benefits of sharing data for our health and wellbeing and how SMEs play a vital part in developing cutting-edge innovations that rely on access to data. [Our response](#) outlined the many technical and governance-related barriers that exist to data sharing and the impacts of these barriers on health innovation.

On 23 March, Professor Chris Molloy, CEO of the Medicines Discovery Catapult and BIA member, gave oral evidence to this inquiry. He highlighted the important role of SMEs in the research ecosystem, adding that industry involvement is essential to delivering new products and services to patients.

## People, skills and talent

### **BIA advocates for equality, diversity and inclusion in life sciences**

Advocating for equality, diversity and inclusion across the life sciences sector enables access to innovative talent. Throughout this quarter, BIA member feedback was instrumental in influencing policies that affect access to skills and talent pathways for the UK life sciences sector. Member companies provided feedback on the [Science and Technology Select Committee inquiry on improving diversity in STEM](#), current [challenges for R&D businesses with the UK Immigration System](#), and an informal discussion document on the Global Talent Network aimed at attracting international talent to the UK. The BIA's responses to all three inquiries can be found [on our website](#).

The BIA continues to strongly engage on skills and talent in the sector and will respond to UKRI's consultation on the [New Deal for Postgraduate Researcher](#) and joined a virtual roundtable on the subject in April.

### **BIA promotes sector's skills challenges towards delivering its 2022 skills and talent workplan**

The BIA's new [2022 Skills and Talent](#) workplan aims to address significant skills shortages and policy challenges identified by our members. It requires strong alignment with the Life Sciences Vision and collaboration across the sector. The 2022 goals for skills and talent focus on advocating equality, diversity, and inclusion across the sector, developing the next generation of life sciences leadership talent and advancing digital and data-driven skills into biotech.

Developing the next generation of leadership talent relies on building the networks and advocacy for the sector. Throughout March, the BIA engaged with a diverse cross section of our membership to discuss skills:

- **The BIA Regional Event in Oxford** focused on skills and talent with an engaging panel session opening the discussion on attracting, developing, and retaining talent for the sector
- The BIA was invited to take part in a panel discussion focusing on talent pipelines at the **UK Life Sciences Real Estate annual conference** hosted by Bisnow
- The BIA chaired a wide-ranging apprenticeship panel discussion at the **Life Science UK Skills conference** hosted by Discovery Park
- The BIA organised an Early Careers presentation carousel at The Royal Society's **Science of COVID conference**, demonstrating the impact of new talent in the UK COVID-19 response.

To get involved in the BIA's skills work, please get in touch with Skills Strategy Consultation [Kate Barclay](#).

### **Celebrating Apprenticeship Week**

Apprenticeships have undergone significant reform in recent years and offer a real alternative career pathway for new talent coming into the life sciences sector, as well as a route for upskilling in areas such as digital skills, data analysis and leadership.

During National Apprenticeship Week in February and Scottish Apprenticeship Week in March, the BIA supported member companies in developing their understanding of vocational routes into the sector, describing science, engineering, leadership, and digital pathways from school leaver to undergraduate and postgraduate programmes and the value these pathways bring. With digital, informatics and data science skills highlighted as key challenges, apprenticeships offer an alternative route to consider.

Learn more about apprenticeships across the sector through the [Advanced Therapies Apprenticeship Community](#), [the BIA's apprenticeship website](#) or by reaching out to BIA Skills Strategy Consultant [Kate Barclay](#).

## Intellectual property and technology transfer

### **BIA shares concerns with UK Government over IP waiver deal**

In March, the EU, South Africa, India and the U.S. reached [a compromise deal](#) following long-running negotiations on a waiver on intellectual property (IP) rights for coronavirus products.

In a letter to the Government in response, the BIA reiterated that IP has not been the barrier to global equitable access to vaccines at any stage during the pandemic, that waiving IP is not the solution to the current pandemic, potentially chilling investment in innovation, and will make it much harder to respond to the next pandemic.

The letter urges the Government to oppose the proposed deal on principle, as it will not solve the problem of access to COVID-19 vaccines and might set an internationally sanctioned precedent for the removal of innovators' IP rights, discouraging critical private sector investment in future vaccine development. Instead, the real challenges to vaccine equity must be addressed, which include lack of deployment capacity in global health systems, the pressures on supply chains through export restrictions and tackling vaccine hesitancy.

The BIA continues to be highly engaged on this issue and represents its members and the UK life sciences sector through influential forums including the International Council of Biotechnology Associations (ICBA) and other global cross-association groups, as well as national and international agencies and governments. To learn more about the BIA's efforts on this issue, please contact Strategic Communications and Media Relations Manager [Jack Fellows](#).

### **BIA re-establishes bilaterals with the UKIPO**

The BIA's [Intellectual Property Advisory Committee \(IPAC\)](#) held its first 2022 bilateral meeting with the UK Intellectual Property Office (UKIPO) in February. Lead representatives from IPAC's seven subcommittees met with the UKIPO's patents policy team, which considers policy issues relating to patents, from trade to Artificial Intelligence (AI) and life sciences, both domestic and international.

The UKIPO team provided the latest update on their [inquiry into AI and IP](#), which IPAC's Data & AI subcommittee [responded to earlier this year](#), and sought further insights from our committee on the role of AI and data in the life sciences sector. The Committee sought views on what the UK joining the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) could mean for grace periods, and briefly discussed the Nagoya Protocol and concerns of linking it to patent applications in genetic resources. The UKIPO also provided an update on the latest Group B+ activities on international patent law harmonisation.

IPAC will continue to meet the UKIPO throughout 2022 to exchange insights on IP issues relating to life sciences and biotech. To find out more about IPAC's activities, please contact Policy and Public Affairs Manager [Linda Bedenik](#).

## Pre-clinical and clinical research

### **BIA joins DHSC Research Reset Oversight Group**

In March, Professor Lucy Chappell, Chief Scientific Adviser, DHSC, Dr Louise Wood, DHSC Director of Science, Research and Evidence, and Dr Tim Ferris, Director of Transformation, NHS England and Improvement (NHSEI), issued a [letter](#) outlining the [urgent action that must be taken](#) to address the current research delivery challenges in the NHS. The National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN) is identifying studies that are behind their targets and potentially 'at risk' of closure to recruitment or set-up based on the principles set out in the letter.

Subsequently, the BIA was invited to participate in the Reset Oversight Group to help shape the DHSC and NHSEI work to revitalise the NHS research portfolio and monitor the situation to ensure the approach is having the intended effect of releasing capacity and achieving competitive timelines for set-up and delivery. This contributes to work under way through the UK Clinical Research Recovery Resilience and Growth (RRG) programme regarding the delivery of a full portfolio of non-COVID clinical research and making the UK the leading global hub for life sciences.

If members have any questions about the DHSC communication and the research reset project, please contact BIA Head of Regulatory Affairs [Christiane Abouzeid](#).

## Manufacturing

### Life Sciences Innovative Manufacturing Fund (LSIMF)

The BIA welcomed the announcement of the [Life Sciences Innovative Manufacturing Fund \(LSIMF\)](#), a £60 million capital grants scheme launched by the Government in March which will support life sciences manufacturing. Capital grants have been called for by the BIA and industry partners in the [Medicines Manufacturing Industry Partnership \(MMIP\)](#) to strengthen the UK's manufacturing capacity.

The UK medicine manufacturing community is buoyant after playing a crucial role in manufacturing and scaling up COVID-19 vaccines coupled with significant private sector investment over the past few years. Anchoring and growing this high-value manufacturing industry in the UK is crucial to the UK's resilience to future health threats as well as the creation of new jobs across the country. Key to the success of this fund will be that it works for companies of all sizes, from big pharma to SMEs, supporting domestic growth as well as attracting businesses from overseas to invest in and manufacture their products here in the UK.

### BIA celebrates 2022 cohort of manufacturing leadership programme MAC LeaP

The 2022 cohort of the [BIA Manufacturing Advisory Committee \(MAC\) Leadership Programme \(BIA MAC LeaP\)](#) successfully kicked off in London in March, with 25 next-generation leaders onboarded, taking the total to almost 100 on the programme since its launch in 2017.



*The 2022 cohort of the BIA's MAC LeaP programme. Currently, 36 member companies are benefitting from LeaP.*

LeaP supports the development and training of managers in the biopharmaceutical and cell & gene therapy industries through cross-sector learning and peer networks, helping deliver future leaders. This programme is led by Kit Erlebach, Chair of the BIA's [Manufacturing Advisory Committee \(MAC\)](#), and the BIA's bioprocessing consultant [Netty England](#), who you can contact to find out more.

## Medicines regulation

### **BIA responds to MHRA consultation on clinical trials legislative proposals**

In March, the BIA responded to the Medicines and Healthcare products Regulatory Agency (MHRA)'s [consultation](#) on proposals to update the current UK clinical trials legislation, the [Medicines for Human Use \(Clinical Trials\) Regulations 2004](#). These proposals have been developed by the MHRA and the Health Research Authority (HRA), in collaboration with an expert working group of stakeholders from across the clinical research sector, including the BIA.

Shaping the future UK legislation for clinical trials is a priority for our members. The [consolidated BIA response](#) was developed with input from our [Regulatory Affairs Advisory Committee \(RAAC\)](#). The consultation process will provide the opportunity to design a world-class regulatory environment for clinical trials to support the development of new innovative medicines and ensure that the UK retains and grows its reputation as a world-leading base for life sciences, in line with the ambitions of the [Life Sciences Vision](#).

### **BIA welcomes EU legislation to address supply chain challenges in Northern Ireland**

On 12 April, the Council of the EU adopted a [directive](#) and a [regulation](#) to ensure continued supply of medicines to Northern Ireland, as well as to Cyprus, Ireland and Malta. This follows the European Parliament approval of the European Commission proposals which were presented in December 2021 to address the supply chain challenges caused by the Northern Ireland Protocol. The EU legislation will enter into force on the day of their publication in the EU's Official Journal, with the measures applying retroactively from 1 January 2022.

The directive aims to safeguard the uninterrupted supply of medicines to Northern Ireland by exempting companies from some burdensome EU rules, while the regulation is aimed at ensuring the supply of investigational medicinal products for clinical trials.

The BIA is delighted that the voice of the industry has been taken into consideration and celebrates this great result after many years of active engagement at EU and UK level.

### **BIA provides members' views on updated EAMS guidance**

In February, the MHRA published the [Government response](#) to the public consultation on the proposed legislative changes to the UK [Early Access to Medicines Scheme](#) (EAMS) to which the [BIA responded](#) in September 2021. A [Statutory Instrument](#) was laid before Parliament on 7 February which came into force on 15 April and extends to England, Wales, Scotland and Northern Ireland. This will help support more patients getting access to important EAMS medicines in advance of licensing decisions and ensure that the UK remains internationally competitive in the pre-market access to medicines landscape.

In April, the BIA submitted our members' views on the new draft MHRA guidance to help with the interpretation and implementation of the new legislation. We were pleased that the MHRA considered our

comments and provided responses and solutions to the points raised by us. A final version of the updated guidance documents will be published on the MHRA's website soon.

Discussions with the DHSC and the MHRA will continue about funding for SMEs to collect real-world evidence to inform and support NHS commissioning for EAMS medicines.

## Access to medicines

### **BIA engages with NICE on implementation of the NICE Methods Review**

In January 2022, the National Institute for Health and Care Excellence (NICE) [announced](#) the conclusion of its large-scale review of the methods, processes and topic selection used for health technology evaluations. In [response](#) to the conclusion of the review, the BIA signalled that, while the review brought about some positive changes, its scope failed to match the ambition that was set out at the start of the review and committed to in the Government's [Life Sciences Vision](#).

As part of its efforts to implement the updated health technology evaluation manual, NICE held two implementation workshops with key stakeholders, including experts from the BIA's [Rare Disease Industry Group \(RDIG\)](#). The workshops focused on the details of NICE's plan to develop a more flexible approach to dealing with clinical uncertainty and its plan to implement a severity modifier.

The BIA looks forward to engaging with NICE in the longer term as it transitions to a modular approach to updating its methods and processes.

### **BIA Rare Disease Industry Group engages on England's first Rare Diseases Action Plan**

In February 2022, the DHSC published the [England Rare Diseases Action Plan](#), setting out how it plans to implement the [UK Rare Diseases Framework](#) in England over the next year. The plan is the first iteration of measurable actions that have been drawn up to address the four priorities identified in the Framework.

Led by the England Rare Diseases delivery group, the nation-specific Action Plan has been developed with the continued engagement of the UK Rare Diseases Forum – a body of rare disease community stakeholders of which the BIA is a core member.

The BIA was pleased to see that much of our feedback on previous iterations of the Action Plan had been carefully considered and acted upon, including improved relevance of the impact measures to assess progress against each action. Over the coming year, we look forward to monitoring the progress of the delivery partners and providing input into the development of the second Action Plan in 2023.

### **BIA raises awareness of challenges involved in developing treatments for rare diseases**

To mark international Rare Disease Day on 28 February, the BIA launched a video which sheds a light on the challenges involved in developing a treatment for rare diseases. The video, developed by the BIA's [Rare Disease Industry Group \(RDIG\)](#), explains that while developing a drug for any condition is a long and expensive process, for rare diseases the situation is even more difficult.

With only 5% of rare diseases having a single licensed treatment, the development of potentially transformative treatments is hugely worthwhile, and industry remain committed to developing treatments for a range of disease areas. The video is part of the BIA's ongoing [campaign](#) to demonstrate why systematic change to the evaluation of rare disease medicines is necessary to ensure patients can access the treatments they need.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Martin Turner, Head of Policy and Public Affairs, at [mtturner@bioindustry.org](mailto:mtturner@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, Head of Membership and Business Development, on 079 2029 3171 or [mmcgivern@bioindustry.org](mailto:mmcgivern@bioindustry.org)

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