

September 2017

Summary

- The Academy welcomes the Life Sciences Industrial Strategy and endorses its recommendations.
- The UK's excellent science base is the key attraction for the life sciences sector and we are pleased that the strategy recognises the importance of balanced funding across basic, discovery science, and translational research. The sector deal must maintain and enhance this environment, supporting the whole research landscape including in academia, industry and charities.
- Despite the strengths of the science base, the UK has been less successful at exploiting and translating research. There is no single reason for this although a relative lack of long term funding (patient capital) for growing biotech firms has been a contributing factor. We welcome the Patient Capital Review by HM Treasury and its proposals.
- In order for this strategy to be successful, the NHS must be a partner in research as well as a customer of innovation. This will include developing robust data sharing agreements, which will allow researchers to access NHS-data and addressing the uptake of innovative medicines, devices and diagnostics within the NHS. Adopting the proposals of the Accelerated Access Review will be a step towards improving long standing issues in this area.
- Life sciences clusters can play an important role in implementing the strategy and driving growth across the country. Continued support for clusters should improve linkage between them to provide a "single front door" for international collaborators and funders. However the strategy fails to provide details of additional support for clusters to fulfil this role.
- A flourishing life sciences sector requires a sustainable skills base, including access to the best talent from around the world. The Academy welcomes the proposals to develop a skills action plan and to establish a recruitment fund to attract exceptional researchers to the UK. This must be underpinned by a fast, efficient and transparent immigration system.
- The implementation of the strategy will require engagement from across Government, including from the Department Business, Energy and Industrial Strategy, the Department of Health, and the Treasury as well as devolved administrations. A dedicated Minister for the life sciences would help to achieve this.
- The strategy must be considered in the context of the UK's exit from the EU, which is likely to influence the funding environment; access to collaboration; access to talent and the regulatory landscape for the sector. We believe that continued regulatory alignment with the EU will be beneficial across many areas of research, particularly around clinical trials and medicines regulation. However, regulation should be considered on a case-by-case basis to ensure that the potential benefits of increased flexibility can be realised.

Introduction

1. The Academy of Medical Sciences promotes advances in medical science, and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts drawn from a broad and diverse range of research areas.
2. We welcome the opportunity to respond to the House of Lords Inquiry into the Life Sciences Industrial Strategy. Our submission highlights the strength of the UK's research base and important influence this has on the UK's life sciences sector. We also highlight

the important role of the NHS in driving innovation and adopting new ideas and technologies.

3. Our submission builds on the Academy's response to the Government's Industrial Strategy Green Paper and has been informed by the expertise of our Fellows, from across the disciplines and sectors we represent and our work with the FORUM, which brings together academia, industry and the NHS.^{1,2}

Science and innovation

4. The UK life sciences sector represents one of the most productive sectors in the UK and is one of the country's great strengths. The sector was identified in the Industrial Strategy Green Paper as world leading and having generated significant growth in recent years.³
5. Underpinning this is the UK's world class research base, particularly within the biological and clinical sciences. This strength represents the key attraction for international life sciences companies to locate in the UK. The UK hosts a highly developed research infrastructure, including at least four universities which regularly rank in the top 10 universities in the world. In 2016/17, four UK universities were placed in the top 10 in the clinical sciences and three were placed in the top 10 in life sciences.⁴ This excellence in UK universities is supplemented by renowned and prestigious research institutes such as the Laboratory of Molecular Biology in Cambridge and the newly established Francis Crick Institute in London.
6. The UK has a diverse research funding base. The Research Councils make significant investment in basic research, whilst Innovate UK and the Catapult Network provide support for later stage research and innovative companies. The establishment of UK Research and Innovation (UKRI) offers an opportunity to build on their existing strengths and to facilitate cross-disciplinary work. Alongside these funding streams the transformational investment from the National Institute of Health Research has helped to strengthen our translational science base, including through establishment of the Biomedical Research Centres. They play a key role in Academic Health Science Centres, which form the basis of strong university-NHS partnerships, many of which are now partnered with industry in "helix" like tripartite arrangements. The sector is also supported by a developed medical research charity sector, which provided over £1.6 bn in research funding in 2016, or 45% of total publicly funded medical research funding in the UK.⁵
7. This funding eco-system is complemented by unique data sets for health research, including the UK biobank which contains health records of 500,000 patients; the 100,000 genomes project, which will soon have sequenced 100,000 whole genomes; and the Million Women Study, a national study of women's health, involving more than one million UK women aged 50 and over. Access to these data sets is a unique strength to the UK's health research and provides further incentive to the life sciences sector to be based in the UK. Furthermore, the NHS as a single healthcare provider represents a rich source of data, an underexploited strength of the UK's life science offering. To capitalise on this resource it is important that appropriate mechanisms exist to support data access. In addition, the NHS

¹ Academy of Medical Sciences (2017) Response to Consultation on Industrial Strategy Green Paper <https://acmedsci.ac.uk/file-download/85348127>

² <https://acmedsci.ac.uk/policy/forum>

³ https://beisgovuk.citizenspace.com/strategy/industrial-strategy/supporting_documents/buildingourindustrialstrategygreenpaper.pdf

⁴ http://www.cancerresearchuk.org/sites/default/files/uk_and_eu_research_full_report_v6.pdf

⁵ AMRC (2016) Medical research charities: our impact at a glance http://www.amrc.org.uk/sites/default/files/doc_lib/2016Infographic.pdf

has a crucial role to play as both a driver of innovation and a market for innovative technologies, treatments and products.

8. These factors, combined with the UK's reputation and history of scientific excellence provide a strong platform for the UK life sciences sector to build upon. However, certain limiting factors have inhibited the full exploitation of this strength.

Building on the research base

9. Despite the exceptional strengths of the UK research, it is widely held that the UK is less successful at developing this research into intellectual property which can drive company growth and deliver economic returns for the UK. Academy Fellows have identified two key causes include the availability of long-term funding and the relative paucity of entrepreneurial skills and/or access to these skills within the research base.

Long-term funding

10. The commercialisation of the ideas and technologies which come from basic research in the life sciences sector takes place over lengthy timelines. Coupled with the high risk of failure in disciplines such as drug discovery, the sector therefore requires long-term funding, also referred to as "patient capital".
11. Venture Capital (VC) funding is an important source of financing for biotech companies and is less well developed in the UK than some comparator nations, e.g. the US. However, recent years have seen increased interest from VC in the UK. In 2015, the biopharma sector attracted over £750 million in VC funding, the majority of which was obtained by companies seeking the first round of VC funding (Series A). Innovative examples of VC funding have also increased in recent years, including the Dementia Discovery Fund. This fund is managed by life sciences venture capital firm SV Life Sciences (SVLS) and brings together a range of public, charitable and industry funders.⁶
12. This recent improvement in availability of funding is demonstrated by the fact that UK companies raised nearly £700m in venture capital in 2016, more than any other country in Europe, but behind the life sciences clusters in either Boston or San Francisco.⁷
13. Despite these positive signals, private financing and VC availability remains concentrated in the South East of England. Later rounds of VC funding (Series B and C) for growing companies has also remained more challenging to obtain. Furthermore, many SMEs particularly struggle to make the transition from private funding sources to Initial Public Offerings. These issues are indicative of the challenges faced by SMEs to grow.
14. Overcoming the challenges identified above to ensure longer term financing to allow SMEs to grow across the country must be one of the goals of the Life Sciences Industrial Strategy. The Academy welcomes HM Treasury's Patient Capital Review and is optimistic that the proposals in this review will help to address these issues.⁸ This includes recognition of the increasing importance of public private partnerships (PPPs) as vehicles to support long-term collaborative arrangements across sectors.⁹ PPPs distribute risk across multiple partners and sectors and are thereby able to use public investment to

⁶ <http://www.alzheimersresearchuk.org/100m-dementia-discovery-fund-launches-to-support-pioneering-research/>

⁷ Building something great: UK's Global Bioscience Cluster 2016, Bioindustry Association
<http://www.bioindustry.org/document-library/building-something-great-uks-global-bioscience-cluster-2016/>

⁸ <https://www.gov.uk/government/publications/patient-capital-review>

⁹ Academy of Medical Sciences (2017): The UK drug discovery Landscape <https://acmedsci.ac.uk/file-download/71272985>

crowd in additional funding. The Patient Capital Review proposes additional Government funding to be delivered through a public-private partnership administered by the British Business Bank.¹⁰ This would be a welcome addition to the funding landscape for SMEs in the life sciences sector.

Entrepreneurial skills and Intellectual Property

15. Consultation with our Fellows has revealed that the academic sector would benefit from additional skills in business, entrepreneurialism and management. Consequently, the Academy welcomes the review into entrepreneurship by Professor Tim Dafforn, Chief Entrepreneurial Adviser at the Department for Business, Energy and Industrial Strategy and the proposal in the Life Sciences Industrial Strategy to include entrepreneurial training at PhD level. The provision of training in entrepreneurial skills at all career stages, as well as the incentives for academic staff to engage with this training and to gain experience outside their own sector will be conducive to ensuring that SMEs and industry have the skilled individuals that it needs to continue to flourish.
16. Alongside the need for entrepreneurial skills within the science base is a parallel requirement for relationship building between academia and industry. This can promote improved cultural understanding of the needs of each sector and increase availability of business skills and research expertise that companies need at different stages of growth. Catapult and Innovation Centres can provide fora for this and the Academy looks forward to the results of the reported review of how Catapult Centres can align with the Industrial Strategy.¹¹
17. Encouraging universities and academia to recognise and value entrepreneurial activities and/or engagement with non-Higher Education Institute (HEI) partners has in part been achieved through the inclusion of "impact" in the Research Excellence Framework (REF).¹² The initial decision for REF 2021, which will place explicit focus on the HEIs approach to supporting collaboration with organisations beyond HEIs is welcome.¹³
18. Building on this, universities must be incentivised to reward a more diverse range of activities from those traditionally associated with academia. In part this will be facilitated by investment in technology transfer services within HEIs and ensuring the provision of expertise and a pragmatic approach to intellectual property as well as policies which facilitate interactions with industry and rapid commercialisation of IP. The Government's review of intellectual property and technology transfer announced in the Industrial Strategy Green Paper should elaborate on this and help to spread best practice within university technology transfer offices.

Industrial Strategy

Impact of the 2011 UK life sciences strategy

19. The Coalition Government's 2011 Life Sciences Strategy was a welcome recognition of the important role of the life sciences sector in improving UK health and driving the UK

¹⁰HM Treasury (2017). Financing growth in innovative firms: consultation https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/642456/financing_growth_in_innovative_firms_consultation_web.pdf

¹¹ <http://www.researchresearch.com/news/article/?articleId=1366937>

¹² Academy of Medical Sciences (2017). Response to HEFCE consultation on the second Research Excellence Framework <https://acmedsci.ac.uk/file-download/85486062>

¹³ HEFCE (2017). Initial decisions on the Research Excellence Framework 2021 <http://www.hefce.ac.uk/pubs/rereports/year/2017/ref201701/>

economy. Given the developmental timelines for drug discovery and innovation in the life sciences, it may be too soon to judge the full effects of the 2011 strategy. Nevertheless, a number of initiatives first outlined in the strategy have proved successful.

20. The establishment of the Biomedical Catalyst (BMC), a joint funding initiative between the MRC and Innovate UK, has added materially to the landscape. The BMC has provided over £250 million in funding for over 300 projects for the development of therapies, diagnostics and devices since its inception in 2011.¹⁴ Through provision of public funding for drug discovery the BMC plays an important role in early stage development.¹⁵ The Academy has previously welcomed the announcement to extend funding for the Biomedical Catalyst to 2020-21.¹⁶
21. The Early Access to medicines scheme, which gives patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation, was established following the 2011 strategy. This scheme provided a welcome route to market for innovative treatments where there was clear unmet clinical need.
22. The 2011 Life sciences strategy recognised the importance of the sector and laid foundations for the 2017 Life Sciences Industrial Strategy through the appointment of life science champions, including Professor Sir John Bell, who oversaw the production of the present strategy. By this measure the 2011 strategy has been successful in making provision for a strong voice supporting the life sciences sector within Government.

Reflections on the 2017 Life Sciences Industrial Strategy

23. The present strategy, launched on 30 August, recognises and reiterates many of the points raised above and presents an ambitious vision for the UK life sciences sector. Implementation of the proposals in this strategy in the form of a sector deal for the life sciences industry can build on existing strengths of the UK research base and life sciences sector. In doing so it can deliver patient benefit and place the UK as a world-leading destination in which to conduct basic, translational and clinical research. However, the Strategy must be considered in the context of the UK's departure from the EU, which will influence many aspects of the strategy, including funding, access to talent and the regulation of research as well as of medicines, *in vitro* diagnostics and medical devices.

i. Reinforcing the UK science offer

24. We are particularly pleased to see the acknowledgement in the strategy that the strength of the UK's science base has underpinned the growth of the life sciences sector. The strategy provides welcome support for a balanced funding principle, recognising the UK's strength in biomedical research and the importance of supporting basic research to ensure that this will continue to flourish. The Strategy's call to increase the proportion of GDP invested in research and development to 2.6% in the next five years, is broadly in line with the joint national Academies' long-term target of 3% of GDP to be invested in research and development.¹⁷

¹⁴ <https://www.mrc.ac.uk/funding/science-areas/translation/biomedical-catalyst/>

¹⁵ Academy of Medical Sciences (2017). The UK Drug Discovery Landscape <https://acmedsci.ac.uk/file-download/71272985>

¹⁶ HM Treasury (2016). Autumn Statement 2016 <https://www.gov.uk/government/publications/autumn-statement-2016-documents/autumn-statement-2016>

¹⁷ Academy of Medical Sciences, British Academy, Royal Academy of Engineering, Royal Society (2016). Open for business <https://acmedsci.ac.uk/file-download/41610-582d965e166ae.pdf>

Charity Research Support Fund

25. Importantly, the strategy recognises the role of the medical research charities in this sector. As highlighted in the AMRC's submission to the Industrial Strategy Green Paper inquiry, medical research charities are an integral part of the UK's funding landscape.¹⁸ Medical research charities fund basic research and research into rare diseases, which is often not well funded via other means. Charities are also able to provide a vital link to the patient groups that they represent.
26. Of the £1.6 bn invested in research in the UK by medical research charities, most of this was spent in universities.¹⁹ The indirect costs of this research, which are born by universities, are subsidised by the Charity Research Support Fund, provided by Higher Education Funding Council for England (HEFCE). This fund has remained static at £198 million per year since 2010. In the intervening years charitable funding in universities has gone up and the impact of the fund has been diluted. Increasing the CRSF would help to maximise charitable investment and ensure the viability of this stream of investment for research in UK universities.

Health Advanced Research Programme

27. The ambition of the "moonshot" programmes proposed as part of the Health Advanced Research Programme (HARP) is welcome. The four opportunities outlined in the strategy represent genuine areas of opportunity for the UK to lead the world, however at present HARP does not provide a bottom-up route for new, disruptive industries inspired by blue-sky research. Further clarity is required on how HARP will relate to the Industrial Strategy Challenge Fund that was announced in the autumn statement 2016.²⁰

Innovative Medicines Initiative

28. We welcome and endorse the call within the strategy to maintain association with the Innovative Medicines Initiative, the world's largest medical research Public Private Partnership, which brings together the pharmaceutical industry with academia, small and medium sized enterprises (SMEs), and others, to accelerate medicines discovery and development. Between 2008 and 2016 the UK received €302.8 million from the EU Commission through IMI funding, the largest amount of any country.²¹ As highlighted in paragraph 14 PPPs are increasingly important. Retaining access to the world's largest PPP offers the most favourable outcome as the UK would not be able to recreate this scheme on a national level.

ii. Growth and infrastructure

29. As highlighted above and in the strategy, the availability of long-term funding to support the development of innovative products has been a limiting factor. The implementation of the findings of the Patient Capital Review by HM Treasury will therefore be integral to the success of the strategy.

¹⁸AMRC (2017). 'Building our Industrial Strategy' response http://www.amrc.org.uk/sites/default/files/doc_lib/Industrial%20Strategy%20Green%20Paper%20consultation%20AMRC%20response.pdf

¹⁹ AMRC (2017).. Medical Research Charities: Investing in research http://www.amrc.org.uk/sites/default/files/doc_lib/Charities%20investing%20in%20research%202017.pdf

²⁰ HM Treasury (2016). Autumn Statement 2016 <https://www.gov.uk/government/publications/autumn-statement-2016-documents/autumn-statement-2016>

²¹ ABPI (2017). UK Participation in the Innovative Medicines Initiative http://www.abpi.org.uk/our-work/library/industry/Documents/UK_Participation_in_IMI.pdf

Clusters

30. One of the key goals of the Government's wider Industrial Strategy is to address imbalances in economic activity and drive growth across the nation. The economic footprint of the life sciences sector is already spread across the UK, as demonstrated by the recent analysis commissioned by ABPI, which showed that every region in the UK contains a UK head office of a Life Sciences firm.²²
31. The Academy strongly endorses the role that life sciences clusters can play in delivering the strategy and in coordinating growth across the country. The nucleating effect of clusters can provide access to the necessary talent for growing companies when they need it. We support the reiteration that support for clusters must occur in the context of improving connectivity and collaboration between clusters to provide a rich UK-wide offering to create a single 'front door' for engagement with stakeholders, including Government, industry, funders and international collaborators.²³
32. It is somewhat disappointing that the strategy does not propose additional funding to support clusters to perform this role. Nor does it fully recognise the need to support the training of development required to provide the interdisciplinary leaders which clusters require. See paragraph 52 for further details of the Academy's work in this space.

iii. NHS procurement and collaboration

33. The strong focus on NHS participation is welcome and will be integral to achieving the aims set out in the strategy. The NHS, as a single healthcare provider and key UK market, must be a customer of innovation.²⁴ The NHS must also be an active partner in research in order to maximise the power of its unique data-sets and to provide a test-bed for innovative new treatments and technologies which can be evaluated using of real world evidence.

Access and uptake

34. As noted in the strategy, access to innovative treatments in the NHS is often slow and the route to market for innovative products developed by the UK's life science's sector is not straightforward. The Academy welcomed the recent investment of £86 million to support the Accelerated Access Review (AAR) and improve access to the NHS as a forum in which to test innovative products.²⁵ We look forward to the Government's full response to the AAR, which must build on this announcement and be synergistic with the proposals in the strategy and a future sector deal.
35. The strategy provides welcome recognition that a broader definition of "value" is important to reflect the true worth of new technologies. Establishing a working group to consider the use of real world evidence to evaluate the safety and efficacy of new interventions (as proposed on p26 of the strategy) can help to re-define value by providing multi-source information on impacts of a medicine.²⁶

²² PWC (2017). The economic contribution of the UK Life Sciences industry http://www.abpi.org.uk/our-work/library/industry/Documents/The_economic_contribution_of_the_UK_Life_Sciences_industry.pdf

²³ Academy of Medical Sciences (2017). Geographical Clusters: a vision for the future <https://acmedsci.ac.uk/file-download/31821958>

²⁴ Academy of Medical Sciences (2017). The UK Drug Discovery Landscape <https://acmedsci.ac.uk/file-download/71272985>

²⁵ <https://acmedsci.ac.uk/more/news/86m-boost-for-new-medicine-and-technology>

²⁶ Academy of Medical Sciences (2016). Real world evidence. <https://acmedsci.ac.uk/file-download/38667-573d8796ceb99.pdf>

36. New models for pricing and reimbursement, such as those presented in the strategy, must also be taken forward to offer a more pragmatic, affordable solution for the healthcare system by more closely aligning price with value.²⁷ This more holistic and longer-term approach can drive uptake and adoption in the NHS. It must be highlighted at this point that the recent BIT by NICE as was proposed in the NHSE/NICE consultation on health technology appraisals did not provide reassurance that access and uptake of innovation in the NHS will improve in the short term. The introduction of BIT would likely result in delays in accessing new and innovative treatments for patients and is not compatible with the ambition demonstrated in this strategy.

Small and Medium size Enterprises (SMEs)

37. For SMEs the navigation of the pathway to regulatory approval and a market in the NHS is a major challenge. Guidance and support for SMEs to engage with NHS providers would be valuable to help SMEs establish how their products can successfully be incorporated into healthcare pathways.
38. The strategy pays special attention to the challenges faced by SMEs and the sector deal, as well as the wider environment must reflect this to facilitate SME access to the NHS market and allow them to expand and grow.

Medtech Centre of Excellence

39. Establishing centres of excellence for medtech to align with regional strengths and supported by local NHS providers would be a welcome step to exploit excellence where it exists, promote development of innovative medtech products and to ensure a strategy that works across the country.

Excess Treatment Costs (ETCs)

40. As highlighted in the strategy work is currently underway between NHS England, Department of Health and Public Health England to review and formulate strategies to address issues relating to NHS payment of ETCs for non-commercial trials. This work is a good example of developing a permissive and supportive environment required to support the implementation of the new life sciences industrial strategy, and we welcome the efforts made by these organisations.

Data

41. The data-rich NHS represents a unique asset to the UK and improving the utilisation of this can deliver patient benefit and world-leading research built on real-world data and linked patient records. The strategy provides welcome focus on the importance of NHS data and the need to improve linkages between data sets as well as developing clear and consistent requirements for access to these data sets.
42. Importantly this must take place in the context of the recommendations of the National Data Guardian.²⁸ It is essential that the establishment a robust data sharing model must

²⁷ Academy of Medical Science (2017). Health economics for stratified medicine <https://acmedsci.ac.uk/file-download/61141574>

²⁸ National Data Guardian for Health and Care Review of Data Security (2016). Consent and Opt-Outs https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF

also facilitate access for researchers. Public dialogue during this process will be crucial and the Academy is collaborating with Understanding Patient Data to achieve this.²⁹

Artificial Intelligence (AI)

43. Algorithms and AI have the potential to transform processes across the healthcare system, providing an opportunity for greater efficiency in the NHS. Although the extent of potential benefits of using algorithms is not yet known, they are predicted to have a sizeable health and economic impact and it is important to fully understand this impact and the efficiencies afforded in healthcare as well as research and development processes. The development of algorithms for use in healthcare and in research and development should be informed by robust evidence, the source of which must be open to scrutiny. The Academy's recent response to the House of Commons Science and Technology Select Committee provides further details on the potential of AI in the life sciences.³⁰

iv. Skills

44. The global nature of research and innovation means that international talent plays an important role in the UK research base. For example, in 2015/16 17% of the total academic staff in UK universities were non-UK EU nationals.³¹ For clinical medicine and biosciences this figure rises to 21% and 24% respectively.³² This totals over 7000 non-UK EU nationals working in UK HEIs in either clinical or bio sciences. The status of these researchers following the UK's departure from the EU remains unclear.

45. As noted in the strategy continued access to the talent required to support the UK life sciences sector will be dependent on an immigration system which is fair, efficient and transparent. It must also recognise that, alongside research leaders, strategically valuable individuals also include early-stage researchers, technologists and technicians with specialist expertise that support them.³³

46. The Academy welcomes the recommendation to establish a high-level recruitment fund to attract exceptional talent to the UK and looks forward to further information about how this might relate to the recently announced Rutherford Fund.³⁴ Implementing this recruitment fund should learn from existing examples of a successful international model to attract such "stars". The Government of Canada's Research Chairs funding, which invests approximately Can\$260 million a year to recruit and retain exceptional talent to Canada is one such example.³⁵

Skills Action Plan

47. The proposal to develop a skills action plan across NHS, commercial and academic sectors is welcome to help address skills shortages, evolving skills needs and the skills sustainability of the sector. Recognising and addressing these issues will be essential for the strategy to achieve its ambitions. For example, in recent years drug discovery activities have been increasingly outsourced to biotech, CROs and academia. SMEs in the UK have

²⁹ <https://understandingpatientdata.org.uk/>

³⁰ Academy of Medical Sciences (2017). Response to the House of Commons Science and Technology Committee inquiry into algorithms in decision-making <https://acmedsci.ac.uk/file-download/79291192>

³¹ <https://www.hesa.ac.uk/data-and-analysis/staff> accessed 24/08/17

³² HESA data, unpublished

³³ Joint submission from the Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering and the Royal Society (2017). Response to House of Commons Home Affairs Committee inquiry on immigration <https://acmedsci.ac.uk/file-download/12658478>

³⁴ <https://www.gov.uk/government/news/100-million-rutherford-fund-to-attract-best-researchers-to-the-uk>

³⁵ <http://www.chairs-chaieres.gc.ca/home-accueil-eng.aspx>

benefitted from the ability to recruit senior staff with diverse experience from large pharmaceutical companies to fill their leadership positions. Obtaining the diversity of experience required to lead successful SMEs will therefore be more challenging as a result of the changes in the presence of large pharmaceutical companies' research facilities in the UK impacting on the long-term sustainability of the UK's skills pipeline.³⁶

48. In addition to these broad concerns a number of other specific skills areas have been identified as being in short supply, including: medicinal chemistry, the design and synthesis of drugs; and clinical pharmacology, which is crucial for translating basic research into medicines for patients. ABPI surveys on skills gaps in the biopharmaceutical sector in 2008 and 2015 identified clinical pharmacology as a top priority area, with both the quality and number of candidates being an issue.³⁷ The skills action plan must recognise these shortages and consider the necessary support and career structure required to address them, ensuring that the sector has access to the skills profile it needs.

Academia-Industry collaboration

49. The modern innovation pathway is complex with diverse stakeholders. Increasingly, innovation relies on collaborative and cross-disciplinary work often taking place at the academia-industry interface. The UK is already home to several successful examples of academia-industry collaboration, including the Division of Signal Transduction Therapy at the University of Dundee, which was first established in 1998 and recently had its funding renewed by a partnership of Boehringer Ingelheim, GlaxoSmithKline and Merck.³⁸ This strategy should build on these existing examples of academia-industry collaboration and embrace new models of Open Innovation.
50. Open Innovation often takes place across organisational borders and can be supported by the ability of those organisations, institutions and people to work closely with one another. For example, at the Francis Crick Institute, laboratories are arranged to facilitate interaction of scientists, including between academic and industry groups.
51. Consequently, we welcome the proposed fund to support convergent science activities through cross-disciplinary sabbaticals and joint appointments. Existing models which promote the skills required to work at the interface of academia and industry, such as the Immunology Catalyst at GSK, should be considered when designing this fund. As part of this scheme, academic immunologists are able to work at GSK alongside industry scientists. These researchers gain access to GSK's platforms whilst retaining ownership of IP. This model enables the scientists to return to their academic institutions after a few years.³⁹

Developing future leaders

52. To realise our aspirations and those laid out in this strategy we need the most gifted and capable people to occupy the cross-sectoral leadership positions of the future. This requires us to look across disciplines and sectors, to consider how we can best incubate our future talent and generate the cohorts of agile and adaptive leaders we will need. The Academy believes there is a clear need to develop a robust, innovative leadership

³⁶ Academy of Medical Sciences (2017). The UK Drug Discovery Landscape <https://acmedsci.ac.uk/file-download/71272985>

³⁷ ABPI (2015). *Bridging the skills gap in the biopharmaceutical industry: Maintaining the UK's leading position in life sciences*. http://www.abpi.org.uk/our-work/library/industry/Documents/Skills_Gap_Industry.pdf

³⁸ <http://www.lifesci.dundee.ac.uk/news/2016/sep/20/award-winning-academia-industry-collaboration-attracts-multi-million-pound>

³⁹ www.gsk.com/en-gb/careers/areas-of-opportunity/research-and-development/immunology-catalyst/

programme focused on trans-disciplinary working that will produce leaders capable of accelerating the translation of research into benefits for patients and society. We are currently scoping the potential for such a programme and consulting with stakeholders to inform discussions

Responsibility and accountability

53. Achieving the vision set out in the strategy will require collaboration across central Government and agencies, crucially including BEIS, the Department of Health, the Home Office and, through the implementation of the Patient Capital Review, HM Treasury. This cross-departmental approach must be supplemented by involvement of devolved administrations as well as numerous agencies including the MHRA, HRA, NICE and NIHR.
54. In this context, the Office for Life Sciences (OLS), with its cross-departmental structure bridging between the key departments of BEIS and the Department of Health, will be essential for effective implementation of the strategy. OLS Ministers must be well connected and collaborative. Oversight of the strategy, the Accelerated Access Review and uptake of new drugs and medical technologies all fall within the portfolio of a single Minister, Lord O'Shaughnessy, within the Department of Health, however this fails to take account of the need for strong collaboration with BEIS in the implementation of the strategy. A single Ministerial position for the OLS, spanning both the Department of Health and BEIS would help to achieve the necessary cross-departmental cooperation.
55. The strategy recognises the presence of the life sciences industries in Scotland, Wales and Northern Ireland, however it lacks sufficient detail about the role that devolved administrations will have in implementing the strategy. For example, Scotland, which hosts 4 of the top 25 UK universities in the biological sciences and where the life sciences sector employs over 37,000 people receives little attention in the strategy.⁴⁰ In addition, NIHR, which receives substantial focus in the strategy, funds research only in England. Some of the functions performed by NIHR are carried out by devolved governmental departments in the other nations of the UK (e.g. National Institute for Social Care and Health Research in Wales and the Chief Scientist Office in Scotland), however this picture can be fragmented. The strategy does not fully recognise this. A genuine UK-wide approach must coordinate with devolved administrations and build on existing strategies in operation, such as the Life Sciences Strategy for Scotland 2025 Vision.⁴¹
56. It is also important to recognise that many aspects of the strategy will be underpinned by the wider Industrial Strategy, for example through strengthened digital infrastructure and digital skills base and a national approach to infrastructure. These dependencies further highlight the importance of cross-Governmental involvement and, as advocated by the Royal Academy of Engineering, a systems approach the industrial strategy and sector deals.⁴²
57. The Government response to the House of Commons Science and Technology Committee's Thirteenth Report of Session 2016–17 on Industrial Strategy: science and STEM skills

⁴⁰ Life Sciences Strategy for Scotland 2025 Vision (2017).
<http://www.lifesciencesscotland.com/pdf/Life%20Sciences%20Strategy%20for%20Scotland%202025%20Vision.pdf>

⁴¹ Life Sciences Strategy for Scotland 2025 Vision(2017).
<http://www.lifesciencesscotland.com/pdf/Life%20Sciences%20Strategy%20for%20Scotland%202025%20Vision.pdf>

⁴² <http://www.raeng.org.uk/news/news-releases/2017/april/systems-not-silos-new-industrial-strategy-must-del>

considered the relationship between the ISCF and the sector deals.⁴³ It is not clear from this response whether the funds to implement the sector deal will all be derived from the challenge fund, or whether additional funds will also be made available. Clarity on this important point is required.

Brexit

58. The Life Sciences Industrial Strategy must be seen in context of the uncertainty stemming from UK exit from EU. The Academy considers there to be four key strands to the UK's relationship with the EU.

59. **Mobility** – UK research and development in universities and businesses is highly dependent on access to global (and EU) talent (see paragraph 43). Urgent clarification of the long-term rights of EU researchers in the UK is essential. In the longer term the continued ability of the UK to attract and retain talented researchers from across the globe must be encouraged by this strategy.

60. **Collaboration** – Collaboration between the UK and the EU is mutually beneficial, increasing the impact of research compared to that conducted by UK or EU researchers alone.⁴⁴ Access to EU support for collaborations and access to EU-funded consortia facilitate this kind of research. Further global partnerships should augment, rather than replace, collaborations with EU researchers.

61. **Funding** – UK research and development benefits from a wide range of EU funding sources, for example:

- Clinical medicine research received the highest volume of funding of any discipline, securing almost £120 million in 2015.⁴⁵
- UK SMEs have been more successful at drawing down EU funding than any other member state, securing £658 million between 2007 and 2013.⁴⁶
- The UK has been the largest beneficiary of the Innovative Medicines Initiative (see paragraph 28).

In the long-term the Academy believes that UK research would be best served by the closest possible association with EU research programmes in any future relationship. We welcomed the Government's recent discussion paper outlining the UK Government's desire for an "ambitious" future relationship with EU research and innovation, however further clarity on the nature of this relationship is urgently required.⁴⁷

62. **Regulation** - we believe that continued alignment with EU regulations is beneficial across many areas of research, particularly around clinical trials and rare disease research. However, regulation should be considered on a case by case basis to ensure that the potential benefits of increased flexibility or bespoke national regulation can be realised. Of particular importance to the life science sector is the harmonisation to the incoming clinical trials regulation (CTR) and co-operation with the European Medicines Agency. In

⁴³ House of Commons Science and Technology Committee Industrial Strategy: science and STEM skills: Government Response to the Committee's Thirteenth Report of Session 2016–17 <https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/335/335.pdf>

⁴⁴ Technopolis (2017). The Impact of Collaboration: the value of UK Medical Research to EU Science and Health <https://acmedsci.ac.uk/file-download/72060732>

⁴⁵ Technopolis (2017). The role of EU funding in UK research and innovation <https://acmedsci.ac.uk/file-download/70343877>

⁴⁶ Technopolis (2017). The role of EU funding in UK research and innovation <https://acmedsci.ac.uk/file-download/70343877>

⁴⁷ <https://acmedsci.ac.uk/more/news/dexeu-publishes-position-paper-on-science>

addition two new regulations for medical devices and *in vitro* diagnostic medical devices are due to come into force in 2020 and 2022 respectively.

Clinical Trials Regulation

63. The incoming CTR is intended to create a favourable environment to conduct clinical trials with the highest standards for patient safety. This legislation has been updated to address inefficiencies and delays associated with the previous Directive.
64. The new Regulation is expected to streamline the process for multi-country trials and provide greater harmonisation. An EU clinical trial portal and database, which will act as a single entry point for submitting clinical trial information into a publically accessible database (subject to transparency rules). The creation of this portal is key to the timeline of the Regulation. In June 2017 it was announced that delays in completion of the portal have pushed back the implementation of the Regulation to 2019.⁴⁸ The European Medicine's Agency Management Board will meet in October 2017 to discuss a delivery timetable for the EU portal. This delay raises some uncertainty over the future relationship with CTR as it takes the Regulation outside the scope of the EU (withdrawal) bill.
65. Delegates at the Academy of Medical Sciences' FORUM meeting on "Regulation and governance of health research: five years on" agreed that continued harmonisation with the EU clinical trials regulation and access to the EU portal should be prioritised.⁴⁹

European Medicines Agency

66. The European Medicines Agency (EMA), which is currently located in London, will have to relocate to be housed in a Member State. The decision for where the EMA is to be located is expected in November 2017. The movement of the EMA away from London represents a potentially major loss to the life sciences sector. Currently the UK regulator, the MHRA, provides substantial support to the EMA, acting as Scientific Advise Co-ordinator in at least 20% of centralised EMA medicine approvals.⁵⁰ The loss of this support function could have negative impacts for both the EMA and MHRA. The EMA would stand to lose up 20% of its capacity, whilst the prestige of the MHRA may be affected if its influence within the EMA is diminished.
67. Academy Fellows foresee mutual benefits to the MHRA retaining access to the EMA. The Academy was encouraged to see the Secretary of State for BEIS and the Health Secretary outline the Government's position regarding continued cooperation with the EMA, which was reiterated in the Government's recent discussion paper.^{51,52}

⁴⁸ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp

⁴⁹ Academy of Medical Sciences (2017). Regulation and governance of health research: five years on <https://acmedsci.ac.uk/file-download/14145196>

⁵⁰ Technopolis (2017): The Impact of Collaboration: the value of UK Medical Research to EU Science and Health <https://acmedsci.ac.uk/file-download/72060732>

⁵¹ <https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b>

⁵² Department for Exiting the EU(2017). Collaboration on science and innovation: A Future Partnership Paper https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/642542/Science_and_innovation_paper.pdf