Life Sciences and the Industrial Strategy

House of Lords Science and Technology Committee

September 2017

Summary

1. We welcome the opportunity to respond to this inquiry on the Life Sciences and Industrial Strategy. This response has been led by the Royal Academy of Engineering, with contributions from the Institution of Mechanical Engineers and the Institute of Measurement and Control. It has been developed with input from the Academy's Medical Technologies Community of Practice, composed of Fellows working in healthcare technologies, and our Biomedical Engineering Panel, a special interest group hosted by the Academy with membership from across the biomedical engineering landscape.

2. The key messages can be summarised as:

3. **SMEs are central to the medical technologies sector** – The large majority of companies in the medical technologies sector are SMEs, with 41% employing fewer than five employees. Support for the commercialisation of research, research and development in SMEs, and growing companies are therefore key for this sector.

4. **Long-term availability of funding is crucial** – Long-term public and private investment are crucial in the life science sector. We welcome recommendations in the *Life Sciences Industrial Strategy* for further long-term, large-scale funding for the life sciences sector and the government's ongoing review of patient capital, which will have important implications for the sector.

5. **Research in the NHS is central to healthcare innovation** – Innovators, particularly of disruptive technologies, can find it difficult to access the NHS for research. The Academy recommends the establishment of '**national innovation assets**' across sectors to act as testbeds for new innovations and highlight innovation opportunities across the UK and attract investment. For the life sciences sector, these could build on National Institute for Health Research (NIHR) infrastructure and focus on improving access for innovators, particularly SMEs.

6. **The route to market must be clear –** For some disruptive technologies, the route to regulatory approval and market access in the NHS can be unclear. Further clarity and guidance, particularly for SMEs, as proposed in the Accelerated Access Review (AAR), would be valuable and we welcome the proposal to implement these recommendations. The Academic Health Science Networks (AHSNs) should also collaborate to facilitate the diffusion of innovation nationally in addition to supporting local innovation.

7. **Transparent, easy-to-access procurement opportunities are vital for SMEs** – Support for research and development in SMEs, without support for market access, cannot facilitate industrial growth. Increased and improved use of the Small Business Research Initiative (SBRI) could be one mechanism to support procurement.

8. **The industrial strategy should take a systems approach** – A coherent strategy must bring together research, innovation, regulation, evaluation, and uptake in the NHS. This depends on a joined-up approach across all relevant departments and agencies, as well as with devolved governments, regional and local institutions. Interdependencies with the broader industrial strategy must also be recognised to maximise opportunities and ensure that strategies do not become siloed.

Introduction

9. This response has been led by the Royal Academy of Engineering, with contributions from the Institution of Mechanical Engineers and the Institute of Measurement and Control. It has been developed with input from the Academy's Medical Technologies Community of Practice, composed of Fellows working in healthcare technologies, and our Biomedical Engineering Panel, a special interest group hosted by the Academy with membership from across the biomedical engineering landscape. The response also draws on the wider work of the Academy, notably of our Enterprise Hub that supports the country's most promising engineering entrepreneurs and has over 40% of current members working in the biomedical or health engineering fields.

10. Biomedical engineering creates new medical technologies and systems that can greatly improve patient care and quality of life and is an increasingly important area of engineering in which the UK is taking a lead. This response focuses on the field of biomedical engineering and the associated rapidly advancing industrial sectors of medical and digital health technologies.

Science and innovation

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?

Investment

11. In recent years, there has been significant investment in life science innovation in the UK by both public and private sectors. The following paragraphs outline areas of success in attracting investment, which should be built on, and areas where investment has been lacking or could be improved.

12. **Public funding** – There have been a number of public funding programmes that have been successful at supporting innovation and leveraging private investment and these should be sustained and built upon. These include the Biomedical Catalyst and the NIHR i4i programme[1,2]. It is important that public funding instruments are available to support product development as well as research and, given the long time frame of the innovation cycle in the life sciences, there should be a focus on large-scale long-term funding in addition to short-term grants, with a joined-up approach across the Research Councils, Innovate UK, and NIHR. Proposed funding for research and innovation as outlined in the *Life Sciences Industrial Strategy*, including for large-scale projects, is therefore welcome. The recent launch of the Digital Health Technology Catalyst by Innovate UK to expand funding opportunities, specifically for the digital health sector, is also welcome, and this should accelerate progress and leverage further investment in this field.

13. **EU funding** – The UK has received significant support from EU research and innovation framework programmes and the European Investment Fund (EIF). UK SMEs received over £650 million in funding from European Framework Programme 7 which ran from 2007 to 2013[3], and in the Innovative Medicines Initiative (IMI), an EU life sciences public-private partnership, UK SMEs have attracted 21% of total SME funding[4]. From 2011 to 2015, the

[1] The Biomedical Catalyst: Making the case to continue, BioIndustry Association, 2015
[2] Evaluating the Impact of the NIHR Invention for Innovation (i4i) Programme, RAND Europe, 2015
[3] The role of EU funding in UK research and innovation, Technopolis, 2017
[4] UK Participation in the Innovative Medicines Initiative, ABPI, 2016

EIF supported 144 venture capital and private equity funds in the UK and had a total of €2.3 billion in commitments in the UK, leveraging a further €13.8 billion of additional funds[5]. It will be crucial for the UK to maintain or replace the support for SMEs in the life sciences sector that is currently provided by EU sources to ensure that investment is not lacking in this sector going forwards.

14. **Early-stage private investment** – Compared to other sectors, private investment in early-stage life sciences companies is in relatively good health. In the UK in 2016, the overall number of equity investment deals and the amount of equity invested fell by 18% and 12% respectively compared to 2015. However, investments in the UK life sciences sector was an exception, with a 19% increase in the number of seed stage deals and a record £202 million invested in 2016[6].

15. **Scale-up private investment** – Despite this seemingly healthy environment for early-stage life sciences companies, concerns remain about a lack of investment to support UK companies to grow to scale, as noted in the *Life Sciences Industrial Strategy*. Although this problem is not limited to the life sciences sector the government's recent Patient Capital consultation document observes that 'only one quoted UK incorporated firm in the life sciences industry has grown beyond a £5 billion market capitalisation since 1999, with other firms being acquired before this point'[7], and the long time frame of the innovation cycle makes patient capital particularly important for this sector. A further concern in this sector is the need to ensure that capital is available throughout the supply chain, not just to high profile therapy or device developers. There are a number of reasons why scale-up funding and patient capital have been lacking in this sector; the Academy welcomes the government's ongoing review of patient capital and will be submitting evidence to it.

16. **Pathway to market** – Investors must consider the whole value chain of innovation, including the route to market. For some disruptive life science technologies, the route to regulatory approval and market access in the NHS can be unclear, which can be a barrier to investment. Further clarity and guidance as proposed in the AAR[8] would be valuable to facilitate investment in the sector (see questions 10 and 11, paragraphs 53-58).

Infrastructure

17. The following paragraphs describe areas where UK infrastructure could be further developed to support translation and innovation and to attract investment into the UK as a world-leading centre for the life sciences.

18. **Catapults** – Catapults play an important role supporting innovations to bridge the gap from R&D to commercialisation. The existing life sciences Catapults are focused on medicines and therapies; it may be valuable to consider whether there are gaps in the Catapult network for supporting other areas of the life sciences sector. It has been suggested that the Catapults could be developed to further support collaboration between academia, SMEs, and large industry in the life sciences sector. Further collaboration across Catapults could also be valuable to ensure that UK expertise is accessible across sectors. For example, the life sciences sector will benefit from developments in artificial intelligence (AI), robotics, and virtual and augmented reality technologies.

19. **Incubators and other supportive infrastructure** – The UK medical technologies industry is disproportionately populated by SMEs compared to other areas of the life

[5] EIF in United Kingdom, European Investment Fund, 2016, p1

[6] The Deal, Year 2016, Beauhurst

[7] Financing growth in innovative firms: consultation, HT, July 2017

[8] Accelerated Access Review An independently chaired report supported by the Wellcome Trust. 2016

sciences sector (see paragraph 23), which can lead to a fragmented landscape. Supportive infrastructure such as hubs, incubators, or regional networks should aim to facilitate connections across the sector, and support SMEs to form partnerships and work collaboratively, building on their distinct strengths and expertise. Such infrastructure may be particularly valuable in supporting regional innovation[9].

20. **Clinical research in the NHS** – Clinical research within the NHS is vital for innovation in the UK life sciences sector. The NIHR and associated infrastructure have facilitated such research, but SMEs still report challenges in accessing and conducting research in the NHS. The government's commitment to continued development of the NIHR infrastructure as suggested in the *Life Sciences Industrial Strategy*, particularly the £14 million further investment in NIHR medical technology co-operatives is welcome. These should particularly seek to take into account the needs of SMEs in collaborating with the NHS (see question 12, paragraphs 59-62).

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?

21. There is a widely held perception that other countries have been more effective at extracting economic value from ideas generated by the UK knowledge base than the UK has been itself. Although quantitative evidence for this is hard to find, there are certainly numerous examples that suggest this is the case[10].

22. Foreign investment based on UK-generated knowledge should be welcomed, especially where those companies have UK-based development and manufacturing operations. Nevertheless, it is essential that the UK possesses the ability to capture value from its own investments in research, and from ideas generated overseas.

23. There are currently very few global medical device or technology firms with a UK R&D presence; in these sectors only 3% of companies in the UK have over 250 employees[11]. The large majority are SMEs, with 41% of companies employing fewer than five employees[11]. This sector has a high level of emerging and innovative companies: the Academy's Enterprise Hub, which supports the country's most promising engineering entrepreneurs[12], has over 40% of current members working in the biomedical or health engineering fields. It therefore follows that, since the UK medical device and technology sector is dominated by very small SMEs, interventions targeted at supporting the growth of these companies, from establishment through to maturity, could have a significant impact on the sector:

24. **Commercialisation of academic research** – The UK has an excellent academic research base in biomedical sciences and biomedical engineering; measured by citation impact the UK ranks second in the world in quality of biomedical engineering research[13]. This research base generates wide-ranging ideas for the improvement of health, many of which can be commercialised. As part of their mission to deliver impact for society, including the

[9] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017

[10] Principles of Economics, Marshall, 1890; Plan I The Case for Innovation-Led Growth, NESTA, 2012

[11] Strength and opportunity 2015, Office for Life Sciences

[12] https://enterprisehub.raeng.org.uk/

[13] Biomedical Engineering: Advancing UK healthcare, Institution of Mechanical Engineers, 2014

economy, universities should ensure that the primary objective of their approach to the commercialisation of research is the exploitation of intellectual property (IP), not just its protection.

25. Spin-out companies are one route for the commercialisation of academic research. The overall perception in the UK engineering community is that there is still room for improvement in the spinning out process[14]. A lack of understanding by the academic entrepreneur of the spin-out process and of the different perspectives of stakeholders contributes to difficulties encountered in the spin-out process and puts academic founders at a disadvantage when entering negotiations. Levelling this information asymmetry between academic entrepreneurs new to the process and experienced university staff should result in an improvement in the spin-out process for all parties involved. Universities should ensure that their IP policies and information about their approach to the spin-out process are easy to find and, ideally, publicly available.

26. The division of equity is a key element of the spin-out process and should both incentivise exceptional academic founders to drive the company forward and reflect the amount and quality of support provided by the university. The Academy can see considerable value in a two-tiered model for UK spin-outs. Following this model, academic entrepreneurs could decide whether they wish to access commercialisation support from the university or from an external provider, with universities adjusting their equity stake in the spin-out to reflect this. This decoupling of the support provided by the university that led to the generation of IP, from the wider package of support such as incubation services, can be beneficial and should be available more broadly[14,15].

27. **Investment and skills** – It is essential for SMEs to be able to access the investment and skills they need to support growth (see questions 1 and 3, paragraphs 11-16 and 30-35). The further development of mentoring opportunities for entrepreneurs, such as those provided by the Academy's Enterprise Hub, could help develop business skills, as well as building trust and collaborative partnerships between large companies, SMEs, and academia. Such schemes would also help entrepreneurs develop the skills to communicate complex science, technology, and business plans effectively to investors.

28. **Support needs to be simplified** – The Dowling Review of Business-University Research Collaborations[16] highlighted the complexity faced by businesses wishing to access public support for collaborative research activities with universities in the UK. Much progress has been made, such as Innovate UK's 'no wrong door approach', which means, regardless of how a business first approaches them, they will ensure that the business is guided to the right part of Innovate UK seamlessly. This 'no wrong door approach' will be operationalised by UKRI[17]. Nevertheless, there is still more work to be done to ensure SMEs can identify and access the support they need.

29. **Infrastructure, regulation, and procurement** – SMEs can find it difficult to navigate pathways for research, regulatory approval, and market access, particularly for disruptive

[14] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017
[15] Managing intellectual property and technology transfer, House of Commons Science and Technology Committee, Submission from the Royal Academy of Engineering 2016
[16] The Dowling review of business-university research collaborations, 2015
[17] The Dowling review of business-university research collaborations, Government response, 2016

innovations such as digital technologies. Appropriate research infrastructure (paragraphs 17-20), and regulatory and market access clarity (paragraph 45), are essential to support SME growth.

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?

30. **Business skills** – In addition to a strong skills base in research and the NHS, the life sciences sector depends on strong business skills. There is a broad consensus in the engineering community that a lack of business skills is a contributory factor to why the UK struggles to grow businesses to scale[18]. As outlined above, the rapidly advancing medical and digital technologies sectors are disproportionately populated by small SMEs compared to other areas of the life science sector. As these companies progress products through development, manufacturing, regulatory approval, and business development, there is an emerging skills gap in leaders who can oversee and manage this commercialisation process. There are growing numbers of private and charitable initiatives providing high-quality business support. Government should learn from these and partner with them where appropriate. Another strategy could be to support secondments, partnerships, or mentoring between SMEs, large companies, and academia, which would help build business skills as well as develop trust and collaboration across the sector.

31. Increasing business and entrepreneurship training as part of further and higher education would also be beneficial. Early education in these areas may help increase the scale of ambition of UK entrepreneurs as well as embed skills for good business practice from the outset of new businesses.

32. We therefore welcome the recommendation in the *Life Science Industrial Strategy* to support entrepreneurship training at all levels, and incentivise the mobility of scientists between academic and industrial sectors, which should support the development of business skills in the sector as well as catalysing partnerships between sectors[19].

33. **Digital, data analysis, and computational modelling skills** – Rapid advances in science and technology have led to 'big data' and digital technologies playing an increasingly important role in the life sciences. There is a significant digital skills gap in the UK and it is important that the definition of basic skills be broadened to include digital skills for the UK's 21st century economy, including the life sciences sector[16]. The development of more advanced data analysis and, beyond this, computational modelling skills will also be important (see box at end of response).

34. **Interdisciplinary skills** – There is also an increasing need for interdisciplinary skills across biomedical sciences, engineering and data sciences. Many of the opportunity areas highlighted in the strategy, including genomics, innovation to support healthy ageing, and AI, will require skills across biosciences, physical sciences, engineering, and clinical research. Training schemes or apprenticeships that give students experience of working in teams across sectors and disciplines, including academia, industry or the NHS, could be valuable in developing such skills.

35. **Non-UK nationals** – As with many high-tech sectors, the UK life science sector depends heavily on highly skilled staff from non-UK countries across academic research, the NHS,

[18] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017

[19] The Dowling review of business-university research collaborations, 2015

and industry. For example, over 22% of academic staff in UK higher education institutions in medicine, dentistry and health, and over 40% of staff in engineering and technology, are from non-UK countries[20]. The focus in the *Life Sciences Industrial Strategy* on minimising barriers to movement for highly skilled non-UK workers is therefore welcome**.**

Industrial Strategy

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?

Stability, continuity, and building on success

36. There were a number of recommendations in the 2011 *Life Sciences Strategy* that have brought significant benefits for the sector. However, the innovation cycle in the life sciences sector is long, requiring many years to translate ideas through to delivery to patients. It may therefore take time for the full benefits of initiatives from the 2011 strategy to be realised, and many of these initiatives should be allowed to mature, providing stability and continuity for businesses and investors.

37. The Biomedical Catalyst has had a positive impact on the sector[21], accelerating research, leveraging private investment, and facilitating academic-industry collaboration. The recent launch of the Digital Health Technology Catalyst by Innovate UK to expand funding opportunities specifically for the digital health sector is welcome.

38. One of the recommendations of the 2011 UK *Life Sciences Strategy* was for NICE to provide an advice service for medical technology companies to support understanding of data requirements for NICE appraisal. Such clarity is important, particularly for SMEs who may find the system challenging to navigate, and companies developing disruptive technologies that may not readily fit in existing pathways. The recommendation to implement the streamlining proposals outlined in the AAR is therefore welcome.

(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'?

39. The *Life Sciences Industrial Strategy* contains a number of very positive recommendations that would bring benefit to the biomedical engineering and medical and health technology sectors. These particularly include the development of new medical technology centres of excellence, increased R&D funding for the sector, minimising barriers to movement of skilled people, and a focus on increasing the use of health data.

40. **Health Advanced Research Programme –** We welcome the proposals for long-term, large scale funding for projects as outlined in the strategy, particularly with a significant risk appetite. However, it is important that the interaction of these programmes with the Industrial Strategy Challenge Fund is clear and complementary, and that synergies with other sectors are considered (see a systems approach below). The UK has historically had research and innovation strengths in biomedical engineering areas including orthopaedic devices, tissue engineering, assistive technologies, and human factors and ergonomics. Several of the opportunities highlighted in the strategy will depend heavily on engineering and bioengineering input, and could build on these areas of UK strength. These include

[20] HESA data 2015/16 – Academic staff by cost centre

[21] The Biomedical Catalyst: Making the case to continue, BioIndustry Association, 2015

healthy ageing, which may build on UK strengths in orthopaedic devices and assistive technologies in centres such as Queen Mary's Hospital, Roehampton, and Stoke Mandeville Hospital, and the use of AI, which should build on the UK's strengths in computing as well as neuroscience. Delivering innovation in these areas will depend strongly on successful interdisciplinary collaboration between engineers, biomedical scientists, clinicians, and data scientists and across different types of organisation (see paragraph 34).

A systems approach

41. It is important for the industrial strategy to take a systems approach to ensure that the strategy works together as a coherent whole to concurrently support growth in the industrial sector and improve health outcomes for UK patients[22,23]. This was a challenge for some areas of the 2011 *Life Sciences Strategy*. A coherent strategy must recognise interdependencies and bring together research, innovation, regulation, evaluation, and uptake into the NHS. This depends on joined-up, high-level participation by all relevant departments and agencies across government, as well as with devolved governments, regional and local institutions.

42. The *Life Sciences Industrial Strategy* will interact with and be dependent upon the wider industrial strategy in many ways, including research and innovation investment and skills development, but also trade, and the development of infrastructure. For example, progress in the use of health data for innovation and healthcare delivery will strongly depend upon a strengthened digital infrastructure and digital skills base (see box at end of response). There are also synergies between industrial sectors. For example, advances in 3D printing and manufacturing, or in AI and virtual reality, will have a significant impact on the life sciences sector. These interdependencies further highlight the importance of taking a systems approach to the development of the industrial strategy and sector deals to maximise opportunities and ensure that strategies do not operate in siloes.

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?

43. As outlined above, the majority of companies in the medical technologies and digital health sectors are SMEs[24]. It is therefore key that opportunities for support and growth of SMEs are central in the *Life Sciences Industrial Strategy*, as outlined in the following paragraphs.

44. **Commercialisation, investment and support for growth** – See paragraphs 11-29.

45. **Clear pathway to market** – The work of MHRA and NICE to facilitate access to advice for SMEs in recent years has been very welcome. There are still areas where further guidance on appropriate regulatory and assessment routes, and expectations for data provision would help SMEs navigate the route to the UK market. This is particularly the case for digital health companies, app developers, and other low-risk non-interventional innovations, for which the regulatory and appraisal pathways may be less well used. The AAR outlined recommendations to clarify routes to market for these products, and their implementation would be welcome.

46. **Procurement** (see also paragraphs 53-57) – As noted in the strategy, SMEs can find it challenging to engage with the NHS as their primary UK customer. Transparent, easy-to-access procurement processes are vital for supporting SMEs in the life sciences sector.

[22] A review of UK health research funding, Sir David Cooksey, 2006; Innovation, Health and Wealth, NHS, 2011

[23] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017

[24] Strength and opportunity 2015, Office for Life Sciences

Support for research and development in SMEs without support for market access cannot facilitate industrial growth.

47. The Small Business Research Initiative (SBRI) has the potential to be a key mechanism for supporting public procurement from SMEs, and the Academy welcomes the ongoing review of the initiative[25]. The SBRI has successfully supported the development of several healthcare technologies, such as Isansys Lifecare's wireless monitoring platform[26] and Owlstone Medical's breathalyser for diagnosis[27], but its use in the healthcare sector could be significantly expanded. The government has a role to promote use of the scheme, articulating to all relevant departments and agencies the importance of innovation and that responsible risk taking can deliver better value for the UK from procurement.

48. A survey of the engineering community by Engineering the Future found that awareness of the SBRI was currently very low, with 82% of respondents unaware of the scheme[28]. Therefore, there is a need for the profile and awareness of SBRI to be raised among target businesses. Large companies that supply products or services to the public sector could be incentivised to promote the use of SBRI through their supply chains. This would have the additional benefit of facilitating collaboration between large and small companies in the supply chain.

49. The SBRI largely operates in a one directional manner, with government identifying problems to be solved. Forums in which companies and entrepreneurs could present innovative ideas to the NHS or other relevant agencies or departments could facilitate the flow of innovative solutions into the public sector and be used to shape future SBRI competitions.

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

50. Regional networks can be very valuable in facilitating collaboration and the testing of innovations in 'real world' settings. Several Science and Innovation Audits[29] have highlighted digital and health technologies as areas of excellence and potential growth in their regions. It is important that appropriate support is available to facilitate the development of these clusters of excellence, for example through the development of new NIHR Medtech Co-operatives, or incubators. This should include a focus on facilitating partnership between SMEs, large industry, academia, and the NHS, building on the strengths of each partner to deliver local economic growth and accelerate R&D progress.

51. However, multiple local initiatives can lead to a fragmented landscape that can be difficult for businesses, particularly SMEs, to navigate, and do not help diffuse innovation through the national health and care systems. Additionally, there are likely to be synergies between local clusters of excellence. For example, there is a cluster of small companies with excellence in precision medicine and medtech around Southampton, Isle of Wight and Portsmouth, that would be likely to benefit from further collaboration with the hub of digital service and IT companies in the Hampshire region. The emphasis that the strategy puts on the coordination and collaboration of regional and local initiatives to create a 'single front door' is therefore appropriate. Support should be available to the devolved

[25] Review of the Small Business Research Initiative – Submission from the Royal Academy of Engineering, 2017
[26] https://www.gov.uk/government/case-studies/isansys-lifecare-transforming-the-way-we-keep-an-eye-on-patients
[27] https://www.gov.uk/government/news/aviva-deal-boosts-investment-for-uk-breathalyser-diagnosis-firm
[28] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017
[29] Science and Innovation Audits https://www.gov.uk/government/publications/science-and-innovation-audits-first-wave-reports

nations to both support excellence in their own regions, but also facilitate coordination with UK-wide initiatives. As outlined in paragraphs 41 and 42, a systems approach would be valuable to ensure that regional strategies do not operate in siloes.

52. Technological innovations, particularly in healthcare, must be extensively tested and demonstrated in real-world environments if they are to succeed on the market. The Academy recommends the establishment of a wide variety of '**national innovation assets**' across sectors to act as testbeds for new innovations, building on existing infrastructure to facilitate innovation, act as focal points for skills development, and highlight innovation opportunities across all parts of the UK, for both domestic and international audiences[30]. For the life sciences sector, national innovation assets could build on the NHS Test Beds for interconnected devices, or the NIHR Medical Technology or Diagnostic Evidence Co-operatives (see paragraphs 19-20).

NHS Procurement and Collaboration

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?

53. Procurement by the NHS has the potential to be a key driver for innovation in the life sciences sector. Currently, uptake of innovative medicines in the NHS lags significantly behind comparable countries[31], and there is a perception that the NHS is a similarly challenging market for healthcare technologies and other innovations. Increased and consistent uptake of innovative products that help the NHS achieve its mission would greatly facilitate an innovative private sector.

54. Increased use of the SBRI could be one mechanism to improve procurement and support innovation in life sciences SMEs (see paragraphs 46-49).

55. The NHS is not a single strategic customer. Instead there is a fragmented landscape of payers making the landscape challenging to navigate, particularly for SMEs and entrepreneurs with disruptive technologies, such as some digital technologies. It would be valuable to simplify and clarify routes to market for SMEs as outlined in the AAR.

56. As noted in the *Life Sciences Industrial Strategy*, this fragmented landscape also makes diffusion of innovation across the NHS difficult. The AHSNs are playing an important role in promoting innovation locally, but it would be valuable if their remit were extended and resourced to facilitate communication between AHSNs nationally, promoting diffusion of innovation throughout the NHS with benefits for patients, and supporting the life sciences sector.

57. It is also important that the NHS has staff, including clinical engineers and scientists, with the right skills and knowledge for procuring of new technologies, with a deep understanding of current clinical and organisational systems and needs.

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?

[30] Engineering an economy that works for all, Industrial Strategy green paper response, Royal Academy of Engineering, 2017

[31] Life Sciences Competitive Indicators 2017; Comparator report on patient access to cancer medicines in Europe revisited – a UK perspective, IHE 2017

58. The AAR sets out recommendations for an Accelerated Access Pathway for strategically important transformative products, a better process for assessing emerging technologies, incentives to accelerate the uptake of innovation by the NHS, and improved guidance to help SMEs through the development pathway. Importantly, these recommendations were designed to apply to medical technologies, diagnostics, and digital products in addition to new medicines. These recommendations would bring benefits to patients and the NHS, and to the life sciences and medical technologies industries. Support for their implementation in the *Life Sciences Industrial Strategy* is therefore welcome.

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?

59. In recent years there has been a significant focus on innovation in the NHS, with a number of new supporting initiatives[32]. This is very welcome, but it is important that innovation is clearly and consistently defined, and that this culture of embracing innovation is propagated throughout the NHS at all levels. There are several ways in which the NHS could further support research, development, and adoption of new technologies, outlined in the following paragraphs.

60. SMEs can find access to NHS clinicians challenging, particularly early in the innovation process. Time and resource constraints mean that healthcare professionals, particularly at an early stage in their career, may have limited opportunities to engage with innovation in industry. Increasing opportunities for such early engagement would have multiple benefits: directing innovation towards areas of greatest clinical need, improving clinician awareness of new and emerging technologies, creating innovation 'champions' in the NHS, and providing SMEs with vital clinical input at an early stage of innovation. Incentives or recognition for such engagement by clinicians should be considered, and could build on existing NHS programmes to support internal innovators.

61. The AHSNs are making an important contribution to supporting innovation. However, it would be useful if they were resourced further to support commercialisation and disseminate innovation nationally. Additionally, there is some perception that AHSNs are more focused on service delivery compared to clinical technologies. It would be valuable to clarify their remit, and ensure a consistent definition of innovation across the networks.

62. Health data is becoming increasingly important for research and innovation in the life sciences, and the focus in the *Life Sciences Industrial Strategy* on facilitating the use of health data is therefore welcome (see box at end of response).

Brexit

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?

63. EU research and innovation funding, and skilled workers from the EU, currently play a very significant role in the UK life sciences sector (see paragraphs 13 and 35). The focus in the *Life Sciences Industrial Strategy* on increasing funding for the sector and minimising barriers for the movement of skilled workers is therefore welcome to minimise the impact on the sector. It is important that funding instruments continue to be available to support research and innovation in both academic institutions and SMEs and that opportunities for international and cross-sectoral collaboration are maintained and built upon.

[32] https://www.england.nhs.uk/ourwork/innovation/

64. Regulation is vital in the life sciences sector, providing a framework for innovation and for patient safety. The sector is largely regulated at an EU level, through a highly collaborative process in which the UK's MHRA plays a significant role. Continued regulatory collaboration and, where appropriate, international harmonisation, is to be encouraged, particularly since the UK represents a small proportion of the total or potential market for most UK life sciences companies. We are aware of and fully support the ongoing work of the Academy of Medical Sciences and others in the sector on the future of life science regulation following Brexit.

Digital and data

65. Data and digital based technologies have the potential to bring significant benefits to patients in the NHS, from the use of linked genomic data for research into new treatments, to the use of telehealth technologies to streamline healthcare delivery. The UK digital health industry has the potential for significant growth, with the global market predicted to reach £43bn by 2018 (Digital Health in the UK, Deloitte, 2015). However, significant investment is needed for these benefits to be realised for UK patients, and the value to be captured by UK organisations. We therefore welcome the focus on data in the *Life Sciences Industrial Strategy*.

66. Digital technologies are enabling technologies, underpinning advances across sectors. The UK has strengths in the IT, digital, and technology sectors, and growth in these sectors is likely to support growth in other industries, including the life sciences.

67. Several elements of the wider industrial strategy are essential to support the use of data analytics in the life sciences sector. These include investment in the UK's digital infrastructure, and the development of the UK's digital skills base with expertise in data handling, analysis, and computational modelling.

68. The Academy's recent report, *Connecting Data*, based on a series of sector-specific workshops run jointly by the Academy and the Institution of Engineering and Technology, identified several areas that could support growth of the digital economy across sectors, including in healthcare and the life sciences. These include:

    - Strengthening the foundations – growing levels of interconnection between the digital systems used in healthcare, and the potential growth in the use of electronic patient records and connected health devices, create opportunities for improved performance and innovation, but at the same time increase vulnerability. Safety and resilience need to be incorporated into innovation. This is vital in the life sciences sector to build and maintain patient and public trust in the handling of their data, and to ensure the safe operation of connected health devices.

    - Facilitating access to data – technical, organisational, and regulatory barriers to accessing and sharing data were identified across sectors. Improving access to health data would make the data held by the NHS a significant asset for the UK, attracting significant life science industry investment. In the NHS, limited interoperability and siloed operation of data was identified as a major limitation. Increasing the development and use of standards and interoperable systems across the NHS would be valuable, requiring joined-up working across different parts of the health system and industry.

    - Sharing good practice – Examples of excellent practice should be shared, particularly with SMEs and supply chains, to facilitate growth in the digital health sector.

69. Informed consent and confidentiality are clearly of particular importance in the healthcare sector. It is vital that a patient-centric approach is taken to discuss and explain the benefits to patients and society of sharing data, alongside any risks. We welcome the ongoing work of Understanding Patient Data and others in this area.