BSI response to House of Lords S&T committee's call for evidence
Life Science Industrial Strategy
August 2017

Written evidence submitted by the British Society for Immunology

Introduction

- The British Society for Immunology (BSI) is the largest immunology society in Europe. We represent the interests of over 3000 immunologists working in academia, clinical medicine, and industry. Our main objective is to promote and support excellence in research, scholarship and clinical practice in immunology for the benefit of human and animal health.

- As a nation we are world leading in our immunological research and rank first for research in infection and immunology in the G7.[i] Immunological science underpins many aspects of human health and the progression of disease. The application of immunological research extends across communicable disease and vaccination to the management and treatment of chronic diseases such as diabetes, asthma, allergies, and even cancer. It is also now becoming clear that immune responses are key to the development of many common disorders not traditionally viewed as immunologic, including metabolic, cardiovascular, and neurodegenerative conditions. These diseases are growing in prevalence and represent significant health challenges for the 21st Century.

- The UK is a world leader in life sciences research and immunology sits at the sharp end of this innovation. Decades of investment in basic research have served as the foundation for exciting new breakthrough therapies in disease areas as diverse as infection, cancer, autoimmune disease 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 more than half the pipeline products of the top five R&D investors in the UK.[ii]

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?

- Risk is the primary barrier to investment in life sciences research. The development of novel breakthrough therapies from concept to commercialisation is an expensive process characterised by high attrition/failure rates in comparison to other industries. For many immune mediated diseases, regulatory requirements and long-term development times provide too great a commercial risk to investors, particularly given the likely prospect of future competition from new products. From basic research, the bedrock of innovation and so critical to the future of the healthcare industry, practical (and profitable) application of that science is often decades away, while commercialisation is likely only to be possible after additional capital investment. The UK has some of the world's leading academic centres,

pursuing ground-breaking curiosity driven research. Patenting and protecting new intellectual property (IP) is not a strength of academia however, where the culture is more oriented towards publication and securing grant income. Thus, without strong IP protection, the commercial potential of research is diminished in the eyes of investors.

- In considering the place of science and innovation at the heart of the national economy, the value of basic research cannot be understated. Even where no practical application is yet apparent, efforts to improve our understanding of fundamental biology are often the foundation of future breakthrough industries. For example, antibody technology has grown from blue skies research, much of which undertaken at academic centres in this country, to the multi-billion-pound industry it is today. For this reason, it is hugely important that the Government continue to support basic science. We therefore fully back the recommendation of the life sciences industrial strategy document for an increase in funding that would match the upper quartile of OECD countries.

- Even where science has led to the development of an innovation with significant potential for high-return there remain considerable challenges in attracting investment. The costs for new life sciences start-ups and SMEs, even small ones, are considerable, especially in comparison to other industries that are not exposed to the same regulatory controls. It has also been put to us by members experienced in this area that the UK has a relatively small pool of capital available for these high-risk investments, particularly compared to other countries, such as the US. This is in part because large amounts of capital are tied up in pension funds, which tend to be low risk investors. In the US by comparison, tax advantages on investments, an investment culture that has historically been more willing to take on risk, and a diverse pool of public and private investors, make it easier for start-ups and SMEs to find the capital they need to develop and grow. As identified in the life sciences industrial strategy, the emergence of long-term capital – referred to as "patient" capital – is likely to be a key mechanism that helps new life sciences companies access the required long-term investment.

- The life sciences industry itself provides a direct pathway to investment for research. The industry is diverse and in addition to large established multinationals there are many mid-size biotech/pharmaceutical firms that are in a perpetual search for new ideas and assets. Scientists in the UK therefore have good opportunities to link up with these companies, including through a number of formal schemes (such as CASE studentships[iii], the MRC's Industry Collaboration Agreement[iv], and the European Union's Innovative Medicines Initiative[v]). The Biomedical Catalyst scheme, between MRC and Innovate UK, has also had some success in promoting interactions between academics and industry. Strengthening the interface between academia and industry, and in doing so merging the brightest discovery driven minds with the culture of enterprise and innovation of commercially driven organisations, can be a powerful engine for growth and investment.

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?

- It is important to recognise that the UK's "underperformance" in generating IP from basic science is in some ways an artefact of our relative strength in this area, and particularly so in immunology. We have a world class academic research base that leads the world in experimental and translational immunological science, driven in part by technological improvements such as new monoclonal antibody technologies, fragment based chemistry,

and computational biology. In many areas of immunology, a shift in focus has occurred in recent decades, away from almost entirely animal focused research to a more integrated approach combining human experimental medicine with *in vivo* and *in vitro* tools. Immunology therefore performs well in generating new IP compared to other biomedical disciplines and although more can be done to support innovation, we would advise against too much of a push towards translational science. Blue skies research is essential to develop new ideas and hypotheses and has propelled immunology from mouse to man to deliver ground-breaking insights on immune function that have been exploited for clinical benefit.

- More support could be offered to academic scientists to encourage them to patent and protect new IP. Many scientists are simply not aware of the translational potential of their research or indeed have a poor understanding of the processes involved. Even something as simple as sharing work in a poster, which researchers do regularly, can preclude that work from being protected under patent, and many scientists will simply be unaware of this. Moreover, patenting takes time and effort, delaying the publishing of new work which puts the researcher at odds with the "publish or perish" ethos of academia. Enhancing awareness of the opportunities around patenting and indeed educating them on the process would therefore be beneficial.

- The structures within universities for developing and managing IP face significant challenges however. Many simply do not have the financial backing to secure strong patents (again this is a difference between the UK and the US) and consequently the commercial value of the patent is diminished. Further support could also be directed towards promoting awareness of IP protection amongst the academic workforce. Part of the solution here may be in providing more opportunities for training in business development skills, in effect taking academics out of their comfort zones and looking to instil a more entrepreneurial mindset. Indeed, these opportunities could be integrated into undergraduate degree programmes to help blend commercial acumen into the training of the next generation of scientists.

- As an organisation that exists to promote and support immunology, including by encouraging and helping our members to interact with the public, we would also highlight the beneficial role that public engagement can play. In communicating their work to the public, scientists are often forced to think clearly about the public benefit of their research, and articulate current and potential application. This can help scientists think about the translational value of their research which in turn promotes innovation within the research culture.

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?

- Due to rapid technological change, the training needs of the immunological workforce are constantly evolving. As indicated in our submission to the Commons Science and Technology Select Committee inquiry on STEM skills[vi], the expansion of affordable next-generation sequencing technologies is driving an increasing need for the necessary skills to analyse and interpret large amounts of data, namely quantitative and computational expertise. These technologies have wide practical application in translational science, including in the development of new vaccines or in the identification of tumour antigens for cancer immunotherapies. Upskilling the workforce requires support for advanced training opportunities for PhD and post-doctoral researchers as well as integration of numerical and scientific computing elements into undergraduate degree programmes. The Computational Genomics Analysis and Training Group at the MRC Weatherall Institute of Molecular

Medicine[vii] is one such centre that runs advanced training courses, but capacity is limited and unable to match demand. Its model could serve as a template for similar centres around the country.

- Connected to the need to develop more advanced technical capability in emerging technologies is the need to promote problem solving, data analysis, and team working skills. Education in the biological sciences has traditionally focused on memorising lots of information primarily through a competitive solo approach where students work alone or in pairs to develop project work rather than in teams. This contrasts with training in other STEM disciplines, for example engineering, where delivering team reports and working with students with different skills is promoted. Team science and interdisciplinary working is of crucial importance due to the challenges of translating science in the clinic.

- As previously mentioned, enabling immunologists to develop business skills would also be beneficial. Researchers do not need to be business people per se, but an understanding of basic principles (managing budgets, people, health economics, IP management etc) are important if researchers are to have the skills to build a world class life sciences sector. Much of this is addressed at university level although this means opportunities to develop such skills vary depending on how much of a priority translational science is at the institution. In many cases, this learning is self-driven and it can be hard for researchers to know where to start. Integrating these opportunities into degree teaching would be a positive step with more advanced education made available at PhD and post-doctoral levels. However not all universities are equipped to do so (teaching being primarily taken forward by academics). Nevertheless, a number of institutes run enterprise summer schools or other training programmes which provide much needed training in these vital skills.

- A world class scientific sector is built on world class scientific talent. There should be no doubt that being able to attract the very best and brightest, regardless of nationality, is crucial in delivering this aim. The benefits of international mobility in the life sciences should by now be well understood. In addition to attracting talent, fluid exchange across borders also means many of our researchers have been able to develop skills and experience at labs overseas (some 72% of the UK's scientists spent time at a non-UK institution between 1996 and 2012, for example[viii]). As the Government indicated in its Brexit position paper on science and innovation, preserving the collaborative links that exist as part of our EU membership is a priority. The value of these links cannot be understated including exchange programmes (e.g. Marie Sklodowska Curie Fellowships[ix]) and important public-private research partnerships (e.g. IMI[v]).

The NHS

- The NHS is a crucial partner in the development of a world class life sciences sector and one of the greatest assets this country has in performing medical research. Nevertheless, there are clear challenges. For example, our members report difficulties in securing NHS participation in interventional (CTIMP) clinical trials, often because hospitals lack the necessary staff, resources and infrastructure to fully engage with this type of clinical research. Although the NIHR has contributed greatly in this area, many hospitals still need the necessary teams and structures to support clinical research, including for example research nurses, tissue bank managers, structures to access data and more effective mechanisms to permit data and tissue samples to be used in R&D. One key argument to be made, important in the era of fiscal restraint, is convincing NHS service managers just how much participation in cutting edge research can benefit everyday care.

The Life Sciences Strategy

- The recommendations of the life sciences industrial strategy represent an important step forward in our capacity to deliver new innovations in the life sciences and we wholeheartedly welcome its publication. In particular, we are pleased with the announcement of the Vaccine Development and Manufacturing Centre[x], which will be a vital addition to our capacity to respond to future health needs. The UK conducts world leading vaccines research however we are severely lacking in domestic vaccine manufacturing capability. Several academic centres are conducting exciting research into therapeutic vaccines, however this excellence in the research base is not supported by our manufacturing infrastructure, so these highly skilled goods manufacturing (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. It is therefore welcome that the government has committed £146m over four years for to support advanced therapies manufacturing, including £66m for vaccines.

- We await a government response to the strategy; however, a number of additional questions remain unresolved. These include, and as recognised within the strategy itself, the issue of leadership and governance, particularly relevant with regards to the Health Advanced Research Programme (HARP). We look forward to more details in the future.

Brexit

- The far-reaching implications of our departure from the EU have by now been effectively articulated by many in the life sciences community. A world class life sciences sector is a product of a multitude of diverse inputs – talent, a strong research base, favourable funding, access to capital, and collaboration (often both interdisciplinary and international) – to name a few. These inputs are strongly interlinked with our membership of the European Union, and the success of the Government's ambition to develop the nation's economic capacity in the life sciences depends in large part on the success of securing a positive outcome from the Brexit negotiations for science. That said, the recognition of the value of the sector within the industrial strategy, and connected efforts in the development of a life sciences industrial strategy, is a positive step towards mitigating the disruption caused by our departure from the EU. We hope both these initiatives can serve as a good foundation for the development of pragmatic solutions to the challenges of Brexit.

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[i] APPG on Global Health (2015). The UK's contribution to health globally.

[ii] 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

[iii] BBSRC CASE studentships

[iv] MRC Industry Collaboration Agreement (MICA)

[v] The Innovative Medicines Initiative

[vi] British Society for Immunology (2016). Written evidence submitted to the House of Commons Science and Technology Select Committee inquiry on STEM skills.

[vii] Computational Genomics Analysis and Training

[viii] Elsevier (2013). International comparative performance of the UK research base.

[ix] Marie Sklowoska-Curie Fellowships

[x] University of Birmingham. (2017). Major life sciences investment announced at the Institute of Translational Medicine.