Influencing and shaping our sector – BIA update October 2019 – January 2020

UK BioIndustry Association

Influence, connect, save

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Introduction

The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from October 2019 to January 2020.

It has been a busy quarter at the BIA – from engaging with all the main political parties during the General Election campaign and analysing the parties' manifestos, to working with the new Government on the future UK-EU relationship and its new R&D funding plans.

We have published new figures that shows that the UK biotech sector raised £1.3 billion in 2019, the third best year on record and an increase by over 400% since 2012. We have continued our work to enable BIA members to access international opportunities by leading a delegation to China and delivering on a Memorandum of Understanding commitment to exchange member directories with a Japanese trade association. Our team has also continued to work to ensure the sector will have access to the skills it needs in the future and secured representation on government/industry forums to ensure patients in the NHS can access innovative treatments. Read about all this and much more below.

This quarter in numbers:

10+ influence meetings with 6+ MPs, Peers and MEPs, including 3 Ministers

2 consultation responses submitted

4 letters to Ministers

Contents

Engagement with the Government and policymakers on life sciences policy

BIA General Election activities

Engagement with the Government in the final months of 2019 took an interesting, but not unexpected turn when the Fixed Term Parliaments Act proved once again to be a complete misnomer and a General Election was called in the run-up to Christmas. Ahead of the General Election, the BIA published a Biotech Manifesto with three key demands for the next Government:

- Commit to maintaining and increasing public and private investment in R&D;
- Maintain world class medicines regulation in a post-Brexit UK; and
- Deliver rapid patient access to medicines.

We used the Biotech Manifesto in our engagement with all the main political parties. We monitored the party manifestos and published an analysis comparing key policy areas of interest to BIA members. We were pleased to see the inclusion in the Labour Party manifesto of a pledge on genomics for which we had argued: "*Under a Labour government the NHS will be at the forefront of the development of genomics and cell therapies so that patients can benefit from new treatments for cancer and dementia, whilst ensuring the UK continues to lead in medical developments*."

Other parts of the Labour Party's manifesto was influenced by Medicines for the Many and Mariana Mazzucato's UCL Institute for Innovation & Public Purpose. In January, the BIA met with members of the Institute to open a dialogue on these policy issues.

In the foreword to the Conservative Party manifesto, Boris Johnson stated: "We will make the UK the leading global hub for life sciences", echoing the BIA's vision for the sector. The Conservatives pledged a £500m Innovative Medicines Fund, replacing the Cancer Drugs Fund (CDF) with £340m from CDF plus £160m of new money, from existing NHS budgets. Also included in the manifesto was a promise to expand R&D tax credits to include data, something for which the BIA has argued strongly in meetings with the Government, and a commitment to unlock pension funds for science enterprises.

During the General Election campaign, the BIA produced a constituency mapping tool which shows the prevalence of life sciences businesses and jobs in each of the 650 parliamentary constituencies. This tool continues to inform our engagement with the new Parliament. The BIA has engaged with senior Ministers in the new Government and will produce a comprehensive guide for members to the key Ministers and their portfolios following the re-shuffle which is expected soon. The guide will also feature new Select Committee chairs and other Parliamentary figures to watch.

BIA engagement with the new Government

The BIA's engagement with the Government through the Life Sciences Council (LSC) and its subsidiary Boards was also affected by the calling of a General Election for December. The Autumn meeting of the LSC, which had been scheduled for 19 November, fell in the pre-election period ('purdah') and was cancelled. The BIA continues to support government-industry engagement through its membership of the LSC and the joint government-industry secretariat that coordinates the Council's work.

The Life Sciences Industrial Strategy Implementation Board (LSISIB) met on 9 September and discussed the joint Department for International Trade (DIT) and Office for Life Sciences (OLS) initiative to produce a

Global Sales Pitch to promote inward investment to UK life sciences. The Board also discussed life sciences skills and medicines regulation in the context of EU Exit.

The BIA has secured representation on the Accelerated Access Collaborative (AAC), with Ruth McKernan, the BIA's new Chair due to take up our seat on the AAC Board at its biannual meeting in March 2020. We are also represented on the AAC Steering Group, which met on 2 December. The AAC is focusing on Advanced Therapy Medicinal Products (ATMPs) and Histology Independent (formerly Tumour Agnostic) treatments. The BIA will be represented on several key workstreams that support these areas of focus.

The BIA is also represented on the NICE Methods Review and its various Task and Finish groups and the OLS' Early Access to Medicines Scheme (EAMS) strategic group.

An update to the Life Sciences Industrial Strategy was published by the Government at JP Morgan in January, in a report which described the progress made against the targets set in the original Life Sciences Industrial Strategy published in August 2017.

Leaving the EU

BIA continues to support the sector with advice on planning for Brexit

The last quarter has been a time of continued and significant uncertainty on Brexit. In October, the UK Government agreed a new deal with the EU comprising a revised Withdrawal Agreement and Political Declaration, but then failed to gain Parliamentary backing, leading to the December General Election.

October marked the conclusion of our programme of work funded through the Government's Business Readiness Fund (BRF). Our final report concluded that the programme overall had been a very successful and an important source of support for the sector. We recorded strong levels of interest and take-up through our wide range of face-to-face events and digital activities.

To support members through this quarter we continued our series of Brexit webinars, which provide a regular update on the latest position and guidance on preparing for the full range of outcomes. We also hosted two further meetings of the Brexit Lead Network, delivered jointly with the ABPI in October and December.

BIA CEO, Steve Bates has continued to raise the profile of the life sciences sector within the media as part of the wider Brexit debate. In December, Steve contributed to a video by the FT which looked at the implications for science in the UK after Brexit and cited our sector finance reporting.

BIA focuses on the implications of the revised Brexit deal for members

The Conservative's election victory has been followed by the rapid return of Brexit legislation and now both the UK and the EU are on track to approve and ratify the Withdrawal Agreement, with Brexit planned for 31 January 2020. The BIA has been analysing the implications of the revised Withdrawal Agreement, Political Declaration and Northern Ireland Protocol, particularly in terms of the impact on regulations and the future role of the UK's medicines regulator at the end of the Transition Period.

Under the terms of the revised Withdrawal Agreement, there will be a Transition Period from 1 February to 31 December 2020 to allow the UK and EU to negotiate a future relationship. Any extension to the Transition Period would need to be agreed by the UK and EU by 1 July 2020, though the Government has included a clause in the Brexit legislation that rules out any extension. So, if a future relationship and trade agreement is not agreed by 1 July 2020, the UK could still leave with no-deal at the end of the year. The BIA has continued to engage with Department of Health and Social Care (DHSC) on contingency planning to ensure that support is available for a no-deal scenario and will maintain this approach throughout 2020.

Over the next 11 months, the Government will seek to negotiate a future relationship with the EU. Even with a Free Trade Agreement (FTA) in place there will be an impact on customs and trading arrangements for life science businesses trading with the EU because the UK would no longer be part of the Single Market and Customs Union.

EU leaders and the Commission have been clear that tariff- and quota-free access to the EU market will require regulatory alignment – the so called 'level playing field' – meaning that higher levels of access to the Single Market would require higher levels of alignment on standards. The BIA has led a range of industry-government discussions on this issue, including with our members on the Regulatory Affairs Advisory Committee, and we continue to push for the best outcome for our sector.

BIA influences the Government's negotiating mandate for the future relationship with the EU

As the UK prepares to leave the EU on 31 January, there is continuing uncertainty about the potential nature of the future relationship with Europe and trade with the rest of the world. If no trade agreement is in place by 31 December, trade between the UK and EU would revert to World Trade Organisation (WTO) rules-based arrangements, equivalent to the no-deal scenario for which the Government provided guidance ahead of 31 October 2019.

The BIA position remains that close cooperation with the EU in the regulation of medicines – including mutual recognition of regulatory activities and quality testing – is essential to ensure that patients in the UK and the EU can continue to access safe and effective medicines and for the UK sector to thrive.

The revised Political Declaration on the future relationship states that: *"The Parties will also explore the possibility of cooperation of United Kingdom authorities with Union agencies such as the European Medicines Agency (EMA)…"*. The inclusion of this statement has been welcomed by the BIA and the wider sector, but the extent of cooperation is dependent on the negotiations with the EU about the terms of that future relationship.

In December, Steve Bates signed a joint letter to Health Secretary Matt Hancock from life sciences trade association CEOs. The letter welcomed the supportive comments the Secretary of State made at the BIA Bioscience Forum in October and reinforced the importance of maintaining the current high level of alignment and participation in the EU regulatory system.

Health Secretary Matt Hancock speaking at the BIA's Bioscience Forum in October last year.

The BIA has continued to play a significant role in the EU Relationship Group (EURG), a forum where industry engages with ministers from the Department of Health and Social Care (DHSC), Department for Exiting the EU (DexEU) and the Department for Business, Energy and Industrial Strategy (BEIS). The BIA has also engaged directly with government ministers such as Baroness Blackwood and Michael Gove to make sure that the Government is clear about our sector's priorities for a future relationship with the EU and to ensure that those priorities are articulated clearly within the UK mandate for trade agreement negotiations.

BIA pushes for clarity on the operation of the Northern Ireland protocol

The Northern Ireland Protocol to the Withdrawal Agreement means that Northern Ireland will remain aligned with the EU on goods and apply EU tariffs, except for movements within the single customs territory of the United Kingdom. There are provisions within the Protocol which mean that at the end of the Transition Period, the regulation of products in Northern Ireland would be subject to EU, not UK, authorities in order to ensure alignment to EU single market rules.

The BIA was quick to identify concerns about how medicines regulations could operate in Northern Ireland if the Protocol comes into effect at the end of the Transition Period. We have raised questions and concerns about the potential status of the MHRA in this scenario with government officials. Having provided early analysis of this issue, the BIA is well placed to play a key role in an industry-led technical working group, which will consider this issue in more detail and provide advice to government.

Finance, tax and investment

New BIA figures reveal third best year for UK biotech investment

On 22 January, the BIA and Informa Pharma Intelligence revealed that the UK biotech sector raised £1.3 billion in 2019. The total is the third best year recorded by the BIA and shows that since 2012 investment has increased by over 400%.

Highlights from the report, include:

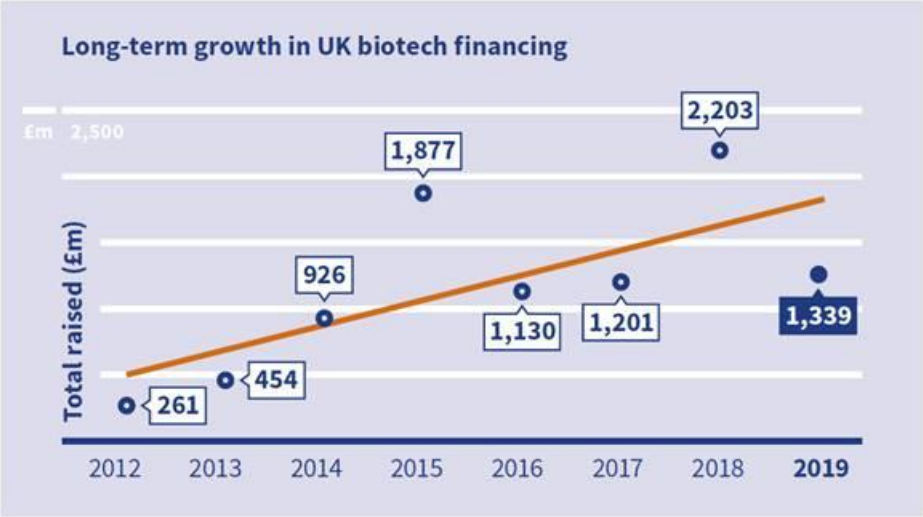
- A total of £1.3bn was raised by UK-based biotech companies in 2019
- Over £679m was raised in venture capital, £64m was raised in Initial Public Offerings (IPOs) and £596m in all other public financings
- The sector has enjoyed five consecutive years of raising over £1billion plus of investment
- The UK remains the leading cluster in Europe for amounts raised through venture capital, accounting for a quarter (26%) of the continent's total

BIA CEO Steve Bates said:

"The UK biotech sector continues to chart an ambitious global path. With five consecutive years of raising over £1billion and a 400% increase in investments since 2012, the sector is in a very strong position heading into a new decade.

"It's clear that UK biotech companies remain an attractive investment opportunity for global investors, meaning there's a greater diversity of capital than we saw five years ago. However, while we welcome overseas investment, diversifying the domestic life sciences investor base is critical to capturing the full benefits of this key sector of the UK economy.

"Government efforts to leverage new scale-up capital through the British Business Bank and the UK pension funds industry should be stepped up, as should grant funding for early-stage companies through the Biomedical Catalyst."



BIA data reveals that since 2012, investment in UK biotech has increased by over 400%.

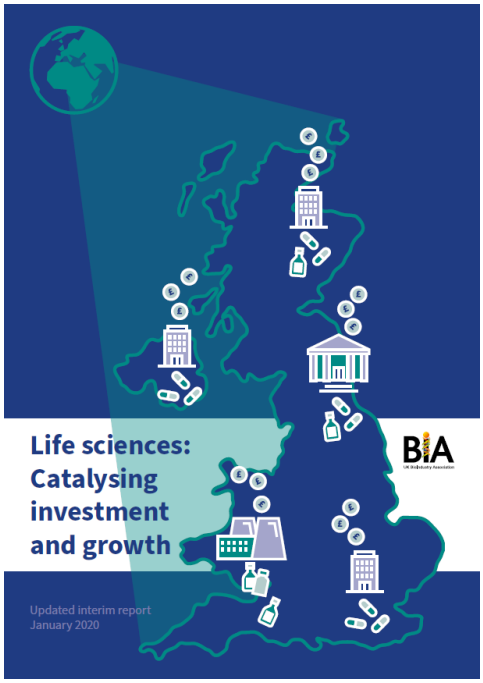
BIA CEO Steve Bates appeared on Sky News to talk about the report and it was also covered in a wide range of press, including The Times, The Telegraph and POLITICO.

BIA writes to No 10 and the Chancellor ahead of the Spring Budget

Ahead of the Spring Budget in March, the BIA wrote to No 10 and the Chancellor to highlight key policies the Government should implement to enable the life sciences sector to increase its R&D investment further, develop new technologies faster and create more jobs across the country. We set out key priorities for the sector that could be implemented in the Budget, including:

- Rapidly deploy the Biomedical Catalyst to maintain the pipeline of bioscience innovation
- Commit to work with the innovative life sciences industry to re-energise British science
- Ensure SMEs are protected and supported through R&D tax credit reforms
- Maintain the UK's influential and progressive regulatory expertise through funding new functions of the MHRA

We also updated our interim report '*Life Sciences: catalysing investment and growth*', which was shared with No 10, the Chancellor and other key policymakers. As the new Government is committed to the fastest ever increase in public science investment and looks to develop new R&D funding plans, the updated report highlights the strength of the UK life sciences sector and makes the case for increased government support in our sector.



The BIA's updated interim report makes the case for increased government investment in our sector.

The updated report also emphasises an independent analysis by IPSOS Mori which showed that the Biomedical Catalyst generates £4.72 in public and business value for every £1 invested by the Government. The study also showed that the programme leverages over £5 of private investment per £1 of public expenditure. As such, the programme outperforms other public funding programmes, which leverages £1.40 of private investment from every public £1. The BIA promoted the analysis widely when it was released in October.

The Government is due to hold a Spending Review later this year, and once the timelines are announced, the BIA will publish a final version of the report with the key asks for the life sciences sector.

BIA leads UK delegation to China Healthcare Summit 2019

In November, the BIA led a delegation of BIA member companies to the China Healthcare Summit 2019 in Shanghai. The BIA delegation attended, presented and networked at the conference, which resulted in a deeper understanding of the valuable and exciting opportunities that exist in the Far East for UK companies.

The conference provided rich analysis and insight into how China is developing its innovation footprint in healthcare to tackle health challenges nationally and across the world. The Chinese market for biotech and pharma continues to grow at scale and the impact of the new regulatory environment has led to numerous new launches. The BIA sponsored the UK track at the conference, which was extremely well attended. Several BIA member companies presented, including LightOx, Arecor, Oxford Biomedica, Crescendo, Vaccitech and Retrogenix.

The British Consulate kindly hosted our delegation and it was great to hear from Chris Wood, the new Consul-General in Shanghai. The trip also allowed us to see first-hand the fast development of the state-of-the-art Wuxi I–Campus and its ability to be a practical launching pad for UK companies into China.

In December, the BIA also hosted representatives from a Guangxi heath delegation to discuss investment and business opportunities and to establish relationships with our member companies who are interested in establishing a footprint in China.

BIA CEO Steve Bates introducing UK companies to delegates at the China Healthcare Summit 2019.

In addition, the BIA hosted an event on Developing a Strategy for China prior to the Gala Dinner on 23 January, building on recent work we have done in this area. This event gave UK life sciences companies a chance to hear about the many opportunities offered by China, and how UK companies can take advantage of these. BIA CEO Steve Bates, Shaun Grady, VP Business Development Operations at AstraZeneca, and Carl Sterritt, CEO of Shield Therapeutics, took part in a panel on these developments from their perspective, and this was followed by a chance to network with Stephanie (Chenxue) Yang and Peng Ke from AstraZeneca and learn more about what the company is doing in Wuxi.

BIA responds to the Smith-Reid Review on international research partnerships

In November, Professor Sir Adrian Smith and Professor Graeme Reid published a report, commissioned by the Government, outlining new opportunities to boost international partnerships on research and innovation post-Brexit. The review highlighted that continued international collaboration, including with the EU, is vital to the UK remaining a global science superpower, tackling the world's challenges and attracting and retaining the talent the UK needs.

The BIA welcomed the publication of the review and emphasised that life sciences SMEs must be a central part of the new vision of the UK's future science and innovation landscape. We also highlighted that we have detailed proposals for how the Government can ensure future funding streams enable SMEs to leverage the maximum amount of private investment needed to meet the 2.4% R&D target.

Regulators, government and pensions industry make progress in unlocking investment following BIA pressure

With £2.2 trillion under management, UK pension schemes could make an enormous difference to the start-ups and scale-ups in innovative industries like the life sciences. Unlocking this capital has been a major focus of the BIA's policy work since the 2017 Patient Capital Review.

In September, the British Business Bank published a new report, bringing together the progress made in removing the barriers to pension schemes investing in venture capital. This included commitments from the Government and regulatory changes called for by the BIA. A blog on the BIA website provides a full summary of the progress made to date and the BIA's role.

BIA responds to government consultation on trade with Japan

In November, the BIA responded to the Department for International Trade (DIT)'s consultation on UK-Japan trade. In our submission, we highlighted that with its advanced economy, high levels of R&D investment and growing biotech sector, Japan offers many opportunities for UK life sciences companies. We also argued that there are opportunities for the UK to work to strengthen Japan's IP system, enable more collaborative R&D partnerships between the countries, and emphasise the importance of transparent processes and stakeholder engagement as Japan implements its new health technology appraisal (HTA) system.

BIA meets HMRC to discuss EMI share valuation problems

BIA members have reported a change in HMRC practice in the assessment of discounts for share valuations for the Enterprise Management Incentive (EMI) scheme. This is causing problems for many companies and undermining the value of the scheme. The BIA has raised the sector's concerns with the Chief Executive of HMRC and met with officials to discuss the matter. The BIA has also agreed to work with the Worked Examples Group, an informal HMRC stakeholder group, to develop a sector-wide solution to the problem.

Strategic technologies and areas of scientific focus

BIA enables cell and gene therapy collaboration with Japan

The BIA (through its Cell and Gene Therapy Advisory Committee, CGTAC) and Japan's Forum for Innovative Regenerative Medicine (FIRM) renewed their Memorandum of Understanding in 2019, with the aim of enabling collaboration between our member companies in regenerative medicine and cell and gene therapy. To improve collaboration, the BIA and FIRM have made available to each other a directory of members engaged in these areas, enabling global access to talent, expertise, education and partnerships. We hope that this shared directory will enable Japanese and UK companies to work cooperatively to solve problems and accelerate mutual commercial outcomes that generate health and wealth gains for our countries. The BIA directory has been translated into Japanese and (along with the English version) can be found by members on our website here .

A ceremony was held at BIO Japan in Yokohama in October at which the BIA's Director of External Affairs, Nicky Edwards, and FIRM's Representative Director, Ken-ichiro Hata, exchanged directories. Following the exchange, there was a discussion that focused on collaboration between innovative cell and gene therapy companies in the UK and Japan, the openness of the UK to the world after Brexit and reimbursement models over long periods of time.

The BIA's Director of External Affairs, Nicky Edwards (fourth left), and FIRM's Representative Director, Ken-ichiro Hata (third left), at the ceremony in Yokohama.

BIA attends workshop on the enforcement of the Nagoya Protocol

In December, the BIA attended a workshop on the enforcement of the Nagoya Protocol. The workshop was organised by the Office for Product Safety and Standards (OPSS), the regulator responsible for ensuring organisations and businesses comply with the UK legislation derived from the Protocol. The workshop was a good opportunity to learn more about the OPSS' approach to enforcement and to highlight how some of the ambiguities with the legislation can have disproportionally negative effects on life sciences SMEs.

The BIA continues to work with government and industry stakeholders to ensure the compliance requirements of the Nagoya Protocol do not hinder innovation. In June 2019, we submitted evidence to the Convention of Biological Diversity (CBD), arguing that digital sequence information should not the adopted into the Nagoya Protocol.

BIA GAC meets with new Genomics England CEO and outgoing Chair

In November, a sub-group of the BIA's Genomics Advisory Committee (GAC) met with the new CEO of Genomics England, Chris Wigley, for a positive and open introductory meeting. Chris was keen to understand how Genomics England has engaged with SMEs previously and what they can do to improve to support the growth of genomics SMEs.

In December, Chris and Jon Symonds, the outgoing Chair of Genomics England (but continuing Board member), also attended GAC's quarterly meeting. This was a good opportunity for GAC members to learn more about Genomics England's priorities following the completion of the 100,000 Genomes Project in December 2018 and to provide direct feedback on their interactions with Genomics England.

This quarter, GAC has also met with the Royal College of Physicians to discuss how industry and medical practitioners can work together to develop joint policy positions in areas such as regulation of genomic tests, genomic training of the NHS workforce, and the National Genomic Healthcare Strategy.

BIA visits the Sanger Institute and Congenica

In December, a group of BIA staff was invited to the Wellcome Sanger Institute in Cambridge to see first-hand the cutting-edge research the Institute undertakes. Adrian Ibrahim, Head of Technology Transfer and Business Development and Chair of the BIA's GAC, and Julia Wilson, Associate Director, gave BIA staff a tour of the world-leading facilities at Sanger and spoke about the institute's outlook for the future.

We also met with the Congenica team, a BIA member SME that is situated within the Wellcome Genome Campus. Congenica demonstrated their innovative clinical decision support platform, which enables rapid analysis and interpretation of complex genomic data.

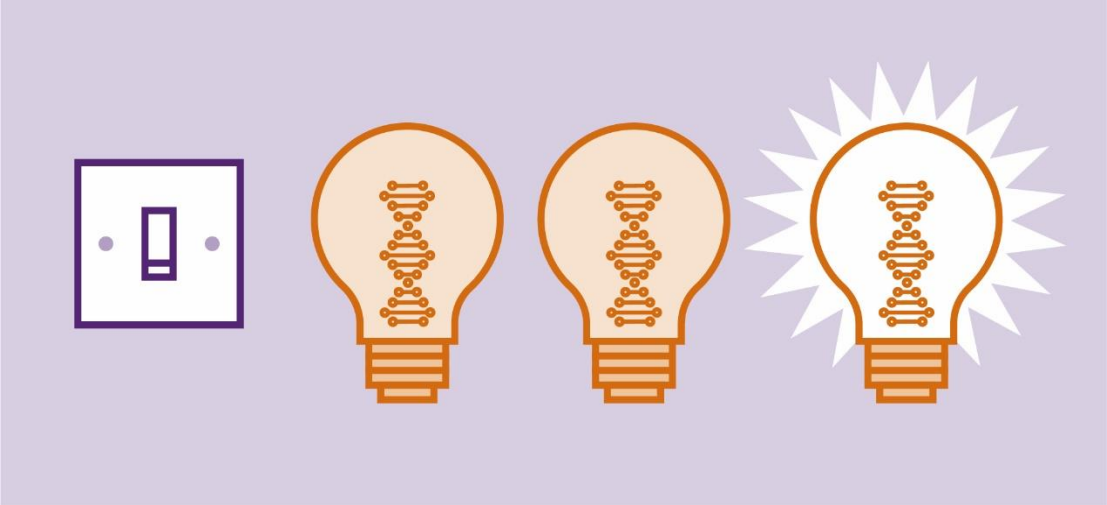
Part of the BIA team visited the Sanger Institute and Congenica at the Wellcome Genome Campus.

BIA comments on RAEng report on engineering biology

In December, the Royal Academy of Engineering (RAEng) published a new report, *Engineering biology: A priority for growth*. The report calls for urgent action to be taken by the UK to capitalise on the potential of its engineering (synthetic) biology research and industry base, warning it risks losing its world-leading position in the field.

BIA CEO, Steve Bates attended the press briefing along with BIA members Arcinova, SYNBIOCHEM and Puraffinity ahead of the publication of the report. Speaking to journalists, Steve emphasised the great innovation driven by UK SMEs and said that Britain is on the brink of a new industrial revolution driven by biology, akin to the emergence of steam power in the 1780s or electricity in 1890s. His comments were reported in several papers, including The Telegraph and Research Professional.

RAEng also attended the BIA's Engineering Biology Advisory Committee (EBAC)'s Q4 meeting to discuss how stakeholders in the sector can work together to implement the recommendations in the report.



Skills, people and talent

BIA continues to engage on the Life Sciences 2030 Skills Strategy

The Life Sciences 2030 Skills Strategy will be launched in late January in the House of Commons. The Strategy has been developed as a collaboration between industry and government as a key deliverable in the Life Sciences Sector Deal 2. The BIA has been a leading partner in delivering the future skills strategy and driving the action plan to deliver on recommendations.

The evidence gathered for the Strategy shows that skills for developing and delivering innovative treatments are important, but also that our changing society needs to be considered along with the expectations of the next generation and the fact that the workplace may be very different in 2030. Companies will need to organise their teams to be more agile, further integrate traditional skills with new transformative, digital skills and design their resourcing approaches to respond to this. According to the Strategy, the sector has potential to create approximately 133,000 jobs over the next 10 years, and that digital skills, statistical literacy, leadership and inter-disciplinary working are essential to the continued success of our sector.

In summary, the Strategy requires the sector's focus to prepare for change and meet these demands by:

- developing home-grown talent alongside supporting transfer and exchange of a global workforce
- building on the strong skills infrastructure to develop multi-disciplinary, industry-ready graduates
- investing in high level apprenticeships and developing flexibility in use of the apprenticeship levy
- fostering a new approach to lifelong learning and sector promotion to inspire, inform and build a diverse, entrepreneurial and resilient future life sciences workforce

The Strategy aims to implement a Life Sciences Skills Action Plan to oversee and coordinate the delivery of the Strategy's recommendations. The BIA will continue to engage on the skills agenda throughout 2020 to ensure that life sciences SMEs are represented.

Accelerated demand for specialist skills in the UK cell and gene therapy industry

At the BIA's bioProcess UK Conference in November, the Cell and Gene Therapy Catapult published *Cell and gene therapy GMP manufacturing in the UK: capability and capacity analysis 2019*, which shows that the cell and gene therapy industry currently supports over 3,000 jobs. Employment in this sector in the UK is set to more than double by 2024, as more therapies are moving towards commercialisation.

This acceleration of job creation in the sector is leading to some concerns over how quickly it will be possible to address this demand, as well as concerns over availability of targeted academic courses. This reinforces the urgent need to act with immediate effect to ensure recruitment and retention of essential talent does not hinder industrial growth and inward investment.

One such initiative, the Advanced Therapies Apprenticeship Community (ATAC), the first apprenticeship programme set-up in partnership with the Medicines Manufacturing Industry Partnership (MMIP), was designed specifically to train and upskill individuals in advanced therapies. The programme has been identified as crucial in addressing the fast growth of the sector, but it is only one part of a wider end-to-end talent management plan that is required.

Full details of the existing ATAC apprenticeships can be found on the ATAC website, and will be showcased during a UK tour in National Apprenticeship week from 4-6 February – registration is available here.

BIA's Manufacturing Advisory Committee launches fourth cohort of leadership programme

The fourth cohort of the BIA's Manufacturing Advisory Committee (MAC) Leadership Programme (LeaP), designed to support development of managers in the biopharmaceutical and cell and gene therapy industries, launched in January. The new cohort met at the BIA office, learned more about the programme and networked with the BIA team.

LeaP meeting at the BIA office in January.

The second cohort, which started in January 2018, is now nearing completion and the participants will then join the alumni group to enable them to continue sharing best practice and developing relationships to encourage future collaborations.

Due to massive oversubscription, two parallel programmes will run again this year, resulting in a total of almost 70 next generation leaders being developed currently through LeaP. Contact Netty England at aengland@bioindustry.org if you would like to hear further details about the programme, which is free to BIA members.

Intellectual property and technology transfer

BIA calls on patent attorney body to support pro bono advice for start-ups

The BIA's IP Advisory Committee (IPAC) has called for updates to professional standards for Patent Attorneys and Trade Mark Attorneys to allow in-house attorneys to provide pro bono advice to start-ups and SMEs. We believe that connecting experienced industry professionals with entrepreneurs and early-stage businesses so that they can provide advice is an important aspect of growing the UK sector. To support this, the BIA called on the regulator to ensure that access to personal indemnity insurance is not a barrier to those wishing to offer pro bono advice.

BIA helps Royal Society organise tech transfer conference

In November, the BIA helped the Royal Society organise a conference on tech transfer with attendees from industry and universities. The purpose of the conference was to focus on the current challenges of translating research into commercialisation and how those challenges can be solved. The life sciences sector had a good presence at the conference, including representatives from AstraZeneca, BrisSynBio and LifeArc. The BIA facilitated several case study presentations by our members.

The Royal Society is currently considering how they could implement some of the recommendations of the conference in their work in the future. The BIA will continue to work with the Royal Society to ensure the voice of life sciences SMEs is represented.

BIA represents UK sector in EU IP policy fora

Members of the BIA's IP Advisory Committee (IPAC) have been involved in coordinating pan-European sector responses to developments in IP policy at an EU level. These included submitting views to the European Commission on the impact of requirements to disclose benefit and sharing agreements under the Nagoya Protocol in patent applications, which would be a burdensome and unnecessary measure harmful to the life sciences sector. IPAC members also represented the BIA in meetings to discuss the European biotech sector's response to an EU review of IP incentives. IPAC will continue to monitor and engage on these issues.

Pre-clinical and clinical research

BIA welcomes new report on Complex Innovative Design trials

In early January, the BIA welcomed the highly anticipated report on the effective delivery of Complex Innovative Design (CID) trials by the Experimental Cancer Medicine Centres (ECMC) CID trials working group. The working group, which includes the BIA alongside regulators, R&D companies, academics, funders and patients, produced ten recommendations which could speed up drug development, allowing faster patients access to new, innovative treatments.

The traditional clinical development pathway involving phases 1 to 4 trials is increasingly being superseded by CID trials that can address multiple questions at once, such as assessing the safety and toxicity of novel medicines in areas like cancer, and also testing their efficacy in biomarker-selected patients, specific cohorts and in combination treatments. It is worth noting that the late Dame Tessa Jowell called for the increased use of such trials in her speech in the House of Lords two years ago.

The report's recommendations aim to improve the conduct, quality and acceptability of oncology CID trials, covering specific stages from trial planning and design, protocol development, patient and public involvement, statistical analysis to publishing trial results, marketing authorisation and reimbursement.

European Commission updates guidance on the EU Clinical Trials Regulation

In November, the European Commission issued further updates to the Q&A guidance document to facilitate the implementation of the upcoming EU Clinical Trials Regulation. The Regulation will come into application once the Clinical Trial Information System, which includes a submissions portal and trials database, has undergone an independent audit and been confirmed as fully functional.

The updates provide clarity on:

- requests for information from the regulators to help ensure compliance with the timelines specified in the Regulation
- the information that should be included in a layperson summary if a trial were to end prematurely, and the sponsor's responsibilities regarding changes to a clinical trial which are relevant for the supervision of the trial
- the circumstances under which an initial clinical trial application, a substantial amendment or the addition of a member state concerned may be authorised subject to certain conditions

Manufacturing

BIA hosts 16th annual bioProcess UK conference

In November, the BIA's 16th Annual bioProcess UK conference came to Liverpool, where 300 delegates from the manufacturing and bioprocessing communities networked and heard about bioprocessing in the digital age from leaders both within and outside our sector.

The pre-conference networking reception at the Town Hall gave delegates the opportunity to catch-up ahead the two-day conference which included outstanding presentations and panels. Delegates also were taken on site tours of local biopharma manufacturing sites at Allergan, AstraZeneca and Seqirus, as well as Jaguar Land Rover to learn from other sectors. The high point of the conference was the dinner in Liverpool Anglican Cathedral, where delegates entered through a candlelit walkway to the sounds of the organ playing in the rafters.

As always, the conference was a roaring success. The plans are already underway for organising this year's conference, which will be announced shortly.

The bioProcess UK conference dinner was held in the beautiful Liverpool Anglican Cathedral.

Medicines Regulation

BIA engagement on priorities for the future EU-UK relationship

The BIA has continued its engagement with the MHRA, the Office for Life Sciences (OLS) and the Department for Health and Social Care (DHSC) on the future of medicines regulation post-Brexit. The BIA's position is that maintaining close cooperation with the EMA and the European regulatory network on medicines regulation will ensure continued access by UK and EU patients to safe and effective medicines.

Following the ratification of the Withdrawal Agreement by both the UK and European Parliament, the UK will become a third country and move into the implementation/transition period from February to December 2020. It is important to note that we do not envisage any changes to the current regulatory processes that would affect member companies during this period, though the MHRA will not have a role as "leading authority" or in decision making. The Agency's attendance at EMA meetings will be on an exceptional basis.

It is worth adding that the Northern Ireland Protocol in the Withdrawal Agreement will present challenges. The working assumptions are that the EU will control the marketing conditions for centrally authorised medicines for Northern Ireland purposes, while the UK will have authority for vigilance and inspections for products authorised though the centralised and decentralised procedures. The BIA will continue its interaction and contribute to the development of clear guidance.

Government prepares new Bill on medicines regulation

The Government's legislative programme for 2020 that was announced in the Queen's Speech includes a Bill on Medicines and Medical Devices. Baroness Blackwood, Parliamentary Under-Secretary of State, stated in the House of Lords that the Bill "is very much part of our agenda to modernise regulation, supporting early clinical trials and the production of personalised medicines but also the development of ever more sophisticated and safe medical devices".

According to the Government's background briefing, the Bill has several aims that support our sector, including ensuring patients have faster access to innovative medicines and developing a streamlined internationally competitive approach to the licensing and regulation of innovative medicines, clinical trials and medical devices. The BIA will be monitoring the draft Bill, which is expected to be published mid-February, to ensure the best legislative outcome for our members.

EMA holds workshop on draft 'Regulatory Science to 2025' strategy

In November, BIA members contributed to the EMA stakeholder workshop on the draft 'Regulatory Science Strategy to 2025' strategy. Participants discussed the outcome of the public consultation on the draft strategy, to which the BIA provided input together with EuropaBio, in order to identify concrete actions to implement the key goals and recommendations. The final strategy will be a key contribution to the EU Medicines Agencies Network Strategy 2020-2025.

Consultation respondents were asked to choose, among 31 recommendations proposed in the strategy reflection paper, the top three that would deliver the most significant change in the regulatory system over the next five years. The following five areas were identified as key priorities: fostering innovation in clinical trials; promoting the use of high-quality real-world evidence in decision making; reinforcing patient relevance in evidence generation; contributing to HTA preparedness downstream; and supporting developments in precision medicines and biomarkers. The presentations are available the EMA website.

Access to medicines

BIA welcomes Orkambi deal between NHS England and Vertex

In October, NHS England and Vertex came to an agreement that allowed Orkambi to be prescribed to cystic fibrosis patients. The deal came after several years of negotiations and was intended to pave the way for future deals between the two parties, particularly on Vertex's 'triple therapy', which the company is committed to submitting for assessment by NICE.

Commentating on the deal, BIA CEO Steve Bates said:

"We welcome the announcement that NHS England and Vertex have been able to reach a deal and that this drug will soon be available to patients and their families. This is one of a number of deals that the NHS has reached with industry to bring life-saving treatments to patients, showing that the UK's health service is committed to innovation and being at the cutting edge of medical products. Developing treatments for small patient populations with rare diseases is difficult and complex and we applaud the efforts of the company, the NHS, the Secretary of State for Health and the thousands of families whose efforts have led us to a deal."

BIA responds to NHS England's Commercial Framework

In November, NHS England published its draft Commercial Framework for medicines setting out how it intends to undertake commercial negotiations with industry to ensure that patient access to medicines is not impeded by these conversations. The BIA was directly involved in the development of the Framework and attended a workshop alongside other industry representatives earlier in the year where the initial draft was shared for comment.

The BIA submitted a formal response to the draft Framework, broadly welcoming its publications and objectives. The Framework is an important piece of work and it is encouraging to see NHS England deliver much-needed direction on these vital access issues. We look forward to seeing NHS England's analysis of responses and hope that the constructive suggestions in our response are taken on board.

BIA welcomes the new Innovative Medicines Fund

Ahead of the General Election, the Conservative Party announced in its manifesto that it would expand the Cancer Drugs Fund to become an Innovative Medicines Fund with a budget of £500 million. The fund would enable doctors to "use the most advanced, life-saving treatments for conditions such as cancer or autoimmune disease, or for children with other rare diseases".

A dedicated fund to support access to new and innovative medicines has been a key aim of the BIA's members and we were encouraged to see it included in the Conservative manifesto. We look forward to working with the Department of Health and Social Care in coming months to deliver this manifesto pledge.

BIA secures representation on NICE Methods Review Task and Finish Groups

In 2019, NICE announced that it would be undertaking a review of its appraisal methods. Since then, a Working Group has been established, along with several Task and Finish Groups. The groups will focus on specific areas, including Health Technology Assessments (HTAs) costs and health-related quality of life.

The BIA worked with the secretariat to secure BIA representation the groups, which have now been constituted and are meeting regularly with NICE to explore the above issues and other. Their contributions will help to form NICE's new methods, which are due to be published for consultation later in 2020.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Eric Johnsson, Policy and Public Affairs Manager, on 0207 630 2197 or ejohnsson@bioindustry.org.

Not a BIA member? If you want to have a say on policy areas key to the life science sector, contact Michael McGivern, Senior Membership and Business Development Manager, on 0207 630 2194 or mmcgivern@bioindustry.org

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