
Now More Than Ever:

Seizing the opportunity to
make the UK a world leader
in the life sciences

EXECUTIVE SUMMARY

2017 marks a pivotal year for the life sciences sector.

As the UK begins the process of withdrawing from the European Union (EU), and parties revisit their manifestos to reflect the changing landscape, there is both great opportunity and significant risk for the UK in cementing its position as a world-leader in life sciences.

Governments frequently and continually herald the life sciences as a sector of great strategic significance. Successive administrations have introduced many programmes, initiatives and workstreams all designed to bolster the UK's position. However, these have been hindered by a lack of alignment across government, limited engagement from within the NHS, insufficient resourcing and the absence of committed leadership across Whitehall.

Ahead of the official publication of the government response to the Accelerated Access Review (AAR), it is critical that the NHS is the centrepiece of the Life Sciences Strategy. Industrial strategies across the world can use fiscal policies and incentives to bolster their economic agendas, but nowhere else has a National Health Service system like the UK.

With the scale of the challenges facing the sector, now more than ever policymakers need to be bolder than before. In particular, government needs to act in three key areas:

BUY-IN AND IMPLEMENTATION

- **Cross-sectoral buy-in**

For the benefit of industry, the NHS and UK plc., it is critical the Office for Life Sciences (OLS) is awarded greater support and resource, and that the Department for Business, Energy and Industrial Strategy (BEIS) exercises greater influence over all aspects of life sciences policy

- **Ministerial buy-in**

To deliver lasting commitment and shared objectives to support the sector and improve uptake, the Ministerial Industry Strategy Group (MISG) needs to become more entrenched in the Department of Health, with guaranteed Secretary of State attendance from both the Health and Business Departments at biannual meetings, who are held accountable through the development of a series of measurable objectives on the use of innovation

- **NHS buy-in and implementation**

Both NHS England and NHS Improvement need to appoint an accountable board member for delivering improved rates of innovation and importantly, implementing the AAR, and a mechanism established whereby trust and CCG leaders are held to account through national frameworks for uptake

MECHANISMS FOR UPTAKE

- **Clarity on the micro-detail around the AAR**

To support what is currently a collection of high-level aspirations, via a designated lead and accountability framework established to drive forward its implementation and ensure the AAR supports adoption at scale

- **Consideration towards fundamental reform of assessment and reimbursement**

The forthcoming PPRS should seek to secure a real commitment towards flexible pricing and more complex patient access schemes, to allow for the adoption of a variant of multi-indication pricing – with NHS England, government and industry all committed to mechanisms which will allow it to work

- **A central resource dedicated to funding early access**

Such as through Early Access to Medicines Scheme (EAMS) and ensuring viable commercial avenues for promising innovative medicines

- **Clearly defined targets to measure improvement in uptake**

To be agreed by industry and government and actively worked towards via the MISG who will be held accountable for its delivery, e.g. for the UK's relative uptake per capita of new medicines approved by NICE to be equal to or above the European average by 2020

CHAPTER ONE: LEADING THE LIFE SCIENCES SECTOR

Successive governments have identified life sciences as a sector of strategic significance. Yet despite numerous strategies and initiatives that have sought to strengthen the foundations of UK life sciences, these policies have not delivered consistent leadership and support.

BUILDING THE FOUNDATIONS FOR GROWTH – PAST AND PRESENT

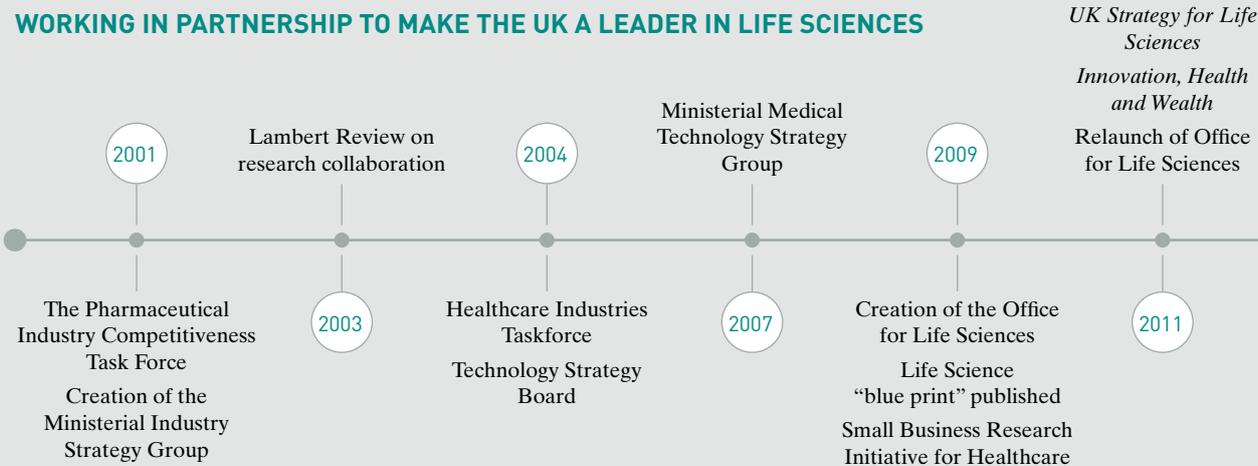
Following the EU referendum, Theresa May’s government moved quickly to introduce reforms designed to support key sectors of the UK economy. The new Industrial Strategy – on pause until the outcome of the June 8th general election is known – pledged more active support from government to boost the UK’s competitiveness and create the foundations for long-term growth. Alongside financial services and the automotive industry, the life sciences industry was prioritised by the Government and a sector specific industrial strategy is set to be published in spring 2017.

Previous strategies, such as the 2011 *A Strategy to UK Life Sciences*, have sought to bind the government and industry into long-term partnership, and in particular, use the power of the NHS as a single integrated system as a differentiator for the UK market¹. However, despite early momentum these programmes have never been fully implemented.

“A prime example of what is needed in a successful knowledge economy.”²

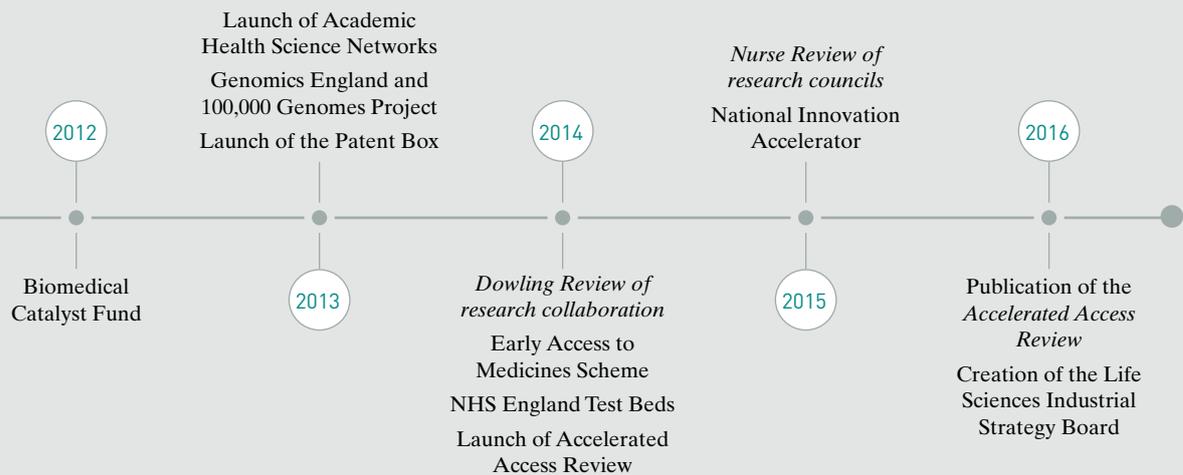
TONY BLAIR, 2001

WORKING IN PARTNERSHIP TO MAKE THE UK A LEADER IN LIFE SCIENCES



¹ Department of Business, Innovation and Skills (2011), Strategy for UK Life Sciences.

² Department of Health (2001), Pharmaceutical Industry Competitiveness Taskforce.



Where the Life Sciences Strategy went wrong

Previous strategies have made repeated promises and proposals, but a range of limitations have meant that each attempt to bolster the sector has failed to deliver long-term and lasting change.

- **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

“A jewel in the crown of our economy.”³

DAVID CAMERON, 2011

³ HM Government (2011), “PM speech on life sciences and opening up the NHS”, 6 December.

What needs to happen this time?

A Life Sciences Industrial Strategy will be a major opportunity to deliver on the promise of the sector to create both health and wealth. To succeed, it is essential that policymakers address the leadership limitations of the last Life Sciences Strategy.

BUY IN AND IMPLEMENTATION

- **Cross-sectoral buy-in**

For the benefit of industry, the NHS and UK plc., it is critical the OLS is awarded greater support and resource, and that the Department for Business, Energy and Industrial Strategy exercises greater influence over all aspects of life sciences policy

- **Ministerial buy-in**

To deliver lasting commitment and shared objectives to support the sector and improve uptake, the Ministerial Industry Strategy Group (MISG) needs to become more entrenched in the Department of Health (and by extension NHS England), with guaranteed Secretary of State attendance from both the Health and Business Departments at biannual meetings, who are held accountable through the development of a series of measurable objectives on the use of innovation

- **NHS buy-in and implementation**

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 (AAR). Alongside this, a mechanism ought to be established whereby trust and CCG leaders are held to account through national frameworks for uptake.

“It is hard to think of an industry of greater strategic importance to the UK than its pharmaceutical industry.”⁴

— THERESA MAY, 2016

⁴ Conservatives (2016), “We can make Britain a country that works for everyone”, 11 July.

CHAPTER TWO: INCENTIVISING RESEARCH AND DISCOVERY

The UK has a rich and long history in the life sciences, second only to the United States as a global leader.

WORLD CLASS SCIENTIFIC INFRASTRUCTURE

- Second highest share of life sciences academic citations in the developed world⁵
- Ranked second globally for the quality of science institutions⁶

REGIONAL CENTRES OF EXCELLENCE

- Home to Europe's largest biomedical centre, the Crick Institute
- NHS hosts some of the world's leading medical centres, including the Royal Marsden, the Christie and Moorfields

WORLD CLASS RESEARCH PARTNERS

- World-leading universities; 3 of the top 10 and 12 of the top 100 global academic institutions are based in the UK⁷
- World-leading medical research charities, such as Cancer Research and Alzheimer's Research UK

GOVERNMENT SUPPORT FOR SCIENCE AND RESEARCH

- Protected science funding from government since 2010, with the total budget now standing at £4.7 billion

However, despite the UK having strong foundations and heritage in the life sciences, evidence is beginning to emerge that the industry is retreating.

- UK investment in private and public R&D currently stands at 1.7 per cent of GDP, below the OECD average of 2.4 per cent⁸; biopharma R&D accounts for the highest spend per sector on R&D
 - 3 of the top 6 R&D spenders in Europe are pharmaceuticals, yet none of these have a significant presence in the UK⁹
- Business investment in R&D is just over half of one per cent, close to half the target rate and other Western European countries, including Germany¹⁰
- The government's own Life Science Competitiveness Indicators, first published in 2015, further revealed that the number of

people employed in medtech¹¹ manufacturing fell by a quarter between 2010 to 2015. A similar trend was experienced in pharma, which recovered slightly in 2015 increasing by 2.2 per cent following a downwards trend for the first half of the decade¹²

- Pharmaceutical spending on R&D has fallen from a high in 2011, recovering only slightly in 2015¹³
- Private equity investment has fallen between 2010 and 2015, from €1.4 billion to €0.72 billion¹⁴; this correlates with few new biotechs being able to secure the necessary investment to scale up and ending up in the so-called "Valley of Death" between seed-funding and venture capital

⁵ Office for Life Sciences (2016), Life Sciences Competitiveness Indicators.

⁶ House of Commons Science and Technology Committee (2015), The Science Budget.

⁷ HM Government (2017), Building our Industrial Strategy: Green Paper.

⁸ HM Government (2017), Building our Industrial Strategy: Green Paper, p.26.

⁹ European Commission (2014), EU R&D Scoreboard.

¹⁰ HM Government (2017), Building our Industrial Strategy: Green Paper, p.26.

¹¹ Office for Life Sciences (2017), Life Sciences Competitiveness Indicators, p.9.

¹² Office for Life Sciences (2017), Life Sciences Competitiveness Indicators, p.8.

¹³ Office for Life Sciences (2017), Life Sciences Competitiveness Indicators, p.25.

¹⁴ Office for Life Sciences (2017), Life Sciences Competitiveness Indicators, p.19.

Brexit means new threats are emerging for industry.

Since the EU referendum, the UK life sciences sector has faced considerable uncertainty. “With the Conservative Government setting the path for a ‘harder’ Brexit”, some of the key features that have ensured the UK has remained an attractive site for life science investment have been thrown into doubt.



ACCESS TO TALENT

The ability for industry, research institutions and the NHS to attract the best talent in the world is widely recognised to be essential to the strength of life sciences in the UK.

While Theresa May declared that the UK will remain open to immigration, particularly high-skilled immigration, there was little detail on what a future system might look like or how it would work in practice.



REGULATION

Leaving the European Medicines Agency (EMA) will not only require significant amounts of time and resource, but will mean the smaller UK market may become a less attractive location for product launches. Such an approach could leave NHS patients waiting 12 – 24 months after patients in Europe for access to new medicines, worsening the existing perception that the UK is “low and slow” in the adoption of medicines.¹⁵



ACCESS TO SCIENCE FUNDING

The UK has been a major net beneficiary of EU funding for research.¹⁶ Nearly one fifth of EU funding to the UK is spent on research and development. To date, the UK has secured 15.4 per cent of the seven-year Horizon 2020 research and innovation investment programme.¹⁷

While the incumbent government has pledged to match all EU-funded projects signed before the referendum, it is unclear if funding and pan-European science projects will be maintained post-Brexit.



GROWING GLOBAL COMPETITION

The challenges posed by Brexit and cost-containment policies in the NHS come at a time when global competition for life science investment is growing.

Other European markets have been developing their own life science clusters, and several European cities are now queueing up to be the next location of the EMA when it leaves its current base in London. The next country to host the EMA will likely benefit from an immediate boost in investment and interest from pharmaceutical companies.

Many countries have improved their use of fiscal incentives in recent years to attract inward investment, with all eyes on the Trump administration in the US and emerging markets such as Singapore and South Korea, which are rapidly becoming fertile ground for biotech and mid-sized pharmaceutical companies due to active state support and a strengthening science base.

¹⁵ ABPI/BIA (2016), Maintaining and growing the UK’s world leading Life Sciences sector in the context of leaving the EU.

¹⁶ House of Lords Science and Technology Committee (2016), EU Membership and UK science.

¹⁷ House of Commons Science and Technology Committee (2016), EU regulation of the life sciences.

How can the government create opportunity for the life sciences?

May's government set out its intention to strengthen many of the pillars of the UK life science sector. Many of these build on past initiatives and the cornerstone commitment to protect science funding since 2010; for example, the 2016 Autumn Statement also announced a review of R&D tax incentives and of patient capital, as well as an extension of the Biomedical Catalyst Fund.¹⁸ More can be done to encourage and improve investment in research and development.

INCENTIVES FOR RESEARCH AND DISCOVERY

- **Greater ambition in our economic incentives**

To create fiscal conditions that strengthen or attract investment and support start-ups – namely via patient capital and tax relief schemes – with an expansion of this support to third sector leaders in R&D (namely medical research charities)

- **An extension of intellectual property rights**

To provide a powerful incentive for discovery, as well as direct aid to support inward investment in manufacturing and R&D sites

¹⁸ HM Treasury (2016), Autumn Statement.

CHAPTER THREE: NEW MECHANISMS TO DRIVE UPTAKE

Previous efforts to improve uptake in the NHS have failed.

An essential theme in the 2011 Life Sciences Strategy and Innovation, Health and Wealth (IHW) was making the NHS a stronger partner in uptake and discovery.¹⁹ However, beneath the creation of new bodies and initiatives, there was limited change in how the NHS introduced and supported innovation.²⁰

Despite a commitment in the 2014 PPRS that NHS England would implement IHW fully, the initiative has had limited impact. Although pledges in the PPRS indicated measures towards flexible pricing and more complex patient schemes, there has been little movement in introducing reforms such as multi-indication pricing. Despite assurances given at the time, the PPRS rebate has not been reinvested in innovation in the English NHS.

Initiatives to support discovery and launching products – such as data sharing through care.data – have also stalled, while some parts of the NHS continue to be reluctant partners with life science innovators.

A lack of resource to drive change has hindered the success of previous initiatives designed to bolster the life sciences. Targeted funding to support the ambitions of both the Life Sciences Strategy and IHW were not believed to be sufficient to change behaviours, while central funding for AHSNs has been limited, with the Networks increasingly expected to raise their income to support their work.

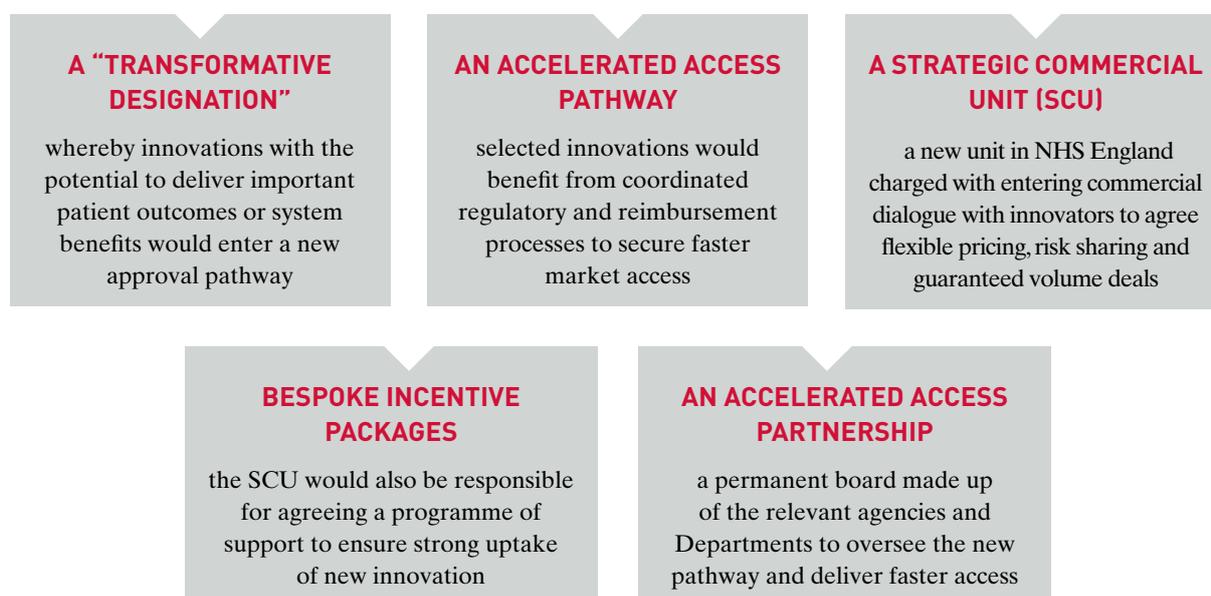
¹⁹ Department of Health (2011), Innovation Health and Wealth: Accelerating Adoption and Diffusion in the NHS.

²⁰ Bienkowska-Gibbs, T. et al. (2016), Evaluating the role and contribution of innovation to health and wealth in the UK, RAND Europe.

Accelerated Access Review – making the NHS the best placed to launch medicines?

Building on the unique strengths of the NHS will be an essential differentiator for the UK market. The AAR has set out a number of important reforms that could ensure the NHS is able to become a true partner in innovation, both in delivering better uptake of medicines but also leading the discovery and development of next generation treatments.

The final report, published in October 2016, set out 18 core recommendations focused on facilitating coordinated action across agencies and Departments to shorten timescales to give patients access to the most innovative treatments by up to four years.²¹ In particular:



Alongside the proposals to fast-track access for a selected number of medicines and other technologies, the AAR also sought to identify ways to improve uptake of all medicines.

The AAR essentially built on many of the changes that were first introduced by IHW, and would have likely formed the basis of an expected "refresh" of that initiative. The final AAR report highlighted several changes that could be introduced to strengthen the existing infrastructure, designed to improve adoption and diffusion:

- **New mandate for AHSNs**

A new "charter" to reset expectations, with a sharper and more specific focus, and to enable accountability, with additional funding available to allow AHSNs to commission evaluations of medicines and pump-prime service redesign

- **Improve incentives for adoption**

NHS England, NICE and NHS Improvement to partner to align budgetary and financial incentives for adoption of medicines

- **Better data and transparency**

Improved digital infrastructure through implementation of changes proposed in the Wachter Review and improvements to make the Innovation Scorecard more accessible

However, the final AAR report failed to capitalise on the bold thinking of the interim report, which considered solutions to complex issues of how to price multi-indication therapies and implement new commercial models. Commercial viability and attractiveness, defined by inward investment, will be a key component of delivering the latest innovations to patients.

²¹ Department of Health (2016), Accelerated Access Review: Final Report.

Where next? Implementing the AAR

Successful and timely implementation of the review, particularly in light of previous reports that set out similar proposals to fast-track the approval process and harness incentives for better use of innovation, remains the key challenge.

GETTING ONTO THE PATHWAY

- Final report provided limited detail on how the “transformative designation” would be applied to innovations, and what criteria would determine which medicines were selected for the Accelerated Access Pathway
- System only prepared to recognise between 5-10 products and technologies each year; without wider reform to assessment, pricing or funding mechanisms many medicines will still be in the slow lane
- Participation on the Accelerated Access Pathway is also ultimately dependent on innovators being able to agree a commercial deal with NHS England to manage access or share risk with faster reimbursement

STILL NO UPTAKE

- The AAR included few concrete proposals to address slow and low uptake; the most definite suggestions were to improve the infrastructure and mechanisms created by IHW, such as AHSNs and the Innovation Scorecard

MAINTAINING MOMENTUM

- The fate of other cross-governmental taskforces suggests that too often joint action and momentum can be hard to maintain; making the partnership work will require determined leadership and lasting ministerial interest in holding it to account

INNOVATION IS GOING BACKWARD

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”²².

However, a focus on cost-containment across the NHS played an important part in slowing down the adoption of innovation in the NHS. 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 HST²³.

It is critical that cost-containment does not act as a barrier to the successful implementation of the AAR.

²²PharmaTimes (2016), “Gov’t publishes findings of Accelerated Access Review”, 24th October.

²³ABPI (2017), Response to NICE/NHS England consultation on “Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE’s Technology Appraisal and Highly Specialised Technologies programmes.”

Making the NHS a partner in innovation

For life science companies, the ability to partner and access a single integrated healthcare system with a single payor and comparatively centralised and coordinated national policy, has long made the NHS an attractive feature of the UK life sciences ecosystem.

With the benefit of real-time and real-world data on clinical effectiveness, the NHS can be one of the best systems to launch new medicines. The recent “Test Bed” programme provides industry with the opportunity to partner with local NHS health economies to trial new technologies and prove their effectiveness.

The next twelve months will be an important time to harness the role of the NHS to foster innovation. To deliver on the vision of the AAR, policymakers need to be bold in creating policies that can put the UK ahead of other markets in allowing faster access and uptake.

MECHANISMS FOR UPTAKE

- **Clarity on the micro-detail around the AAR**

To support what is currently a collection of high-level aspirations, via a designated lead and accountability framework established to drive forward its implementation and ensure the AAR supports adoption at scale

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ABOUT THE BIOINDUSTRY ASSOCIATION

Founded over 25 years ago, at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative enterprises involved in UK bioscience.

Members include emerging and more established bioscience companies; pharmaceutical companies; academic, research and philanthropic organisations; and service providers to the bioscience sector. The BIA represents the interests of its members to a broad section of stakeholders, from government and regulators to patient groups and the media.

Our goal is to secure the UK's position as a global 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.

This report was produced following a roundtable hosted by the BIA on January 19th 2017, sponsored by AbbVie, Sanofi and UCB. The event brought together the following key stakeholders to discuss "Making the UK a global centre for life sciences through the Industrial Strategy":

1. **Steve Bates**, Chief Executive, BioIndustry Association
2. **Aisling Burnand**, Chief Executive, Association of Medical Research Charities
3. **Ross Carroll**, Public Affairs Director (UK), UCB
4. **Sir John Chisholm**, Executive Chair, Genomics England
5. **Sir Andrew Dillon**, Chief Executive, National Institute for Health and Care Excellence (NICE)
6. **Ms Tara Donnelly**, Chief Executive, South London AHSN/Health Innovation Network
7. **Mike Farrar**, former Chief Executive of the NHS Confederation (Chair)
8. **Dr Steve Feast**, Chief Executive, Eastern AHSN
9. **Hugo Fry**, General Manager (UK), Sanofi
10. **Amy Galea**, Senior Strategy Advisor, NHS England
11. **Ellen Graham**, Head of Medicines, Diagnostics and Personalised Medicine, NHS England
12. **Dr Ian Hudson**, Chief Executive, Medicines & Healthcare Products Regulatory Agency
13. **Dr Nicole Mather**, Director, Office for Life Sciences
14. **Dr Matt Norton**, Director of Policy, Alzheimer's Research UK
15. **Lord Prior of Brampton**, Parliamentary Under Secretary of State, Department for Business, Energy and Industrial Strategy
16. **Sir John Savill**, Chief Executive, Medical Research Council
17. **Dr Phil Schwab**, Director of Governmental Affairs (UK), AbbVie
18. **Dr Beth Thompson**, Senior Policy Adviser, Wellcome Trust
19. **Dr Hakim Yadi**, Chief Executive, Northern Health Science Alliance
20. **Professor Tony Young**, National Clinical Lead for Innovation, NHS England

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