Immunology

and the UK's life sciences industry

British Society for immunology

Immunology

and the UK's life sciences industry

This is an exciting time for immunology. The discipline sits at the sharp end of research and innovation in the life sciences sector, with decades of investment and collaboration in basic research beginning to yield exciting new breakthroughs in critical disease areas such as infection, cancer, autoimmunity and allergy. Moreover, advances in our understanding of the immune system are only now beginning to unravel the complex immune processes underlying many other diseases, including metabolic, cardiovascular and neurodegenerative conditions. It is perhaps no surprise then that the discipline sits at the very heart of the drug development process, with immunology underpinning over half the pipeline products of the top five R&D investors in the UK.

With the publication of the industrial strategy Green Paper, 'Building our Industrial Strategy', Prime Minister Theresa May's then Government began the process of developing a comprehensive and ambitious new industrial strategy for a post-Brexit United Kingdom.

The life sciences industry is a key part of the UK economy and one of our most successful industrial sectors. It invests more in R&D than any other industry – almost half (48%) of the total R&D investment by UK businesses is from the life sciences industry – and directly employs over 140,000 people. Many of these individuals are highly skilled scientists with responsibility for developing, in partnership with the NHS and academia, the next generation of life changing and life enhancing medicines and health technologies. It is identified within the Green Paper as a sector of key strategic importance to the national economy and the focus of a discrete sector deal to build on this strong foundation.

This report is the British Society for Immunology's response to the industrial strategy Green Paper. Feeding into the 'science and technology' pillar, we make a number of recommendations that fall under seven priority actions.

Actions:

1 Make the most of our transition from the EU

- Maintain access to the EU's Horizon 2020 programme (and its successor).
- Design an efficient immigration system that supports our ability to recruit and retain the very best high value workers (including scientists).

2 Increase science funding to ensure the UK remains competitive

- Set out a roadmap to bring UK science spend more in line with other developed economies, targeting public and private investment in R&D of 3% GDP.

3 Develop our capability and skills in key areas, such as computational biology and vaccines research

- The government should work with stakeholders to develop a national skills strategy that seeks to address the acute skills gap in systems biology and bioinformatics, which are of increasing importance to the research and development of new medicines.
- The government and universities should explore means of embedding bioinformatics, genomic technologies and systems biology into the curricula of life sciences degree courses.
- Research funders should increase the funding of fellowships in systems biology and bioinformatics to skill up PhD-qualified scientists.
- Identify UK opportunities for high-value small-scale vaccine manufacturing, particularly outside of the 'Golden Triangle' region, as interest grows in the development of 'personalised' vaccines.

4 Strengthen the relationship between academia and industry

- Break down barriers between academia and industry: extend support for programmes such as CASE PhD studentships and the MRC's Proximity to Discovery Fund, which encourage interactions and knowledge exchange between industry and academia.
- Use the expertise of learned societies, tapping in to existing member networks that span academia and industry.
- Target action in the pre-competitive space, encourage partnership at the early stages of the R&D pipeline (during basic disease research) before the complexities of intellectual property (IP) ownership arise.

5 Promote workforce diversity in the life sciences

- Develop a wide-ranging strategy to identify and address the issues responsible for the 'leaky pipeline' phenomenon for women in STEM sectors, including the life sciences.
- Support STEM outreach initiatives, such as the Sutton Trust's 'Pathways to STEM' programme for non-selective state school students from low to middle income families.
- Successful examples of diversity programmes, such as the London Universities' B-MEntor scheme (for Black and Minority Ethnic early career researchers), should be widely publicised.

6 Maximise the research potential of our unique NHS

- Working with partners and building on the recently published one year NHS Research Plan, NHS England (and equivalents in the devolved administrations) should develop a comprehensive research strategy to embed research and innovation at the heart of the health system.
- The Department of Health should instigate a national conversation on the use of anonymised patient data in health research to promote a broader understanding of the value of these records in the development of new medicines. This dialogue should include participation from all stakeholders involved in patient care and research.

7 Support SMEs and help them scale up

- 'Incubator' initiatives that provide business expertise and small early-stage loans and investments should be widened to other areas of the UK with government support.
- Innovate UK should bring forward the launch of its 2019 programme of 'innovation finance products' to increase the pool of capital available to new small and medium-sized enterprises (SMEs).
- Promote SME pairing schemes, linking more mature SMEs with new start-ups, to help support their development. These interactions could be supported through tax and other benefits.
- Help scientists develop the skills they need to commercialise their ideas, for example through the development of a dedicated online portal.
- Examine how scientists can be incentivised to develop SMEs from their research, for example through the REF.

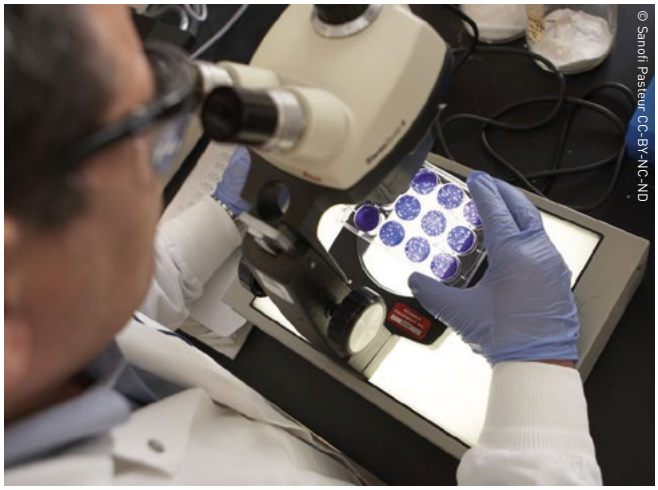
Introduction

The life sciences industry has often been described as the 'jewel in the crown' of the UK economy. It is a large and diverse sector with almost 5,000 companies, covering pharmaceutical, medical technology and biotechnology.[1] The life sciences industry employs around 175,000 people and invests more in research and development than any other sector in the UK – £4.2 billion in 2015.[2]

The UK has many assets that help place it in a particularly privileged position compared to its international competitors. Three of the world's top 10 universities – Oxford, Cambridge and Imperial – are British institutions, one of which has helped to found the largest biomedical research facility in Europe: the Francis Crick Institute in London.

The NHS presents golden opportunities for recruitment of patients into clinical trials, and intelligent sharing of medical records for large scale research studies. The regulatory processes in the UK are considered to be gold standard, with the status of the Medicines Healthcare products Regulatory Agency (MHRA) as one of the most respected national regulators in Europe. Furthermore, the UK has a business-friendly tax environment for research intensive companies, with financial incentives for start-ups and the Patent Box initiative, enabling industry to protect its profits from intellectual property.

Immunology has always played a leading role in the UK's life sciences industry. For example, the British company Allen & Hanburys (now part of the Glaxo group) invented the four most widely used asthma/COPD medications in the world including the contents of the famous blue reliever and brown preventer inhalers: salbutamol (Ventolin) and beclomethasone (Becotide).[3] In other areas of immunology, British companies have also taken the lead. Building on the Nobel Prize winning work of Milstein, Köhler and Jerne, who discovered the principle behind the production of monoclonal antibodies (see box), Cambridge Antibody Technologies developed techniques to create the first fully human monoclonal antibody, adalimumab (Humira). This type of therapy has revolutionised treatment in many disease areas, such as cancer and rheumatoid arthritis.



Even since the development of adalimumab in the early 1990s, our knowledge of the immune system has increased substantially. We increasingly appreciate how fundamentally important the immune system is, both in keeping us healthy and in the development and progression of disease. New advances mean we know more about inflammation and its role in conditions not previously thought to be immunological, such as dementia. We are rapidly beginning to unravel the intricacies of the populations of bacteria that live in our gut, lungs and other places, and the role that these microbes and their products (metabolites) might play in maintaining our optimal health. Moreover, new research is beginning to reveal how these microbiota might

1. LSCC 2014 ***Life sciences industry and UK analysis***
2. Office for National Statistics 2017 **UK gross domestic expenditure on research and development: 2015**
3. Barnes & Breckenridge 2012 *Thorax* doi: **10.1136/thoraxjnl-2011-201522**

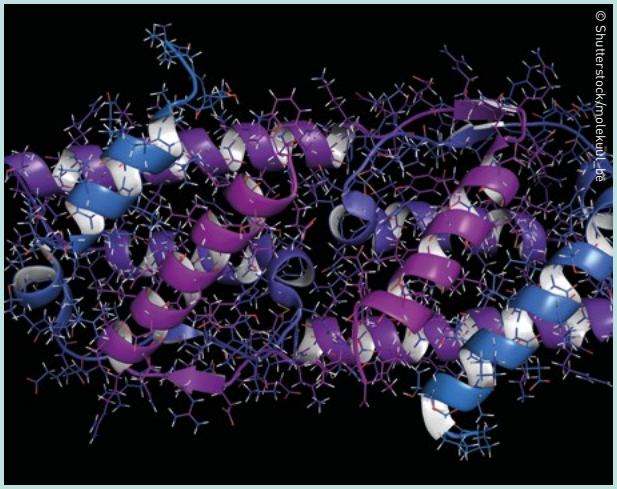
> *We increasingly appreciate how fundamentally important the immune system is, both in keeping us healthy and in the development and progression of disease*

be involved in the development of conditions including cardiovascular disease, obesity, type 2 diabetes, depression, Alzheimer's disease and Parkinson's disease. Meanwhile our knowledge of immune dysfunction and hypersensitivity – in autoimmunity, immunodeficiency or allergy – has identified a hidden epidemic of disease. These conditions are growing in prevalence and represent significant health challenges for the 21st century, and therefore comprise important areas for the future of medicines development.

The importance of the immune system in health and disease and the potential application of immune research in the development of new therapeutic strategies against these conditions is reflected in the prominence of immunology in the R&D portfolios of the life sciences industry. Examining the top five investors in UK R&D, an average of 56% of their pipeline products are drugs for the treatment of immune conditions (e.g. asthma, COPD, infectious disease), or are drugs that manipulate or modulate the immune system in their mechanism of actions (e.g. vaccines, monoclonal antibodies).[4] A number of these immunomodulatory compounds are being applied to disease areas not traditionally associated with the immune system, such as oncology and dementia.

The development of a new industrial strategy by the government, and within that a focus on the UK life sciences sector, is an opportunity to build on our global reputation as one of the best places in the world to research and develop new medicines. This also means nurturing the foundation that underlies this innovation: basic, discovery led science. Immunology is a core component of this and our discipline will continue to play a vital role in moving the UK's economy forward in the coming years and decades.

This report is timed to coincide with the development of the UK's industrial strategy, with recommendations highlighting key areas that we believe can benefit from targeted government support. These recommendations cover seven priority areas, from how to make the most of our transition out of the EU following Brexit, to making the most of the research potential of our unique NHS. Some of these may be out of scope of the industrial strategy consultation but remain absolutely critical, particularly in the case of the impact of Brexit on science and research, to the future success of our life sciences industry.



Monoclonal antibodies

Antibodies are proteins that are produced by the B cells of the immune system to bind to specific targets on microbes, cells or proteins, blocking interactions or making it easier for other immune cells to detect and eliminate them. Monoclonal antibodies are engineered forms of these proteins that are designed to target a specific part of a disease, such as a molecule on a cell or a chemical that a cell produces. Early types of monoclonal antibody were based on rat or mouse proteins and this caused some side effects in humans. The first fully human monoclonal antibody, adalimumab, resulted in fewer side effects than those antibodies based on rodent proteins. Therapeutic monoclonal antibodies have grown in importance over recent years and now occupy a key place in the field of medicine. Adalimumab (Humira) is currently the world's best-selling drug, and it is predicted that in 2020, nine of the top twenty best-selling drugs worldwide will be monoclonal antibodies.[5] By 2020, worldwide sales of monoclonal antibody products are expected to reach $125 billion.[6]

4. Based on figures of UK R&D investment levels 2009–2010, the top five companies (Roche, AZ, GSK, Pfizer, Shire) pipelines (updated 2016) were assessed for products that treated immune conditions, drugs where the mechanism of action is targeted against an immune component, or where immunology has significantly contributed to the development of the technology (e.g. monoclonal antibodies). These products were then compared to the total pipeline. Identical products for different indications were excluded, unless used in a new combination, or formulation, or given via a different route.
5. Staton 2017 **The top 20 drugs in 2020 – worldwide sales** *FiercePharma*
6. Ecker *et al.* 2015 *MAbs* **7** 9–14

Supporting the life sciences industry:

our recommendations for the industrial strategy

The industrial strategy is an opportunity to cement the role and reputation of the UK as a global leader in the life sciences, supporting basic science and nurturing the research and development of the next generation of breakthrough medicines.

It is also a chance to confront the challenges that can hamper innovation. The industrial strategy should seek to mitigate the risks and maximise the opportunities of our transition out of the EU. It should also seek to address key skills shortages and increase diversity in the life sciences workforce. Moreover, despite recent increases in the funding available for research, spending on science in the UK continues to lag some way behind our competitors across the EU and the world.

In this report, we make a number of recommendations across seven priority domains, each highlighting specific areas for government action. Each recommendation is designed to support a vibrant research ecosystem, building on our strengths across basic and translational science, and providing the necessary foundation for innovation and economic prosperity.

Action 1

Make the most of our transition from the EU

Brexit presents both immunology and the wider life sciences sector with several acute challenges, particularly in gaining funding, facilitating collaboration, and enhancing our ability to access the very best international talent for academia and industry.

Horizon 2020, the EU's flagship scientific programme, has played a key role in funding translational science and collaboration throughout Europe, often with UK researchers employed in a leading role. We welcome the Government's commitment to underwrite successful grants for universities and businesses for the duration of the current programme, but access beyond this date is still unknown. Many of Horizon 2020's funding strands directly support industry, in part through the facilitation of joint working between academia and industry. The Innovative Medicines Initiative (IMI), for example, brings together companies, universities, public laboratories, small and medium-sized enterprises (SMEs), patient groups and regulators to accelerate medical research. It has had an influential role in promoting immunological research and innovation, including through projects such as the €30 million funded RESCEU grant on respiratory syncytial virus,[7] and Be The Cure[8] a €34 million funded collaboration focusing on rheumatoid arthritis. Both initiatives link diverse academic and industry expertise from across Europe with major representation from UK centres. These large-scale public-private scientific partnerships do not exist elsewhere (IMI is the largest public-private research framework in the world) and are just one example of the significant benefits that come through the UK's participation in the scientific apparatus of the EU.

'We urge policymakers to explore bold options for streamlined entry systems for scientists and other high value workers'

Membership of the EU has also enabled UK universities and businesses to access the very best talent from across Europe. Many of those who come here plug key skills gaps for UK businesses (75% of roles on the Home Office's Shortage Occupation List are in STEM areas). Likewise, our own scientists and workers can freely travel across the continent to broaden their horizons and learn new skills. This fluid transmission of skills is a fundamental element of modern research; between 1996 and 2012 72% of UK scientists spent time at a non-UK institution. To make a success of Brexit, we must be able to compete for the brightest minds from across the continent. We urge policymakers to explore bold options for streamlined entry systems for scientists and other high value workers, for example through a flexible visa framework, that preserves access to the skills and expertise that sectors like science and academia so crucially rely on.

Recommendations:

- **Maintain access to the EU's Horizon 2020 programme (and its successor).**
- **Design an efficient immigration system that supports our ability to recruit and retain the very best high value workers (including scientists).**

7. RESCEU website
8. Be The Cure website

Action 2

Increase science funding to ensure the UK remains competitive

The recent pledge of an additional £2 billion annually for science and innovation is a welcome commitment from the government. However, gross expenditure on research and development (taking in public and private sources) in the UK only represents 1.7% of GDP, the lowest in the G7, less than the OECD average of 2.4% GDP, and significantly less than many of our European competitors who have met the Europe 2020 Agenda target of 3% GDP.[9]

'Implementing the central recommendation to produce a long term roadmap targeting % GDP spend on science would send a powerful message about our willingness to cultivate a thriving knowledge based economy'

Despite the fact that businesses spend significantly more than the government on research, public investment is a crucial part of the equation and influences the investment decisions of research intensive companies. There is strong evidence of a 'crowding in effect', with every £1 the government spends on research bringing in an extra £1.13 – £1.60 from the private sector.[10] As with other areas of central spending, austerity has eaten into the science budget, and this has anchored the brakes on overall research spend. In their 2015 report on the science budget, the Commons Science and Technology Committee warned that the UK's lagging investment in this area risked jeopardising our status as a world leader in research and innovation, with impacts on jobs and productivity. Our transition out of the EU means it is now more important than ever to create the right conditions for research and innovation. Implementing the central recommendation of the Science and Technology Committee to produce a long term roadmap targeting 3% GDP spend on science would be a significant step in the right direction, and would also send a powerful message about our willingness to cultivate a thriving knowledge based economy.

Recommendations:

- **Set out a roadmap to bring UK science spend more in-line with other developed economies, targeting public and private investment in R&D of 3% GDP.**

9. Science and Technology Select Committee 2015 *UK must increase science funding to keep up with competitors*
10. AMRC 2016 *Inquiry into Government's industrial strategy*

Action 3

Develop our capability and skills in key areas such as systems biology, genomic technologies, and vaccines research and manufacturing

The enormous progress in computing power over the last two decades has led to the emergence of some powerful new technologies relevant to immunology.

Systems biology, driven by the 'omics' technologies (single cell transcriptomics, genomic technologies, proteomics etc.) blends experimental and computational research to better understand complex biological systems in a holistic way (e.g. proteomics assesses changes in protein expression across the entirety of a specific biological context, such as a cell). Together with bioinformatics, which uses statistical methods to interrogate complex systems, computational and quantitative techniques are driving the 'big data' revolution in the life sciences and are an increasingly prominent aspect of innovation and many biomedical research activities, including in immunology. There is also untapped potential in embedding these methods into patient care pathways within the NHS. The Farr Institute is a good example of an organisation who use health data analysis to help drive improvements in public health and patient care[11] and, in the future, it is hoped that treatment decisions based on a patient's genomics data will become the basis of routine personalised care in clinical practice.

Systems biology has significant application in the research and development of new medicines. For example, these approaches have been employed to great effect in vaccine development to better understand the molecular processes, immunogenicity and safety profile of potential vaccines, and using this information to inform and accelerate research and development of promising candidates. In the field of cancer, the sequencing of tumour cell DNA has also played a critical role in the identification of new tumour antigens that are important in the development of cancer immunotherapies. Another exciting area of computational biology in immunology is machine learning, used to quickly analyse huge volumes of biological data using mathematical algorithms. Machine learning allow computers to learn how to solve problems rather than follow step-by-step instructions, and are widely applied in many different areas of the life sciences, such as predicting drug interactions or predicting a patient's disease status.

'The strategic importance of these skills demands that government explore the development of a skill strategy that seeks to make the UK a world leader in the application of computational and mathematical technologies.'

The emergence of these technologies is driving huge demand for the skills required to both generate and interrogate this information in a sophisticated way (i.e. the demand for researchers with both the computational skills and 'wet lab' experience to manipulate and explore the data intelligently). Training in this area is a key strategic need for the life sciences workforce and, we believe, requires targeted action at both undergraduate and postgraduate levels in higher education, for example through integration of non-elective courses in basic programming languages such as 'R' and

11. The Farr Institute website – **Research**

'Python', systems biology, genomic technologies, and bioinformatics into taught degree programmes. Teaching and seminars at university can then serve as the foundation for more advanced learning for postgraduates to give them an intimate knowledge of coding and programming their own discrete software applications.

For postdoctoral students, the MRC funded Computational Genomics Analysis and Training (CGAT) programme at the MRC Weatherall Institute of Molecular Medicine, based at the University of Oxford, is a training model that could be replicated on a larger scale as a means of developing more advanced computational capability. In any case, the strategic importance of these skills, not just in the biomedical sciences, but for the UK economy as a whole, demands that government explore with stakeholders the development of a skills strategy that seeks to make the UK a world leader in the application of computational and mathematical technologies.

Building on our world-class vaccines research capability should be another priority. It has been noted previously that, with the exception of influenza vaccine production, the UK is severely lacking in domestic vaccine manufacturing capability.[12] Several UK institutions are conducting exciting research into therapeutic vaccines for tropical diseases and cancer, some of which are in clinical trials funded by the UK Vaccines Network, UK charities and research councils. However, this excellence in the research base is not supported by our manufacturing infrastructure, and so these highly skilled good manufacturing process (GMP) jobs are being lost to contract manufacturing organisations overseas. It is unrealistic to expect large pharmaceutical companies to relocate long established vaccine operations from the European continent to the UK, but the lack of any significant manufacturing facilities in Britain represents a missed opportunity to capitalise on this emerging area of science, and to add valuable diversity to the UK's research ecosystem.

The UK Vaccines Network is currently investigating opportunities for facilities in the UK, and the increasing interest in therapeutic vaccines tailored to specific cancers is one example of a small-scale, high-value, growth area that the UK could benefit from exploring.[13] Supporting small-scale, high-value manufacturing also presents an opportunity to spread the economic benefits of the life sciences industry to areas other than the Golden Triangle (London, Oxford, and Cambridge). Funding for a 'Future Vaccine Manufacturing Research Hub' has recently been made available,[14] and the proposed 'hub and spoke' model for this initiative should take care to fully engage expertise in the regions, particularly as the little manufacturing capability the UK has is based in north west England,[15] and near Edinburgh.[16]

Recommendations:

- **The government should work with stakeholders to develop a national skills strategy that seeks to address the acute skills gap in systems biology and bioinformatics, which are of increasing importance to the research and development of new medicines.**

- **The government and universities should explore means of embedding bioinformatics, genomic technologies and systems biology into the curricula of life sciences degree courses.**

- **Research funders should increase the funding of fellowships in systems biology and bioinformatics to skill up PhD-qualified scientists.**

- **Identify UK opportunities for high-value small-scale vaccine manufacturing, particularly outside of the 'Golden Triangle' region, as interest grows in the development of 'personalised' vaccines.**

12. House of Commons Science and Technology Committee 2016 *Science in emergencies: UK lessons from Ebola*
13. UK Vaccines Network website
14. EPSRC 2017 *Future vaccine manufacturing research hub – quick reference*
15. Seqirus website – About
16. Valneva website – Locations

Action 4

Strengthen the relationship between academia and industry

Nearly three quarters of publicly funded research in the UK is carried out in universities.[17] Working together, collaborations between universities and businesses can be a powerful engine for research and development, merging the brightest discovery driven minds with the culture of enterprise and innovation of commercially driven organisations.

However, in many instances, collaboration between academia and industry is low. There are many historic reasons for this. Past relationships between pharma and healthcare professionals have frequently been a source of tension and distrust,[18] and industry is often considered impenetrable to academics, with inaccessible communication channels. Perhaps as a result, industry scientists are less included in activities of the scientific community such as conferences and the peer review process. Where collaboration does occur, there are significant complexities around the ownership of IP and technology transfer, which can dissuade further partnerships.

'Collaborations between universities and businesses can be a powerful engine for research and development, merging the brightest discovery driven minds with the culture of enterprise and innovation of commercially driven organisations.'

Overcoming some of these challenges and strengthening the interface between academia and industry has much to do with breaking down perceived cultural barriers and increasing permeability between the two sectors. In this regard, initiatives such as the MRC's Proximity to Discovery Fund and CASE PhD studentships have proved very successful in helping build early collaborative relationships. To encourage collaboration from the academic side, impact case studies in the Research Excellence Framework could be better used to recognise translational work and cooperation with industry. It is important too to realise the potential of using the existing networks of learned societies, many of which have memberships that span industry and academia, that can be exploited to cultivate dialogue between potential partners with shared interests. On the issue of IP, initiatives such as Open Targets, a collaboration between Biogen, EMBL-EBI, GSK and the Wellcome Trust Sanger Institute to identify potential new drug targets in immunology and other therapeutic areas, have been successful in promoting partnership across a range of diverse expertise to advance drug discovery in a pre-competitive space.

Recommendations:

- **Break down barriers between academia and industry: extend support for programmes such as CASE PhD studentships and the MRC's Proximity to Discovery Fund which encourage interactions and knowledge exchange between industry and academia.**
- **Use the expertise of learned societies, tapping in to existing member networks that span academia and industry.**
- **Target action in the pre-competitive space, encourage partnership at the early stages of the R&D pipeline (during basic disease research) before the complexities of IP ownership arise.**

17. Universities UK 2014 **The funding environment for universities 2014: research and postgraduate research training**
18. Rosenblatt 2013 *Ann Am Thorac Soc* **10** 31–38

Action 5


© Shutterstock/pressmaster

Promote workforce diversity in the life sciences

As with most STEM sectors, the immunology and life sciences industry workforce lacks diversity, and this represents a huge loss of talent to the UK economy.

Unsurprisingly there is a lack of women in leadership roles, despite female students comprising the majority from undergraduate to doctoral level study.[19] The proportion of women in most fields decreases sharply in correlation with seniority – only 16% of professors in the biosciences are women. The reasons for this 'leaky pipeline' are complex and varied, but they urgently need to be addressed to allow women in STEM to reach their full potential.

However, diversity doesn't just apply to gender. It is critical that the sector is accessible to all, irrespective of gender, ethnicity, disability, sexuality or socio-economic background, to ensure fair and equal representation, and a comprehensive exchange of ideas and experience. Achieving this will require a proactive approach to attract people into STEM from historically disadvantaged groups.

'It is critical that the sector is accessible to all, irrespective of gender, ethnicity, disability, sexuality or socio-economic background, to ensure fair and equal representation, and a comprehensive exchange of ideas and experience.'

Recommendations:

- **Develop a wide-ranging strategy to identify and address the issues responsible for the 'leaky pipeline' phenomenon for women in STEM sectors, including the life sciences.**
- **Support STEM outreach initiatives, such as the Sutton Trust's 'Pathways to STEM' programme for non-selective state school students from low to middle income families.[20]**
- **Successful examples of diversity programmes, such as the London Universities' B-MEntor scheme.[21]**

19. Royal Society 2014 A picture of the UK scientific workforce
20. The Sutton Trust Pathways to STEM
21. Royal Society 2014 B-MEntor case study

Action 6

Maximise the research potential of the NHS

The NHS is a unique asset to life sciences research. In terms of research potential, no other health service in the world can match the NHS as a gateway to patients. Patient data is an exceptionally valuable resource for researchers. In immunology, large patient datasets can be crucial in the investigation of infectious diseases, such as flu, and in understanding the safety and effectiveness of new drugs that act on the immune system. Large patient cohorts are also key in the study of rarer diseases, which includes many immunodeficiency disorders. The 100,000 Genomes Project is an excellent endeavour in this area and an opportunity to gain new insight and understanding into the causes (and potential treatments) of rare genetic diseases.

As the Government's mandate to NHS England makes clear, a strong NHS depends on the proceeds of a strong economy; but a strong health system can also help build a strong economy, particularly in the life sciences.[22] Fully maximising the research potential of the NHS will require a comprehensive research plan. The recently published NHS England research plan is a positive step and key to its success will be the implementation of its commitments within the context of a pressurised health system with multiple competing resource priorities. However, this plan only covers the year 2017/18, and we believe a longer-term strategy is required to fully embed research and innovation at the heart of the NHS. This plan should be developed in partnership with relevant strategic partners, such as patient groups, learned societies, research charities and clinical bodies, and should also involve commercial bodies such as the pharmaceutical industry. The plan should be multi-phase, prioritising quick-win opportunities (for example, profiling exemplar practice and helping diffuse this throughout the system) before looking to tackle more difficult questions, such as those around information systems.

There are, however, some outstanding challenges. Patient and public trust in the way their data is used is paramount and there needs to be further dialogue to restore public confidence on the way health data is collected, anonymised, stored and shared, particularly with commercial bodies. Much of this centres around privacy and trust, but future communication efforts should also focus on the value of patient data records to clinical research, and how these can be crucial to future medical discoveries. Promoting a broader understanding of the value of anonymised health data

© Shutterstock/MonkeyBusinessImages

'In immunology, large patient datasets can be crucial in the investigation of infectious diseases, such as flu, and in understanding the safety and effectiveness of new drugs that act on the immune system.'

to future medical discoveries is a national conversation that should incorporate all those involved in health research: from healthcare professionals and patients, to universities, research institutes, private companies and national leaders from the NHS and government. Doing so would put the UK in an excellence position to capitalise on the research potential of the NHS, accelerating the development and delivery of new breakthrough medicines.

Recommendations:

- **Working with partners and building on the recently published one year NHS Research Plan, NHS England (and equivalents in the devolved administrations) should develop a comprehensive research strategy to embed research and innovation at the heart of the health system.**

- **The Department of Health should instigate a national conversation on the use of anonymised patient data in health research to promote a broader understanding of the value of these records in the development of potential new medicines. This dialogue should include participation from all stakeholders involved in patient care and research.**

22. Department of Health 2017 The Government's mandate to NHS England for 2017-18

Action 7

Support SMEs and help them scale up

Not all medical innovation is carried out by 'Big Pharma' – far from it. 85% of life sciences companies are SMEs and many have developed with assistance from public investment through initiatives such as Innovate UK.

To maintain our reputation as a life sciences powerhouse, there needs to be strong links between the UK Government, public organisations and the life sciences industry for research and innovation to continue to flourish. Public money spent in this area generates a significant return on investment as every £1 of government investment leverages returns of up to £1.60 in private funds.[10] Despite support from public initiatives such as Innovate UK, the barriers to new SMEs are still high. Companies often need existing capital to qualify for public investment, and this is a significant barrier for less-established companies. To address this, Innovate UK should bring forward the launch of its 2019 programme of 'innovation finance products' (i.e. loans) to increase the pool of available finance for new SMEs.[23] The government could also provide tax incentives for venture capital funding of life sciences SMEs, where the start-up costs are particularly high. The UK does have a relatively business friendly tax environment, with favourable R&D tax credits and the Patent Box, but both are only beneficial if a company is established enough to make a profit.

Non-financial support and advice are also critical to the success of a start-up. The pairing of mature SMEs with start-up SMEs can be highly impactful on the early development stage of a new company. Successful SMEs also benefit from insight into new business areas, although further incentives are needed to attract and retain mature SMEs in pairing schemes.

Incentivising pairing schemes could also be beneficial to academics who are looking to develop SMEs from their research but who have no prior business knowledge. There are significant cultural barriers to creating spin-outs, with academics who are entrenched in research having little or no experience in commercialising their ideas. Pairing schemes could help overcome these steep barriers but there is also a need for more training and resources to help scientists develop their own skills. There may be a range of learning resources available, but one idea might be to develop a dedicated online portal to act as a central resource for useful information. For example, a similar website (f6s.com) currently exists for tech start-ups.[24]


© Shutterstock/Point Images

There may also be merit in examining how scientists could be further incentivised to develop SMEs from their research. Publications are the classical measure of academic success, so further recognition of the value of commercialisation, which does not always lead to publications, from research funders and through Research Excellence Framework impact case studies may also be of merit.

Recommendations:

- **'Incubator' initiatives (for example Biocity and Medicity in Nottingham)[25] that provide business expertise and small early-stage loans and investments, should be widened to other areas of the UK with government support.**
- **Innovate UK should bring forward the launch of its 2019 programme of 'innovation finance products' to increase the pool of capital available to new SMEs.**
- **Promote SME pairing schemes, linking more mature SMEs with new start-ups to help support their development. These interactions could be supported through tax and other benefits.**
- **Help scientists develop the skills they need to commercialise their ideas, for example through the development of a dedicated online portal.**
- **Examine how scientists can be incentivised to develop SMEs from their research, for example through the REF.**

23. MSC R&D 2016 *Innovate UK to push ahead with loans plan by 2019–2020*
24. F6S website
25. Biocity website

The British Society for Immunology's mission is to promote excellence in immunological research, scholarship and clinical practice in order to improve human and animal health.

We are grateful to all our members who contributed to this report.
This report was authored by Beth McKendrick.

British Society for Immunology
34 Red Lion Square
London
WC1R 4SG
www.immunology.org
@britsocimm

Registered charity: 1043255 in England and Wales; SC047367 in Scotland
Registered in England and Wales as company: 3005933

Design: Qube Design Associates
Front cover image: Shutterstock/Sergey Nivens

British Society for immunology