The award-winning trade association for UK bioscience

UK BioIndustry Association

The BIA's submission to the House of Lords Select Committee on Science and Technology on the Life Sciences and the Industrial Strategy

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About the BIA

Established in 1989, the BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises. BIA members include emerging and more established bioscience companies, pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector.

Our members are responsible for over 90% of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.

Our goal is to secure the UK's position as a global bioscience hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

For additional information or clarification on any of the points raised please contact Rachael Mann, Policy and Public Affairs Manager, on 0207 630 2187 or by emailing rmann@bioindustry.org.

Summary

Science and innovation

- Venture capital funding for UK life sciences is currently relatively healthy but there is a lack of scale-up capital available to support SME growth.

- UK life sciences is supported by a small number of specialist investors, which poses a risk to the long-term stability of the sector. There is a need to increase the pool of knowledgeable investors. Using current British Business Bank investment and the proposed National Investment Fund to support up-and-coming specialist fund managers could help. Scientists should also be supported to enter the profession.

- The Biomedical Catalyst and tax-advantaged venture capital schemes have been critical in encouraging early-stage investment in the sector. The Enterprise Innovation Scheme and Venture Capital Trusts should be enhanced to support access to scale-up capital. In addition, the small and large business R&D Tax Credit schemes are often cited by BIA members as the most valuable form of innovation support and are a competitive advantage for the UK compared to other countries' commercial environments.

- The majority of university-industry interactions work well but there are issues around IP licensing, which constitutes a small but crucial part of the technology transfer system. Creating a more connected and open technology transfer system between the UK's universities could improve this. UKRI has an important role to play here.

- UK life sciences companies are led by talented and experienced management teams. However, there is a shallow pool of these individuals and the UK is in constant competition with our global competitors to attract the best management talent. As the sector grows, demand for these people will increase. The government should conduct an international benchmarking analysis to compare UK incentives for attracting and retaining talent with those elsewhere.

- The UK is an internationally-competitive environment for creating and growing life science businesses. Compared to other European countries, the UK has a very strong fiscal and scientific position. However, increased access to later-stage VC funding is needed to bring the UK closer to the US.

Industrial Strategy

- The UK life sciences sector has achieved its present-day strength through the support of industrial strategies spanning a generation and implemented by governments of all colours. Continuity of support is essential to maintaining global investor confidence in the UK sector.

- For the recently published Life Sciences Industrial Strategy (LSIS) to lead into an effective sector deal and associated policy for the life sciences sector it will require cross-departmental buy-in, ministerial leadership, NHS buy-in, and investment.

- The BIA supports the LSIS' vision to build the UK "life sciences industry into a global hub", which echoes the BIA's 2015 Vision to build a third global bioscience cluster.

- We are pleased to see enabling SME growth as a core aim of the strategy, as without a focus on this key constituent the sector cannot be sustainable or bring prosperity to all parts of the UK. The other components of the strategy are enablers for this: building on strengths in discovery and translational research; supporting innovation in the NHS; harnessing digital technologies and NHS data for R&D; provision of skills; and maintaining the international competitiveness of the UK life science environment.

- All initiatives in the strategy should be open to SMEs and geared towards enabling growth. This includes HARP, opportunities for NHS collaboration and access to digital resources, and skills provision initiatives.

NHS procurement and collaboration

- The LSIS correctly identifies the government's privileged position as a significant and monopolistic purchaser to create a pull for healthcare innovation and support the supply chain.

- The NHS could become a powerful and unique asset for patients and UK life sciences through the combination of world-leading R&D capabilities, ability to create rich data assets, and procurement processes that promote early adoption and real-world product validation.

- Innovation horizon scanning should be used to inform government procurement, enable better budget planning, and ensure value assessments are kept valid and supportive of innovation.

- The government should implement the Accelerated Access Review, including a funded Early Access to Medicines Scheme to enable SME participation and establish the NHS as a world leader in medical innovation.

- Despite previous government initiatives aimed at improving the adoption of innovation by the NHS, the uptake of new treatments remains low and slow. Polling of NHS staff commissioned by the BIA reveals that health care professionals, even at CEO and Board level, have little to no awareness of government initiatives aimed at improving the uptake of innovation across the NHS.

- This lack of awareness among NHS staff is the result of leadership limitation and a lack of robust accountability structures across government and the NHS.

Responsibility and accountability

- For the LSIS to succeed where other similar initiatives have failed will require:
    - cross-departmental buy-in;
    - ministerial leadership;
    - NHS buy-in; and
    - investment from both government and industry.

Brexit

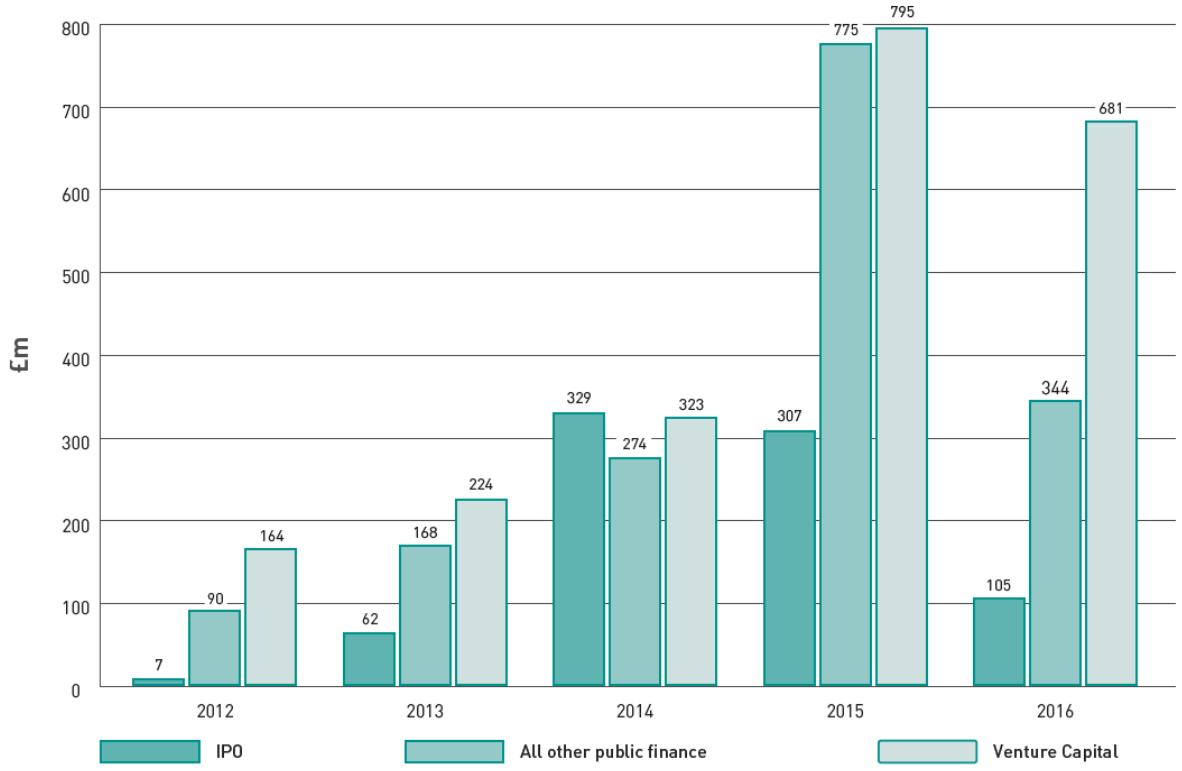
- The impact of Brexit on the life sciences in the UK will be dependent on the deal that the UK achieves with the EU. To secure the best possible outcome for UK life sciences the government should:
    - Secure predictable funding and collaboration for scientific research;
    - Secure cooperation on the regulation of medicines;
    - Secure the ability to trade and move goods and capital across borders; and
    - Secure access to the best talent.

Science and innovation

1. How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector? Does the research base have the necessary infrastructure to be world-leading?

1. The BIA report *Building something great: UK's Global Bioscience Cluster 2016* shows that private investment in UK bioscience has increased significantly in recent years and venture capital funding is notably strong at present[1] (Figure 1). A total of £1.13 billion was raised by UK-based bioscience companies from private and public market sources in 2016. £681 million venture capital (VC) funding was raised, continuing the strong performance seen in 2015, when £795 million was raised. However, lower Initial Public Offering (IPO) activity in 2016 saw only £105 million raised, compared to £307 million in the record-breaking year of 2015. Finance from other sources was also hit by the challenging climate, with £344 million raised in 2016 compared to £775 million in 2015. It is therefore access to scale-up capital that is currently a challenge for life science companies. As Figure 1 shows, the public markets are not a viable source of funding for many companies.

Figure 1: Bioscience financing, 2012-2016



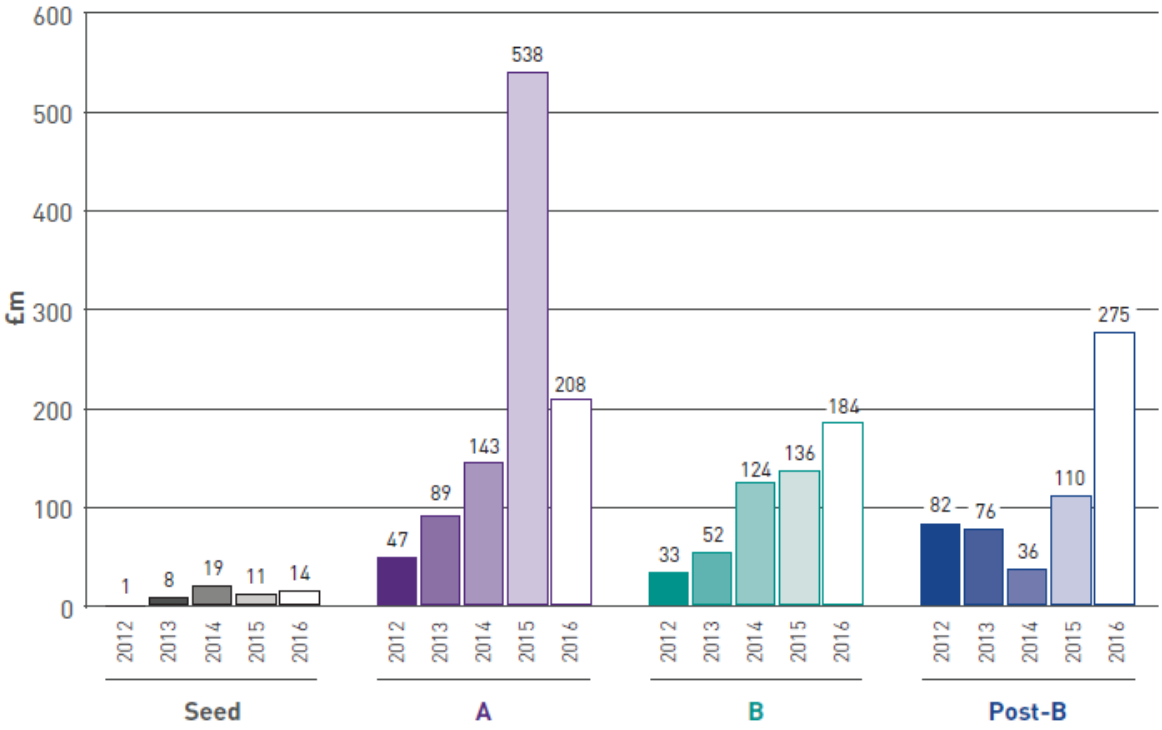
Source: Informa, Strategic Transactions and Scrip

2. Looking specifically at venture capital funding, which is required for turning basic life science research into new innovations, we see the bumper 2015 series-A fundraising has led to larger post-series B fundraises: £275 million was raised in 2016, up from £110 million in 2015 (Figure 2). There was also an increase in series-B funding, with £184 million raised, up from £136 million in 2015. This increase in follow-on funding is reassuring but these later-stage (B and post-B) funding rounds are still not as large as they need to be to support the growth of medium-sized bioscience companies.

[1] BIA (2017), *Building something great: UK's Global Bioscience Cluster 2016*: https://goo.gl/CyQyf6

3. The strong performance seen in 2015 and 2016 has been bolstered by the presence of the Patient Capital Trust and related funds managed by Neil Woodford. In 2016, Woodford's funds invested approximately £300 million in venture capital in the UK, around half of the UK's total, and in 2015 they invested approximately £400 million, around two-thirds of the UK's total. Although there are other significant players – Syncona for example – this lack of diversity in funding sources, and especially sector specialists, has hampered investment to date and does pose a risk to the long-term future of UK life sciences.

Figure 2: Bioscience venture capital financing by funding round, 2012-2016



Source: Informa, Strategic Transactions and Scrip

Increasing investor capacity

4. Technology sectors need investors who understand what they are investing in and have the business skills to support a company throughout its growth. Investors at the early stages of a company's life should be active participants in the stewardship of the business. Without prudent investing, bubbles can form and burst and harm the long-term viability of the sector. The government's currently-ongoing Patient Capital Review[2] should therefore focus more on addressing this potential weakness in the supply of UK long-term patient capital.

5. Increasing the pool of specialist investors would help increase the capital flow into the sector and support long-term sustainable growth. Although we do not have evidence of impact, the BIA welcomes the British Business Bank's support of new fund managers raising their first funds through the Enterprise Capital Fund. This should also be a key focus of the National Investment Fund, proposed in the Patient Capital Review, with sector-specific funds established to focus specialist knowledge. A proactive programme to seek out promising fund managers would also be welcome, targeting such initiatives to sectors afflicted by the greatest dearth of specialists. Supporting young up-and-coming fund managers who have an interest in the long-term health of the sector will support the aims of the Patient Capital Review.

[2] HM Treasury (2017), *Financing growth in innovative firms*: https://goo.gl/1ycw6h

6. A fellowship programme, modelled on the US Kauffman Foundation initiative would also be welcome and should be linked up to science PhD training programmes to increase awareness of such career opportunities to this cohort. It is widely acknowledged that a large proportion of scientists will leave academia at some point in their career as only a few are able to secure tenure. These experts should be considered as prime candidates for specialist investment managers. Many specialist fund managers in the life sciences sector have a PhD, and often post-doctoral research experience, combined with an MBA. These courses are expensive (the Imperial College London full-time MBA is £47,000[3]), which creates a barrier to accessing a career in finance for scientists who typically have modest salaries. The government could support scientists to become specialist investors by providing interest-free loans for MBAs, or a proportion of it, contingent on the individual working in the UK for a set period of time post-award.

Encouraging investment

7. Maintaining the UK's world-leading science base, supported through the Research Councils, is essential to the UK's long-term attractiveness for life sciences investment.

8. Innovate UK funding is also critically important, and directly leverages investment. Through the Biomedical Catalyst, for example, grants to businesses totaling £130 million leveraged over £100 million of additional private capital for the projects[4]. Beyond the government investment, post-award funded companies and academics realised in excess of a further £1 billion in the form of additional private finance, grant funding, via licencing or acquisition. This grant funding supports innovative early-stage companies to conduct R&D in order to attract VC funding. Innovate UK has also recently launched the Investor Accelerator pilot, which aims to better link grant recipients with VC investors.

9. The Enterprise Innovation Scheme (EIS) (and its associated seed scheme, SEIS) incentives have been particularly effective at stimulating investment and are extremely valuable to bioscience companies. These incentives support angel investing by individuals direct into fledgling companies and spin-outs, and also support the raising of specialist VC funds that will be professionally managed. Interestingly, the BIA has also seen evidence that EIS is a strong motivating factor in biotech investors using crowdfunding platforms, which is another welcome route for private money to be channelled into the sector[5]. Venture Capital Trusts (VCT) are also valuable for raising money for later-stage companies. All venture capital schemes should be maintained and enhance where State Aid rules allow.

10. The inherent flaw in EIS and VCT schemes is that investors cannot follow their money in future non-qualifying fundraises. This penalises early investors as they become diluted as a company progresses. To incentivise greater and longer-term investing, EIS and VCT investors should be able to benefit from continued tax relief when investing further in companies they have backed at an early stage, and have preferential access to those further fundraises.

11. Finally, it is worth noting the importance of a supportive commercial environment for attracting investment and supporting company growth, which feeds a virtuous cycle. The small and large business R&D tax credit schemes are often cited by BIA members as the most valuable form of innovation support and are a competitive advantage for the UK compared to other countries' commercial environments. Tax credits provide a minimal-bureaucracy system that rewards and amplifies companies' own investment in R&D. It is crucial to note that tax credits are particularly important for the survival of small companies with negative cash flows, as they provide a non-dilutive source of finance. As the precise research project that will lead to innovation can be difficult to predict, R&D tax credits complement government grant-based schemes, such as the successful Biomedical Catalyst, by providing universal support for R&D.

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3 https://www.imperial.ac.uk/business-school/programmes/admitted-students/fees-and-funding/

4 BIA (2015), *The Biomedical Catalyst: making the case to continue*: http://goo.gl/3MtwaO

5 Helen Wise, Imperial College Business School (2016), MBA dissertation: *Will Crowdfunding Become a Viable Source of Funding for the UK's Biotechnology Industry?* (unpublished)

11) Why has the UK underperformed in turning basic research in the life sciences into intellectual property? What needs to be done to address this historic weakness in the UK and grow new companies to commercialise new research and related technologies in the life sciences?

12. The UK is often said to be an underperformer in the commercialisation of its basic research but this is difficult to measure. The UK's life science sector is strong with a vibrant SME community, many of which are university spin-outs or companies that have acquired university IP. Generally, the environment for creating a science-based company in the UK is very good.

13. However, there are areas for improvement in the UK's technology transfer system. Academia-industry collaborative and contract research constitute the vast majority of technology transfer activities and work well in the UK. IP licensing makes up a small fraction of academia-industry interactions but is where the most friction occurs. This system is not owned by any one constituency; ensuring it works smoothly requires all parties to work well together: research funders, academics, universities and their technology transfer offices (TTOs), entrepreneurs, VC investors, and industry all have a role to play. Equally, there is not one right way, a diversity of approaches to technology transfer should be encouraged.

14. The UK TTO community contains many great people with specific technical and business expertise but there is little incentive or ability to share knowledge or work together across the national ecosystem. There must be ways to increase communication and collaboration beyond the silos of individual universities, leading to more of a matrix approach (not centralised, not siloed).

15. One way to break down barriers and allow more flexibility is to remove the exclusivity universities have on IP generated on their premises; the University of Cambridge provides a precedent for this. Inventors in theory can use any TT channel they want, as long as they meet any obligations to funders.

16. With the creation of UK Research and Innovation, there is an opportunity to assess how the major basic research funders can best promote the commercialisation of the research that they fund.

12) What can be done to ensure the UK has the necessary skills and manpower to build a world class life sciences sector, both within the research base and the NHS?

17. UK life sciences companies are led by talented and experienced management teams. However, there is a shallow pool of these individuals and the UK is in constant competition with our global competitors to attract the best management talent. As the sector grows, demand for these people will increase.

18. This is recognised for academic talent in Pillar 1 of the Industrial Strategy green paper and we would welcome schemes targeted at science industry professionals also, including attracting back British citizens who have worked abroad. The government should conduct an international benchmarking analysis to compare UK incentives with those elsewhere. For example, the Danish expat scheme means that employment income and many company benefits are taxed at a flat rate of 26% for up to five years after the individual returns to Denmark to work[6].

19. The Enterprise Management Incentive (EMI), which provides tax reliefs on employee-owned shares, is a valuable scheme for companies that do not have the cash-flow to pay market-rate salaries. This is true for cash-burning early-stage bioscience companies. However, there is a risk that some individuals, for example part-time Directors or management, are not able to benefit due to the requirements on working hours (>25/week) and total working time (>75% of the individual's total working week). The government should review this to ensure the scheme is equitable and supporting young businesses to access the talent and skills they need to grow.

[6] Deloitte (2017), *Working and living in Denmark*: https://goo.gl/4TfMbv

20. Entrepreneur's Relief is another valuable scheme for rewarding individuals who start and grow a business. However, there is a particular issue for bioscience entrepreneurs when repeated capital raises push their own holding below 5% of the company, at which point they are ineligible for the relief, even though they have built a personal company at risk over several years. This can be a barrier to successful bioscience entrepreneurs exiting companies in a financial position where they are able to reinvest in new ventures. In some circumstances, it can also be a perverse incentive for early, sub-optimal exits to the detriment of the company. A revision of this would be welcome to ensure a fair incentive exists for this level of high risk and personal investment and to encourage a "virtuous cycle" of entrepreneurism. It was helpful for the LSIS to acknowledge that improvements should be made to the Relief.

21. Finally, the immigration system plays a key role in facilitating access to talent of all levels. As the UK leaves the EU the system will likely change. Continued ability to secure the most talented people for UK science can be delivered through an immigration system which facilitates ease of movement for talented students, researchers and workers. This should be needs-based, straightforward, and rapid – providing certainty of outcome. It should project a welcoming and open Britain.

13) How does the UK compare to other countries in this sector, for example Germany and the United States?

22. The UK is an internationally-competitive environment for creating and growing a life science business. However, as is the case for other sectors, the UK lags significantly behind the US in bioscience VC fundraising. The US' two major bioscience hubs, the San Francisco Bay Area and Boston Massachusetts, raised £1535 million and £1550 million, respectively, compared to the UK's £680 million. However, one should take into account the differing sizes of the UK and US economies when viewing these statistics.

23. Closer to home, the UK performs admirably against the rest of Europe, making up over a third of the continent's total VC fundraising. The UK also has a healthy pipeline born of a long history as a venue for drug development. Figure 3 shows that the number of drug products in development (or in registration with the regulators) is higher in the UK than in anywhere else in Europe. The UK cannot afford to be complacent: it faces a strong challenge from France, Germany and the Nordic nations (collectively: Sweden, Denmark, Norway and Finland) in the development of late-stage assets (compounds in Phase III trials or registration). However, behind those late stage assets, the UK also has the strongest early pipeline of drugs in Phase II, Phase I or preclinical development.

Figure 3: European bioscience drug development pipeline, 2016

Country	Preclinical	Phase I	Phase II	Phase III
UK	141	46	74	14
France	99	26	40	14
Italy	25	8	18	13
Germany	119	37	56	9
Denmark	31	12	15	7
Netherlands	54	13	21	7
Belgium	27	15	13	6
Sweden	67	17	37	6
Austria	25	15	10	5
Spain	45	9	23	3
Czech Republic	–	–	3	1
Finland	5	–	6	1
Ireland	13	15	5	1
Poland	10	–	1	1
Hungary	6	2	–	–
Portugal	16	2	3	–
Slovakia	1	–	1	–
Switzerland	–	25	24	12

Source: Informa, PharmaProjects

Note: This assessment of European drug pipelines sets aside the contribution of companies that already have existing products on the market. That means that the extensive development pipelines of the three major UK pharmaceutical companies – GlaxoSmithKline, AstraZeneca, and Shire Pharmaceuticals – are excluded, as are smaller firms such BTG, Allergy Therapeutics and GW Pharmaceuticals and Vernalis which have already launched a number of specialist products between them.

Industrial Strategy

14) What can be learnt from the impact of the 2011 UK Life Sciences Strategy? What evidence is there that a strategy will work for the life sciences sector? How can its success be measured against its stated objectives?

24. The UK bioscience sector has benefited from at least a generation of industrial strategy, including both horizontal and vertical policies (Box 1). These have continued and built upon earlier successful policies from governments of different political make-ups (Box 2), from Margaret Thatcher, to Tony Blair, to Theresa May. Life science R&D is a long-term activity and requires long-term policy commitment and continuity. Through successive policy initiatives and strategy documents, governments have provided direct support to the sector through funding, proportionate regulation, and coordinating functions, for example. But perhaps the most valuable feature of these industrial strategies is the signal they send to global investors that the UK government is committed to making the sector a success.

25. We are half way through the present ten-year 2011 *Strategy for UK Life Sciences,* created by the Coalition Government. *Innovation, Health and Wealth* was also published in that year with the intention, in part, to support the life sciences sector. These strategies have been successful to an extent – for example the Biomedical Catalyst was a key part of the *Strategy for UK Life Sciences* – but have failed to achieve large-scale, systemic change for the sector, especially in respect of the NHS. Understanding how the impact of these strategies was limited in the past will be crucial to the success of a future strategy.

Box 1 - Industrial Strategies for biotechnology, 1980-present

- The Spinks Committee Report – 1980
- Biotechnology Clusters – a report led by Lord Sainsbury, 1999
- Biosciences 2015 – a report to Government by the Biosciences and Growth Team, 2003
- A review of UK health research funding, a report by Sir David Cooksey, 2006
- The Life Sciences Blueprint – 2009
- Innovation, Health and Wealth – 2011
- The UK Life Sciences Strategy - 2011

Box 2 - Key policies for biotechnology, 1980-present

- **1980** – Margaret Thatcher establishes Celltech, a publicly- and privately-owned firm to kick-start the biotechnology industry
- **1984** – the state-owned British Technology Group's monopoly on publicly-funded research intellectual property is abolished
- **1995** – the Alternative Investment Market (AIM) is launched by the London Stock Exchange, providing a source of public capital with lighter-touch regulation than the main market, which largely prevent biotech from listing
- **1997** – the new Labour Government introduces the Enterprise Innovation Scheme (EIS) and Venture Capital Trusts (VCT) to increase availability of venture capital
- **2000** – R&D Tax Credits scheme is introduced
- **2006** – the National Institute for Health Research is established to make the NHS more receptive to research and innovation
- **2009** – the Office for Life Sciences is created
- **2012** – The Biomedical Catalyst is launched (refilled in 2013 and 2016)
- **2013** – the Patent Box is introduced (first announced by Gordon Brown in 2009)

15) (If published) Does the strategy contain the right recommendations? What should it contain/what is missing? How will the life sciences strategy interact with the wider industrial strategy, including regional and devolved administration strategies? How will the strategies be coordinated so that they don't operate in 'silos'?

26. The BIA welcomes the publishing of the Life Sciences Industrial Strategy (LSIS). It is a very positive sign that the entire life sciences sector – biopharmaceuticals, diagnostics, medical research charities, and government agencies – have been able to come together to produce the strategy in such a short period of time. It shows the strength of this highly collaborative community.

27. The BIA supports the strategy's vision to build the UK "life sciences industry into a global hub", which echoes the BIA's 2015 Vision to build the third global bioscience cluster[7]. The BIA agrees that the UK has a globally-unique life sciences ecosystem which we can build upon.

28. We are pleased to see enabling SME growth as a core aim of the strategy, as without a focus on this key constituent, the sector cannot be sustainable or bring prosperity to all parts of the UK. The other components of the strategy are enablers for this: building on strengths in discovery and translational research; supporting innovation in the NHS; harnessing digital technologies and NHS data for R&D; provision of skills; and maintaining the international competitiveness of the UK life science environment.

29. The Healthcare Advanced Research Programme (HARP) is another welcome initiative, although the details of its delivery will be crucial to its success. The US DARPA model, which the programme is to be modelled on, is well-respected in UK industry but scale is important. Getting the funding model and commitment right will be critical to success. Crucially, to meet the aims of the strategy, HARP must be designed to support SME growth, with all aspects open to SME involvement awarded in a fair and open process.

30. Many fiscal measures that could be included in the strategy to support SME growth have been deferred to the Patient Capital Review. The BIA is engaging in this directly and would urge all parties to the strategy to work with the Treasury to ensure the Patient Capital Review and the LSIS aims and policies are aligned.

31. We understand that the strategy will inform the sector deal, part of the wider Industrial Strategy. As stated in response to question five, cross-departmental buy-in and ministerial leadership will be essential to ensuring the implementation of the strategies is coordinated. The Ministerial Industry Strategy Group (MISG), which includes industry and government representatives chaired by the Secretary of State for Health, should be the main forum for industry engagement.

16) What opportunities for small and medium sized enterprises (SMEs) are there/should there be in the strategy? How can they be involved in its development and implementation?

32. The BIA has represented SMEs throughout the development of the strategy and facilitated direct engagement between the strategy's secretariat and our members. We will continue to take this approach as the sector deal is developed and implemented alongside the strategy.

33. All initiatives in the strategy should be open to SMEs and geared towards enabling growth. This includes HARP, opportunities for NHS collaboration and access to digital resources, and skills provision initiatives. If implemented in this way, the strategy provides great opportunities for SMEs. These companies are agile and innovative – exactly what is required to make the best use of the UK's unique science capabilities. Crucially, the strategy identifies a number of disruptive technologies that present opportunities for the UK, including synthetic biology and advanced therapeutics, which are being pioneered by SMEs, many of which are in the BIA membership. Support for these fledgling sub-sectors is very welcome in the strategy.

[7] BIA (2015), *A vision for the UK life sciences sector in 2025:* https://goo.gl/SWM2W5

17) Where should the funding come from to support the implementation of the strategy?

34. The Life Sciences Industrial Strategy has been developed collaboratively between all members of the ecosystem, including government, charities, academia and industry. Equally, the sector deal is to be developed in collaboration. Each party has a responsibility to ensure it is implemented successfully and it will be appropriate for different parties to fund different aspects of its implementation.

18) How do the devolved administrations and city regions fit into the strategy? Scotland has its own life sciences strategy, how will the two interact?

35. The UK life science ecosystem, like the UK itself, has different strengths in different regions and nations. Reflecting this diverse heritage, different organisations play a key role in nurturing, developing and selling the sector in different parts of the country.

36. Some of these organisations link the public sector, local government and the NHS with SMEs and are supported with public money to deliver local economic goals or NHS innovation (for example MedCity and the Northern Health Science Alliance). Others are member owned not for profit organisations paid by company subscription (BioNow, MediWales and One Nucleus). Some (like Scottish Enterprise) are supported by devolved governments, which themselves have different leadership, priority, heritage, power and remit with regard to taxation, the NHS and social care.

37. Despite this complexity the vast majority of ecosystem participants see the virtue in selling the UK proposition to global investors with a common vision and an allied strength. Support for the strategy should and is part of this.

38. As part of this strategy the UK government should map and co-ordinate the full spread of effective clusters/partnerships at local and regional levels and only build on that diversity with appropriate national coordination where required. There is a clear need to do this when selling the UK proposition overseas.

NHS procurement and collaboration

19) How can public procurement, in particular by the NHS, be an effective stimulus for innovation in the Life Sciences Sector? Can it help support emerging businesses in the Life Sciences sector?

39. The Life Sciences Industrial Strategy rightly recognises that the government, through the NHS, is a significant and monopolistic purchaser of healthcare and therefore has considerable opportunity to create a pull for innovation. Procurement should also aim towards supporting the supply chain and establishing robust market participation by several players to drive innovation. The NHS can be harnessed as a powerful and unique asset for patients and UK life sciences when this ability to pull through innovation is combined with the UK's R&D and data capabilities.

Use horizon scanning to inform procurement planning

40. To improve planning of uptake in the NHS, the UK's horizon scanning capacity should be harnessed to inform the Department of Health's annual mandate for NHS England. This annual 'innovation outlook', produced in consultation with industry, would inform NHS planning, patient expectation, and industry forecasting. It would support the Department of Health's budgeting for reasonable expectations of innovations that will be available in 1, 2, 3, 4 and 5 years to enable proper planning for entry of new therapies. This would enable the long development horizons of the drug development industry to be married to NHS service budgeting, planning, and service design, accelerating access over time for new therapies as they arrive. Such horizon scanning would allow value assessment to remain relevant and supportive for innovation.

The Small Business Research Initiative

41. The Small Business Research Initiative (SBRI) is another valuable mechanism for the government to support innovative companies through its own procurement. However, the government must ensure that it is fully utilised across government and the NHS, and a focus placed on how this process can be used for new therapies.

11. How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled?

42. The BIA agrees with the Strategy's recommendation to utilise and broaden the Accelerated Access Review (AAR) to encourage UK investment in clinical and real-world studies and to deliver a conditional reimbursement approval, for implementation as soon as licensing and value milestones are delivered so that patients can benefit sooner.

43. Industry has welcomed that NICE has been forward-thinking about the forthcoming challenges. However, concerns remain around how innovative therapies will meet cost threshold criteria and challenges around 'immature data' and data uncertainty. Marrying the high cost of developing and manufacturing advanced treatments often for low patient numbers with the widespread need for affordable treatments in healthcare systems is a challenge. The UK must acknowledge the challenge and work constructively with all relevant partners - industry, NICE, NHS and government to work through a sustainable and viable pathway for these products to move from bench to the bedside. Many of these products offer the potential of a lifetime cure instead of many years of chronic management, but the durability of the treatments will only be determined over time.

44. Concerns have been expressed that NHS England's overriding interest is to use the infrastructure of the AAR, particularly the Strategic Commercial Unit, to manage costs. The government has also made clear that implementation of the AAR would need to be "mindful of the need to ensure affordability". However, a hard-headed focus on cost-containment across the NHS has played an important part in slowing down the adoption of innovation. For example, in recent years, NHS England has actively sought to manage spending on specialised services,

e.g. divesting the Cancer Drugs Fund, and it has been estimated that 20 per cent of new treatments will be affected by the new budget impact test and potentially all ultra-orphan medicines will be affected by the £100,000 QALY threshold for Highly Specialised Technologies, both of which were introduced on 1st April 2017. It is critical that cost-containment does not act as a barrier to the successful implementation of the AAR.

A funded Early Access to Medicines Scheme

45. The BIA has long advocated for a globally competitive and funded Early Access to Medicines scheme if the UK government is serious about making the UK the go-to place to develop and launch new innovative treatments. The AAR does not, in our view, go far enough in its recommendations on funding.

46. However, the AAR does recommend that £20million to £30million is made available over five years, and signals SMEs as potential recipients of such funding to make this investment most effective. The current non-funded EAMS has made several products available to patients on an early access basis ahead of licensing. However, as the scheme currently stands, companies must supply EAMS medicines free of charge until such time as they gain a positive recommendation from the National Institute for Health and Care Excellence (NICE) – which is not guaranteed – and are commissioned by the NHS. This lack of funding for the scheme poses a barrier to many small bioscience companies from engaging with it. To date, no SMEs have completed the scheme. The recognition of this challenge in the AAR and recommended funding is therefore welcome.

47. In July 2017, the Government announced £6 million over the next three years to support SMEs to gather evidence about how their products perform in the real world, thereby reducing their barriers to market entry. The funds will form part of an overall support package that helps SMEs to generate the evidence NICE and the NHS need for robust assessment of a product's benefit and value for money. In line with the recommendations of the Accelerated Access Review, it is proposed that for medicines the support would be available to SMEs with products participating in the existing EAMS process. While this level of funding is not comparable to the £30million over five years recommended by the AAR, the BIA welcomes the funding as a step in the right direction and we will work collaboratively with government to ensure these limited funds are used to maximum effect. We also await what further commitments may be possible when the government response to the AAR is published.

48. The BIA maintains that to ensure the UK remains internationally competitive and to deliver the Conservative manifesto promise to speed up patients' access to innovative medicines, the government should commit to implementing a globally competitive and funded EAMS. This would result in a win-win-win situation for the UK, enabling NHS patients to be amongst the first to access innovative therapies, enabling innovative SMEs to post revenues sooner, and enabling NHS clinicians to remain key global opinion leaders in their therapy areas.

12. How can collaboration between researchers and the NHS be improved, particularly in light of increased fiscal pressures in the NHS? Will the NHS England research plan help in this regard? How can the ability of the NHS to contribute to the development of and adopting new technology be improved?

49. Despite previous government initiatives aimed at improving the adoption of innovation by the NHS, the uptake of new treatments remains low and slow. The latest Life Sciences Competitiveness indicators, published by OLS in April 2017, show that for NICE-approved medicines launched between 2011 and 2015 the UK rate of uptake in the first 12 months after launch was 18.2% of the median usage in comparable countries[8]. The Life Sciences Industrial Strategy rightly explains that to deliver outstanding patient outcomes and to create an innovation-led health system, innovative products that generate patient benefits should be adopted at a rate that places the UK in the top quartile of comparator countries. The BIA welcomes this ambitious target but we have concerns about how this will be achieved given the failure of previous government-led initiatives to deliver meaningful change.

[8] Office for Life Sciences (2017) *Life Science Competitiveness Indicators,* (Chart 16A): https://goo.gl/bLvXb7

50. Successive governments have introduced many programmes, initiatives and workstreams all designed to bolster the UK's position in the life sciences by improving the adoption of innovation by the NHS. These have been hindered by:
    - A lack of alignment across government and the NHS
        - The Department of Health and the Department for Business has not always integrated the NHS wholly into its life sciences policy
        - Government's ability to coordinate active support for the life sciences sector has been undermined by NHS England's increased role in delivering innovation
    - A lack of consistent and committed leadership
        - The split between Departments for Business and Health for the life sciences remit has meant a lack of consistent and overarching leadership
        - Engagement from the Department of Business and HM Treasury has been inconsistent
        - The Ministerial Industry Strategy Group (MISG) has not always been a driver of long-term partnership due to concentration on short-term challenges, a lack of accountability and variable commitment from sitting members
    - A lack of accountability
        - Lack of leadership and prioritisation from the centre has meant local NHS leaders have rarely been active supporters of the sector
        - Despite the potential of initiatives outlined in the Life Sciences Strategy to drive improvement, these programmes have suffered from lack of focus and lack of national ownership limited engagement from within the NHS, insufficient resourcing and the absence of committed leadership across Whitehall.

51. Polling commissioned by the BIA in March 2017 reveals that staff across the NHS are generally unaware of the challenges around the adoption of innovation and have little to no awareness of previous government initiatives aimed at addressing these challenges and improving the uptake of new treatments[9].

52. In a survey of 1064 NHS staff:

    - 81% of respondents rated the NHS as an average or better than average adopter of innovation compared to alternative health care systems in economically comparable countries, despite the Life Science Competitiveness indicators showing this is not the case.
    - 82% of respondents were not aware of either *Innovation, Health and Wealth* or the Accelerated Access Review, two government-led reports aimed at improving the uptake of innovation across the NHS.
    - Only 11% of respondents were aware of the Accelerated Access Review. This only rose to 36% for CEO and Board-level staff.
    - Only 12% of respondents were aware of *Innovation, Health and Wealth*. This only rose to 29% for CEO and Board-level staff.
    - *Innovation Health and Wealth* recommends a range of initiatives aimed at improving the adoption of innovation across the NHS, many of which are now operational. When presented with a list of these initiatives, almost half (46%) of the respondents said they were not aware of any of them.
    - One output of *Innovation, Health and Wealth* is the Innovation Scorecard, which monitors variation in the uptake of NICE approved medicines in the NHS and is published on a quarterly basis. Only 5% of respondents were aware of the Innovation Scorecard. Even at a Chief Executive and Board level awareness of the initiative was only 11%.
    - The Early Access to Medicines Scheme was introduced via the previous Life Sciences Strategy, published in 2011, and has been operational since March 2014. Yet, only 20% of respondents were aware of the scheme.

53. The Life Sciences Industrial Strategy outlines measures for overcoming what its describes as 'the issue of diffusion and widespread adoption within the NHS,' including shared assessments of UK uptake for NICE approved medicines and audited reports from healthcare providers.

[9] Dods (March 2017), *The adoption of innovation in the NHS: A survey of healthcare professionals on behalf of the BioIndustry Association*

While such initiatives are laudable they will only work if the leadership limitations and lack of robust accountability structures which has led previous, similar initiatives to fail are addressed. The next section of our response sets out how this could be achieved.

Responsibility and accountability

13. Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

14. What is the role of companies within the sector, particularly the large pharmaceutical companies, in the implementation of the strategy? How are they accountable for its success?

15. Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Sciences Minister? If so, should that Minister have UK-wide or England-only responsibilities?

54. The Life Sciences Industrial Strategy and subsequent sector deal are major opportunities to deliver on the promise of UK life sciences to create both health and wealth. To succeed, it is essential that policymakers address the leadership limitations which have resulted in previous similar initiatives failing to deliver meaningful change. This should include:

- *Cross-departmental buy-in*
  The government must ensure that all departments and the NHS are committed to honouring and supporting the sector deals. For life sciences, the Office for Life Sciences should be awarded greater support and resource to coordinate activity in both the Health and Business Departments and link into other departments. Further efforts are required to draw in and engage other critical government departments, namely the Departments of International Trade and Exiting the European Union, alongside HM Treasury, to create a fully functioning and supportive ecosystem that propels the industry.

- *Ministerial leadership*
  Life sciences needs to become a senior Ministerial responsibility. Since the EU referendum the Ministerial Industry Strategy Group (MISG) has proven to be an effective forum for high-level engagement. It is essential this level of prioritisation is maintained. To deliver lasting commitment and shared objectives, MISG needs to become more entrenched in the Department of Health. As well as senior Ministerial attendance from across Whitehall at biannual meetings, MISG needs a permanent presence to provide a forum all year round

- *NHS buy-in*
  Committed leadership and support is also needed from within the NHS to improve rates of innovation uptake and build on the system's potential as a world-class R&D asset for the UK. Both NHS England and NHS Improvement need to appoint an accountable board member for delivering improved rates of innovation and importantly, implementing the Accelerated Access Review. Leadership and accountability for innovation needs to be driven deep into the NHS. Trust and Clinical Commissioning Group leaders should be held to account through national frameworks for uptake.

- *Investment*
  Strategic investments in research and health infrastructure and funding for key policies will be essential to ensure that sector deals have the resources to make a real impact. Industry is ready and willing to be a partner in these investments, with matched-funding a viable option for supporting many facilities and infrastructure.

  The recent investment commitments through the Industrial Strategy Challenges Fund and Biomedical Catalyst are welcome signs that the Government understands that investment is a necessary component of industrial strategy.

Brexit

16. What impact will Brexit have on the Life Sciences sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

55. The impact of Brexit on the life sciences in the UK will be dependent on the deal that the UK achieves with the EU. Additionally, as the life sciences sector requires talented and skilled individuals to thrive, the supply of this talent is impacted by the future immigration system and the development of skilled UK workers in the future. These key elements are issues that the UK government has the ability to deliver upon.

56. Following the outcome of the EU referendum, the BIA worked in conjunction with the ABPI and PwC to consider the impact on our sector. We engaged Government officials and Ministers and in September 2017 presented the findings of a report to the UK EU Life Sciences Steering Group. Our work had covered six areas: regulation; people; manufacturing and supply; R&D; IP; fiscal & trade. Our report distilled this work into four workstreams which highlighted what industry values in each area and how this could be achieved. Our work has sought to provide government with potential solutions, within parameters announced by the Prime Ministers, that impact the life sciences sector:

    - Research Collaboration – there should be long-term, predictable funding for scientific research, and continued ability to collaborate at scale.
    - Trade and supply – there should be the ability to trade and move goods and capital across borders.
    - Regulation – there should be continued regulatory cooperation.
    - People – there should be the ability to secure the most talented people for UK science and industry through a system which facilitates ease of movement for top students, researchers and workers.

17. How should the regulatory framework be changed or improved after Brexit to support the sector?

18. To what extent should the UK remain involved with and contribute to agencies such as the EMA post Brexit?

57. The BIA and ABPI, are seeking regulatory cooperation/partnership for the UK going forward. We believe that cooperation is achievable within the legal parameters required by UK Government. For the mutual benefit of patients and industry in the UK and the EU, the UK should seek to negotiate alignment and commonality with the EU for the regulation of medicines, through:

    - Seeking a regulatory cooperation agreement, or a mutual recognition agreement with the European Medicines Agency
    - Agreeing continued alignment of current and future regulations
    - Ensuring continued UK participation in EU regulatory and medicines safety processes.

58. The BIA welcomed the recent statements by the Secretary of State for Health and the Secretary of State for Business indicating that achieving cooperation between the UK and EU is an objective of the UK Government through the negotiations. We also welcomed the intention of the European Union (Withdrawal) Bill to provide businesses with continuity and certainty as the UK leaves the EU.

59. The UK is a significant contributor to the European Medicines Agency – both in terms of undertaking work and also in contributing data to ensure the safety of patients.

60. The MHRA was Rapporteur or Reference Member State on up to 20% of all centralised procedures and performed over 30% of GMP inspections coordinated by the EMA. Additionally, regulatory procedures for which the UK MHRA is the lead assessment agency (Rapporteur or Reference Member State) will need to be reassigned to an EU Member State agency.

61. It is estimated that approximately 1000 centralised licences are held by a UK-based legal entity and would need to be transferred to an EU-based legal entity in the event of the UK not agreeing cooperation with the EU on the regulation of medicines. The activities were undertaken by industry in good faith prior to the referendum result and industry should not be punitively impacted because of this. If these changes are required, given the short time before the date the UK leaves the EU, it will add significant burden which might impact companies' and regulators' capacity to progress other changes more directly related to medicine quality, safety and efficacy.

62. It should also be highlighted that medical technologies for UK patients are sourced from around the world, with the UK also a significant contributor to global supply. Companies tend to produce medicines on a hub basis and the UK has been a key element of the EU medicines manufacturing hub. Sophisticated supply-chains mean that few products are produced solely in one country of the hub. Simply put, few medicines are produced solely in the UK, and many medicines produced in the EU27 will enter the UK as some time during their manufacture. Barriers at borders could have a significant impact on the production of medicines and therefore in turn on the supply of medicines to patients in both the UK and the EU.

63. The BIA, together with the ABPI, have argued for transition arrangements, given the scale and complexity of supply chains for medicines. The UK Government has proposed that an interim phase be considered, and that any transition be a single transition from the current trading arrangements (including non-tariff, regulatory requirements) to the future arrangements. We are sharing with the UK and EU Negotiating Teams (in continued partnership with the ABPI, other UK life science associations and our European trade bodies) our need for the right process, timing, duration and legal clarity about a transition period and the urgency of having this defined and communicated as soon as possible.