Life Sciences and the Industrial Strategy

A response from the Royal Society of Chemistry to the House of Lords Science & Technology Select Committee.

Summary

We welcome the Life Sciences Industrial Strategy, and support much of its content and look forward to seeing how the Government will deliver the recommendations to realise the UK's unique capabilities in the life sciences. We particularly welcome the recognition of the importance of support for curiosity-driven basic research and for translation of research to enable growth, innovation and patient benefit. Points 1 – 12 below are opportunities to strengthen the strategy, with evidence and examples in the main text.

Health Life Sciences: Clarifying scientific scope and linking with other research areas.

1. The vision for UK life sciences must include the application of chemistry, engineering, materials and physics as well as biology if it is to deliver maximum impact. The formation of UK Research and Innovation (UKRI) presents a unique opportunity for success because the life sciences span multiple Research Councils and Innovate UK.
2. The Life Sciences Industrial Strategy should seek to leverage expertise, infrastructure and technological advances from sectors like biotechnology, food, fuel and energy.

Research Funding: We support the recommendation to sustain and increase funding for basic science to match our international competition and recommend that:

3. Increased funding for life sciences must also include funding for physical sciences and engineering.
4. Increased funding must support curiosity-driven basic research as well as interdisciplinary and challenge-driven research.
5. Funding for basic science is complemented by additional funding streams to support commercialisation of current breakthrough areas.

Innovation: We understand the need to work across the life sciences ecosystem to remove barriers to the translation and commercialisation of research.

6. It is crucial to engage SMEs in the delivery of the strategy given that many of the barriers identified affect them acutely.
7. There is an opportunity to showcase examples of how to overcome barriers to translation and to build on existing success.

Skills: We support the focus on skills as being critical to life sciences research and innovation, and recommend that in order to secure UK capability:

8. The skills action plan should include physical scientists as the physical sciences underpin many developments in the life sciences.
9. Opportunities for collaboration between researchers from different disciplines and sectors must be encouraged and supported.

EU Exit: As part of the implementation of the Life Sciences strategy there must be a fuller analysis of the critical connections between this sector and the EU, in particular:

10. Access to funding and facilities, especially
    a. Public–Private Partnership
    b. Venture Capital Funding
    c. Cutting edge research instruments and facilities
11. Ability to develop, attract and retain a skilled workforce and play a full role in international scientific collaborations.
12. Crucial role played by regulation in delivering the industrial strategy by balancing support for innovation with protections for the environment and human health.

Health Life Sciences: Clarifying scientific scope and linking with other research areas.

1. **The vision for UK life sciences must include the application of chemistry, engineering, materials and physics as well as biology if it is to deliver maximum impact. The formation of UK Research and Innovation (UKRI) presents a unique opportunity for success because the life sciences span multiple Research Councils and Innovate UK.**

The Life Sciences Industrial Strategy defines ‘health life sciences’ as the ‘application of biology and technology to health improvement, including biopharmaceuticals, medical technology, genomics, diagnostics and digital health.’ This misses the crucial role played by other disciplines such as chemistry, engineering, materials and physics, which underpin the life sciences and are vital in developing new products and innovative technologies. The formation of UKRI presents a unique opportunity to create a holistic approach to supporting research from across the disciplines as well as fostering interdisciplinary research.

A review[1] carried out by the Engineering and Physical Sciences Research Council (EPSRC) highlighted many examples where developments in engineering and the physical sciences led to innovation in the life sciences. Since 2000 most of the Nobel Prizes for Chemistry and half of the Nobel Prizes for Physics have been awarded for discoveries with life sciences applications. Furthermore, developments in the physical sciences will continue to have an impact for life sciences in the future, in areas such as:

- **Miniaturisation** spanning microfluidics, microfabrication, assay platforms and molecular machines. The most recent Nobel Prize for Chemistry was awarded for the development of molecular machines that will pave the way for new materials, drug delivery systems, sensors and energy storage systems.[2] Examples highlighted in recent literature include organ-, body- and disease-on-a-chip systems that have the potential to transform drug development and exploiting microfluidics for single cell sequencing.
- **Spectroscopic, imaging and new analytical techniques** offer improvements in diagnostics, sensors, ‘omics’ and single molecule studies. Super-resolved fluorescence microscopy, recognised by the 2014 Nobel Prize in Chemistry,[3] allows the visualisation of biological processes at the molecular level, which will lead to developments in both biology and medicine. A major theme for the Rosalind Franklin research institute will be next generation imaging methods, including biological mass spectrometry and advanced microscopy.
- **Materials chemistry** for medical devices, self-healing and other smart materials especially prosthetics, implantable and delivery devices. For example, the interfaces between prostheses or biomedical implants and body tissues require the optimisation of many material properties, key amongst which are biocompatibility and softness. Satisfying such conflicting demands requires innovative molecular design to make materials that are biocompatible, hard-wearing and possess appropriate viscoelastic properties, and calls on an intimate knowledge of synthetic chemistry, polymer chemistry, the physics of macromolecules, tribology and lubrication among others.
- **Advances in chemical synthesis and biosynthesis** to generate novel molecules and identify ways to make them more efficiently. This is relevant to molecule dependent sectors such as pharmaceuticals and agrichemicals where small molecule therapeutics account for the largest segment of the life sciences industry in terms of turnover (£23.6bn, 37%) and employment (50,554 people, 21.7%).[4] Researchers use molecules to better understand disease processes and to create new medicines.
- **Data analysis and computational tools** are vital to maximise the rigour and impact of excellent and well-informed research. For example, bioinformatics uses statistical techniques to understand vast amounts of data to describe complex properties of living organisms and will enhance our understanding of the genetic basis for disease as well as predict the activity of drugs in development. Further examples seeking to exploit the power of data include the Dial-a-molecule[5] EPSRC network aimed at transforming synthetic chemistry and Benevolent AI[6], a British based company, using artificial intelligence to mine data to develop new medicines.
- **Energy and manufacturing technologies** including catalysis, 3D printing, robotics, automation and improved energy generation and storage will support the production of medicines and medical devices with multiple classes of materials and functionality; more efficiently and with lower environmental impact.

2. **The Life Sciences Industrial Strategy should seek to leverage expertise, infrastructure and technological advances from sectors like biotechnology, food, fuel and energy.**

The Life Sciences Industrial Strategy focuses on 'health life sciences', however there are opportunities and benefits from leveraging expertise, infrastructure and technological advances from sectors beyond healthcare. Taking a broader and more holistic view will minimise duplication of effort, create links and avoid a 'silo mentality' that can stifle innovation.

The previous Life Sciences minister, George Freeman MP, proposed *'feeding, fuelling and healing the world'* as the *'the three core 'life science' markets'*[7] capturing the breadth of applications that the life sciences have. In December 2016, the Department for Business, Energy and Industrial Strategy published a call for evidence on the UK bioeconomy to help inform future strategy in this area.[8] The final UK bioeconomy strategy has yet to be published, but given the overlap and links between this strategy, the Life Sciences Industrial Strategy and the overarching Industrial Strategy, these must be developed in tandem to benefit from similarities or overlaps between them.

Research Funding: We support the recommendation to sustain and increase funding for basic science to match our international competition and recommend that:

3. **Increased funding for life sciences must also include funding for physical sciences and engineering.**
4. **Increased funding must support curiosity-driven basic research as well as interdisciplinary and challenge-driven research.**
5. **Funding for basic science is complemented by additional funding streams to support commercialisation of current breakthrough areas.**

We welcome the Conservative government's manifesto[9] commitment to increase funding for science. This must include long-term support for physical science and engineering disciplines in addition to curiosity-driven basic research, inter-disciplinary and challenge-driven research. Work carried out by the REF[10] and others demonstrate that curiosity-driven basic research can sometimes take longer to demonstrate impact but that it opens up completely new avenues for research, innovation and technology development, for example:

- curiosity-driven basic research into fluorescent photo induced electron transfer (PET), allowed researchers to create a point of care device, the OPTI blood analyser that measures salt levels in the blood. The initial research was carried out by researchers based at Queen's University Belfast in 1985 and it was some 13 years later before industry pursued its commercial potential. The device has gone on to achieve sales of US$50 million over 5 years[11] and is used in a range of settings from GP surgeries to veterinary practices and in conflict zones.
- curiosity-driven basic research into the sensing ability of membrane proteins carried out by Professor Hagan Bayley, University of Oxford, is being developed into a portable, low-cost, DNA sequencing device with applications in personalised medicine.[12]
- curiosity-driven basic research into catalyst design carried out by researchers at the University of Warwick,[13] led to the development of more efficient catalysts that reduce costs, waste and energy usage in the manufacture of drugs.

We support the recommendations in the Life Sciences Industrial Research Strategy to expand and develop both the basic and clinical science capability in the UK, in particular in areas of higher risk projects or that require large-scale infrastructure. The suggested Health Advanced Research Programme (HARP) will be underpinned by research and technology from across the biosciences, engineering and physical sciences. This potential for research in the engineering and physical sciences leading to advances in the health and life sciences is being championed by the Research Councils through joint initiatives such as Technology Touching Life.[14] It is expected that tools and capabilities will feed into more translational programs such as those run by Research Councils[15] and Innovate UK but there are certainly opportunities that this research will also underpin future large-scale HARP projects.

The Life Sciences Industrial Strategy outlines HARP core principles, one of which focuses on developing technology that is emerging now. Funding programmes can sometimes focus on creating the breakthroughs of the future, however there is a need for funding and mechanisms that exploit and commercialise current breakthroughs, for example, the potential of vibrational spectroscopy[16] for disease diagnosis has been well demonstrated and although translation into clinical practise is slow, it is being championed by networks such as EPSRC Network CLIRSPEC[17] and EU COST Action Raman4Clinics.[18]

The role of EU programmes in supporting basic life sciences research in the UK should also be considered. For example, mechanisms such as the European Research Council provide large, long-term research grants (up to €2.5 million over 5 years) to fund curiosity-driven, basic research at different career stages. As ERC grants are awarded on the basis of excellence alone, there is no requirement for even distribution across member states or associated countries. In 2014 the UK received nearly 24% of the European Research Council (ERC) grants[19] and in 2015, five of the top twenty European institutions hosting ERC grantees were in the UK (France and Germany had three institutions each in the top twenty; Switzerland had two).[20]

Innovation: We understand the need to work across the life sciences ecosystem to remove barriers to the translation and commercialisation of research.

6. **It is crucial to engage SMEs in the delivery of the strategy given that many of the barriers identified affect them acutely.**
7. **There is an opportunity to showcase examples of how to overcome barriers to translation and to build on existing success.**

Across our community we have identified a number of barriers and enablers that can support translation, commercialisation and innovation in the life sciences. In understanding the needs of our community, we were made aware of several issues. Whilst they can all be perceived as barriers, where mechanisms of support can be put in place to address them, these mechanisms then become enablers of innovation.

The life sciences sector comprises an ecosystem of collaborative research partners including large companies, SMEs, CROs, academia, medical charities, government funding bodies and the NHS. Increasingly, novel and emerging technologies are being pioneered by researchers based in academia and small companies. It is estimated that 96% of life sciences companies are SMEs.[4] Therefore, continued engagement with SMEs and academia and their involvement in discussions about implementation investment and skills requirements needs to be in place.

We have referred to a range of case studies, collated as an appendix to our response, that showcase successful translation and innovation in the life sciences, which we hope can act as examples of good practice that can be built upon.

Suitable funding for translational research

Attempting to secure funding to support research translation in the early stages or higher risk projects can be a barrier. This is particularly important given the overall life sciences industrial ecosystem. There can be a tendency, as has been identified in the Life Sciences Industrial Strategy, for smaller companies to be acquired by or license technology to larger competitors. There is a welcome emphasis in the Life Sciences Industrial Strategy on supporting the growth and scale-up of new companies at different stages. This includes non-dilutive grant-funding, which is an important support mechanism for new small companies, as it allows company founders retain control of the company, whilst securing funding for growth and development.

Consideration should be given to how various mechanisms from National Institute of Health Research (NIHR), medical charities and funding bodies fit into the broader translation funding landscape so that researchers are aware of the most suitable funding and mechanisms to best capitalise on their research (see example 7 in Appendix on **LifeArc – Support for Translational Research**).

Patient capital and venture capital

The costs involved in the development of new products and technologies can be high and the process lengthy. Obtaining venture capital support to build and grow a company can be a challenge, with a broader sense across our community that there is a more risk-averse investment culture in the UK, compared to places such as the USA. We also heard concerns around the loss of sources of investment such as the European Investment Fund (see section below on **Life Science and the UK's exit from the EU**), which may impact the life sciences sector more acutely than others.

The findings from the Patient Capital Review[21] will need to be considered as part of the implementation of the Industrial Strategy and the Life Sciences Industrial Strategy. For example, in the development of medicines, the costs associated with bringing a drug to market are vast, in part due to the cost of clinical testing. It will be instructive to see whether the Patient Capital Review identifies any barriers that are specific to certain sectors and how these will be addressed in the implementation of sector specific industrial strategies.

Availability of facilities

The range of facilities required varies depending upon the stakeholder, sub-sector and region. Examples from across our community include scale-up and pilot facilities that can allow the testing of products and technologies that have been developed in a university research laboratory or access to specialist analytical equipment, which can be a challenge for SMEs who are unable to invest in such equipment as a single company. Appropriate laboratory and production space for companies to move through the stages from spin-out and start-up up to a larger company is another key issue and couples with the point regarding skilled workers below.

Other examples of facilities and infrastructure used by the life sciences community include the Diamond Light Source and the National Chemical Database Service in the UK, as well international infrastructure and facilities (see **Funding and Facilities** under section on **Life Sciences and the UK's exit from the EU**).

Links and networks at a regional level (see example 4 in Appendix on **Engaging with local SMEs**) can help to overcome this barrier.

Advice, support and technical knowledge

For those starting a new business, access to agencies and people that can provide advice, guidance and mentorship from their own sector can be invaluable in helping a business to survive and grow in a competitive environment. This is especially true of university spin-outs, where staff may be developing a new company with little or no prior business experience. Some members of our community flagged that an ongoing challenge in research translation remains a lack of access to expert technical knowledge, e.g. for protocol development or scale-up (see example 6 in Appendix on **Adapting to New Business Opportunities**). This can be particularly challenging for researchers based in academia, smaller companies or those working in emerging areas of science, for example in biotechnology or synthetic biology.

Facilitating the provision of tailored advice at different stages of a company's life, whether this is technical, financial or business advice, supports the growth of innovative businesses. (see Appendix for example 1 on **Royal Society of Chemistry and Emerging Technologies competition** and example 2 on **Medical Research Council – 2014 Emerging Technology Winners**).

Links and networks

Links and partnerships between different kinds of institutions and different sectors can help to foster innovation and translation. This can include university-business collaboration (see example 4 in Appendix on **Engaging with local SMEs**) or collaborations between small and large companies (see example 8 in Appendix on **Astex Pharmaceuticals**).

Building on existing links, networks and partnerships can help to showcase good practice (see example 3 in Appendix on **Open For Business – University Business Engagement in Chemistry Departments**)

Skilled workers

See section below on **Skills**.

<u>Skills: We support the focus on skills as being critical to life sciences research and innovation, and recommend that in order to secure UK capability:</u>

8. **The skills action plan should include physical scientists as the physical sciences underpin many developments in the life sciences.**

Chemistry expertise is needed for technical success across the spectrum of the life sciences, from designing new medicines, developing innovative diagnostics to exploiting industrial biotechnology and for the development of new manufacturing technologies. For example, in drug discovery, chemistry remains a key enabling science essential for translating biological insights into new medicines.[22]

Over the last 10–20 years', several large pharmaceutical companies in UK have closed meaning many experienced life sciences researchers are currently employed by research institutes, SMEs and contract research organisations (CROs). While this has had many benefits, there are concerns that as this group dissipates there is a real risk that key areas of expertise will be lost and there is currently a lack of infrastructure to capture or pass on this knowledge.

Members of our community also flagged difficulties in recruiting staff in certain geographic areas, for example outside of the South East, as well as in scientific areas such as computational chemistry, bioinformatics, biophysics and analytical science (see *'Mobility and Collaboration'* under the section on '*Life Sciences and the UK's exit from the EU*'). We also received feedback that there can be difficulties in recruiting researchers with excellent instrumentation knowledge, data and statistical skills. Many of these gaps have also been identified by the Association of the British Pharmaceutical Industry.[23] In addition, process chemistry and physical chemistry were flagged as areas of concern for biopharmaceutical companies, both of which will be critical in positioning the UK as a world leader in advanced manufacturing.

Regular consultation with the life sciences sector through meetings and surveys will be one way to identify future capability needs. In addition, the UK must continue to attract the best global talent and support workforce development encompassing the entire pipeline from STEM in schools, graduate, PhD and postdoctoral programmes, vocational education, apprenticeships and career professional development. Supporting skills development in the life sciences is achieved via a number of mechanisms such as

- **PhD and postdoctoral research programmes** support researchers to develop expertise in core disciplines, as well as providing opportunities to acquire interdisciplinary and transferable skills, for example many Centres of Doctoral Training (CDT) focus on challenge-driven research relevant to the life sciences such as regenerative medicine[24] or applying synthesis to biology and medicine[25]. In addition, CDTs, as well as CASE and industrial CASE studentships support opportunities to work directly with industry.
- **Quality Vocational Education and Apprenticeships** across the life sciences sector are needed. There is a demand to create a high quality, simplified vocational education system that is valued by employers and learners alike. Additional funding is welcome and must focus on the *quality* of vocational training routes in order to achieve parity with academic pathways and to improve diversity and inclusion in the workplace. Equally, successful apprenticeship schemes should not only focus on the number but on their *quality* and value placed on them by the sector. We recommend that any levy funding collected from STEM sector employers should remain in the sector so that it can be re-invested to deliver the economic returns that flow from high value STEM businesses.
- **Entrepreneurial and transferable skills** are needed to be successful life sciences researchers. Opportunities to acquire communication skills, entrepreneurship, problem solving, time management, organisation and team working skills should be developed and actively promoted. Successful examples of these from across university chemistry departments are captured in our *Open For Business* report (see examples in appendix on '*Open For Business – University Business Engagement in Chemistry Departments'* and *'Staff training in enterprise')*.
- **Training and Continuous Professional Development** should be developed and promoted to teachers and researchers. Mechanisms to capture training and continuous professional development include the Innovative Medicines Initiative (IMI) Education and Training portal on-course[26] and the Royal Society of Chemistry Continuing Professional Development portal.[27] However, these will only be effective if they are populated with high quality, up-to-date programmes.

9. **Opportunities for collaboration between researchers from different disciplines must be encouraged and supported.**

Members of our community mentioned challenges in recruiting staff with the necessary interdisciplinary skills to work in areas that are at the interface of individual disciplines or require insights from different disciplines or sectors to make progress. Developing and supporting these types of interactions helps to raise awareness of pressing research challenges, unmet needs and highlight technological developments. Supporting the bi-directional flow of knowledge and expertise can be achieved via various structures, activities and mechanisms such as research institutions, research consortium, interdisciplinary meetings, training programmes, networks, joint appointments and secondments. For example:

- The UK hosts several notable multidisciplinary research institutions including the MRC Laboratory of Molecular Biology (LMB), the Francis Crick Institute, the Institute of Cancer Research, the Structural Genomics Consortium and the John Innes Centre. Common features essential for success of these institutes are that they:
    - include core discipline teams working alongside interdisciplinary groups and are focused on addressing key research challenges;
    - promote mechanisms to encourage collaboration and mobility across discipline boundaries;
    - establish strong links to industry or patients;
    - and are underpinned by access to flexible and longer term funding.
- Research consortia focused on disease areas or research challenges, e.g. the Drug Discovery Alliance and the Dementia Consortium[28], funded by Alzheimer's Research UK, embed experienced drug discovery experts across three universities drawing on chemistry and biology academic research to find new and disruptive treatments for dementia.
- *A year in industry* or *industrial placement* opportunities for undergraduate students, enabling them to gain experience working in a large company or SME as part of their degree programme, e.g. Royal Society of Chemistry industrial placement grant.[29]
- Networks aimed at linking research communities, e.g. the EPSRC Bridging the Gap Networks between Engineering and Physical Sciences and Antimicrobial Resistance[30] and the BBSRC Networks for Industrial Biotechnology and Bioenergy (NIBB).[31]
- Funding for academic and industrial scientists to work on collaborative projects, e.g. Royal Society Industry Fellowships.[32]

Along with developing the necessary skills and providing mechanisms and structures for interactions, there is also a need for wider sharing of data. For example, large pharmaceutical companies can draw conclusions about the causes of attrition in drug discovery programmes, given the breadth and wealth of data available. Mechanisms to share these insights with SMEs, biotechs and academia would help to inform and support both basic research and drug discovery programmes. One way is to establish knowledge sharing agreements, e.g. Cancer Research UK (CRUK) researchers have access to Astra Zeneca's compound library and screening tools.

<u>EU exit: As part of the implementation of the Life Sciences strategy there must be a fuller analysis of the critical connections between this sector and the EU.</u>

This section of our response draws on evidence from our previous submissions to the House of Commons Science and Technology Select Committee,[33] the House of Commons Exiting the EU committee[34] and the House of Commons Environmental Audit Committee,[35] as well as work on this area that we have carried out jointly with colleagues across the research and innovation community.[36]

The Life Sciences Strategy and the overarching industrial strategy can help to mitigate risks and take advantage of opportunities that may arise due to this unique timing, but only if these interconnected changes are considered holistically. Whilst this may be challenging given the live and changing nature of the UK's negotiations to exit the EU, a careful analysis of the connections between the EU and UK life sciences is needed as many of the areas of focus for the Life Sciences Industrial Strategy draw upon links to EU programmes (see examples below). The Industrial Strategy is introduced as *'a critical part of our plan for post-Brexit Britain'*.[37] However, the government's Industrial Strategy green paper provides little detail on the critical interdependencies between the Industrial Strategy's goals and the UK's relationship with the EU and how these will be managed given that the implementation of the industrial strategy coincides with the UK's exit from the EU. Whilst the newly published Life Sciences Industrial Strategy acknowledges the UK's exit from the EU referencing some specific initiatives and recommendations, it does not consider the full range of connections that UK life sciences has with the EU. A fuller analysis of these links and how they may affect our future relationship with the EU will be essential to implement the Life Sciences Industrial Strategy.

With respect to the UK's exit from the EU, it is vital that the UK negotiates an exit that results in an environment that sustains and builds on our already world-class science and an innovation base that will deliver the government's overarching Industrial Strategy and sector specific strategies. For the UK to stay at the forefront of global science and innovation there are three key overarching objectives that apply equally to life sciences, as they do to research and innovation more broadly.

- Maintain access to international research and development funding programmes and research facilities, along with the collaboration opportunities these bring.
- Enable easy movement of skilled and talented scientists and students to and from the UK.
- Develop a future regulatory system that achieves a balance between nurturing innovation, protecting the environment and human health and enabling the UK to trade internationally.

Below we expand on these three areas with examples that illustrate the potential impacts and opportunities for the life sciences sector.

10. **The life sciences require access to funding and facilities, especially:**

a. Public–Private Partnerships

For many of the challenge areas that the life sciences can address, collaborative funding that brings together public and private partners from around the world is key. This relates to the earlier point with respect to barriers to translation – often those working in universities and research institutes will not have the scale of funding, facilities or knowledge needed to translate basic research into, e.g. therapeutics that can reach patients. EU funding supports a range of funding mechanisms to encourage collaborations, varying from schemes to support individual researchers to undertake research through to large scale public-private partnerships that bring together consortia of large companies, SMEs, universities and the public sector.

Vast international public–private collaborations are challenging to facilitate and many schemes of this kind run by the EU are unique globally and so the UK should aim to participate in these fully.

- The Innovative Medicines Initiative (IMI) is the world's largest public–private partnership in the life sciences, with a total second phase budget of €3.3 billion. It aims to speed up the discovery and delivery of better and safer medicines for patients across the world.
- Chem21[38] is one of the IMI's phase one projects and is led by the University of Manchester and GlaxoSmithKline. The project has leveraged funds of over €26m from both public and private sources to develop the manufacture of sustainable pharmaceuticals. The project brings together 6 pharmaceutical companies (2 UK based), 13 universities (4 UK based) and 4 SMEs (2 UK based) from across Europe. Work to date by the group includes the development of cheaper, more environmentally friendly methods for the production of drugs.
- The European Lead Factory (ELF) is a phase one project of the IMI, that brings together researchers from 13 universities (4 UK based), 10 SMEs (2 UK based) and 7 large pharmaceutical companies (2 UK based) to leverage industrial expertise, knowledge and infrastructure to translate biological discoveries into viable drug targets. The project has levered funds of over €196m from both the public and private sectors. Targets evaluated via the ELF have resulted in the formation of a virtual biotech company between the University of Sheffield and Parkinson's UK; a start-up in Sweden; secured further funding for an antimicrobial resistance target; numerous patents; and training for postdoctoral fellows; as well as over 50 scientific publications.

b. Venture Capital Funding

An additional element of EU funding that will affect the life sciences sector (and innovation more broadly) is the loss of the European Investment Fund (EIF) as a source of venture capital (VC) for start-ups and small businesses in the UK. The EIF is part of the European Investment Bank (EIB) group and carries out its activities in EU member states, EU candidate countries and EFTA (European Free Trade Association) states. The members of the EIB must be EU member states and so the UK will need to leave the EIB, on leaving the EU, unless the EU changes the terms of EIB membership.

Lack of access to venture capital has been mentioned earlier in our response as a potential barrier to translation and commercialisation of life sciences research. Amongst its different financing activities, the EIF runs a range of country and sector specific initiatives. In the UK, the EIF focuses its work on *'Early and growth-stage technology enterprises in the ICT, life sciences and advanced manufacturing sectors'*.[39]

Given that the EIF specifically invests in life sciences businesses in the UK, this means that in delivering a life sciences strategy, consideration must be given to the potential impact on the range of VC sources available, when the community already perceives these to be quite limited.

The new life sciences industrial strategy states '*This issue* [Fiscal support for SME growth and retention] *will be further compounded for industry if the European Investment Fund is not replaced or continued in an alternative manner to avoid the potential loss of the (20-30%) core funding source of UK VC funds.'*[40]

Whilst the Conservatives made a commitment in their manifesto to *'fund the British Business Bank with the repatriated funds from the European Investment Fund',*[41] the exact details and timescale for this are not known as this will require an agreement with the EU over the UK's exit from the European Investment Bank, leaving the sector facing uncertainty now about future VC funding arrangements. There have been recent reports in the media that the EIF is already slowing its investment in UK-based venture capital funds explaining that due diligence for investments must take account of wider factors.[42]

c. Cutting edge research instruments and facilities

Cutting-edge research, which can lead to innovation, also requires access to a range of state-of-the-art, instruments and research infrastructure.

The UK has strong capability in some universities and has centres of excellence such as the Diamond Light Source, but it is not possible for any nation to establish and maintain centres of excellence in all areas.

Whilst the UK has synchrotron facilities of its own like the Diamond Light Source, the number and the range of experimental techniques that can be performed using the beamlines varies between facilities. Access to international facilitates means that UK scientists have access to a richer range of experimental techniques that can be applied to their research that complement those available in domestic facilities, allowing UK scientists to carry out a wider range of cutting-edge research.

This means that for many fields of scientific research, including the life sciences, access to international facilities is essential. The use of instruments such as synchrotrons and neutron spallation sources can enable researchers to explore biological structures at the molecular and atomic levels. This can help to design better drugs to target the specific molecules involved in causing different diseases.

- The European Synchotron Radiation Facility (ESRF) in Grenoble generates X-rays that scientists can use to map molecules in detail, helping to uncover the causes of heart disease, as well as understand how viruses spread. Whilst the facility itself is funded by the participating nations both within and outside the EU, access to EU programmes allows UK scientists to apply for funding to visit these facilities and carry out work there. It provides an important complement to domestic facilities like the Diamond Light Source as it is able to offer some beam line opportunities that differ from those available at the Diamond Light Source.

11. **Ability to develop, attract and retain a skilled workforce and play a full role in international scientific collaborations.**

To maintain its world-leading performance in life sciences research and innovation, the UK needs access to the best knowledge, ideas and people. The UK needs to attract the best researchers from all over the world and researchers based in the UK need to collaborate internationally. Conditions are needed that encourage the best international researchers to establish their careers in the UK, attract talented international students to study, train and work here, as well as allowing easy access for scientists at all career stages and of different nationalities to undertake international visits to collaborate or present their research as part of the global scientific community.

International workforces are seen outside the UK in other successful life sciences research nations. A recent analysis of the biomedical workforce using 2014 census data in the USA showed that 48% of workers were native-born American citizens. Over half of the biomedical workforce in the USA were either non-USA citizens or naturalised citizens, demonstrating the diversity of the American life sciences sector.[43] Following recent changes to immigration laws in the USA, a group of over 150 founders and leaders of biotechnology companies published an open letter quoting this study attributing the diversity of the biomedical workforce as a key factor in its success: *'diversity and the free flow of ideas and people have created an American powerhouse of medicine.'* [44]

Data from the Higher Education Statistics Authority indicates that in chemistry at UK universities[45]:

- 19% of staff are non-UK EU nationals
- 15% are non-EU nationals.

There is a link between the need for easy mobility and some of the barriers to innovation identified earlier in our response.

Accessing infrastructure and building collaborations, links and networks requires easy movement of scientists between sectors and across the globe. Barriers to mobility could therefore impact on the delivery of a successful industrial strategy.

Within the life sciences, we have heard from our community about concerns around specific sub-fields (see section on *'Skills and Knowledge Gaps'*). The rapidly changing nature of life sciences has resulted in changes in the way research is carried out, requiring additional skill sets from relatively new and evolving disciplines.

We have heard that in areas such as computational chemistry, bioinformatics and biophysics, access to a global pool of talent (so not only EU or EEA) was essential to find scientists with the skills needed for a company to take advantages of new research fields (e.g. big data) to enable them to innovate further. Building domestic capacity across the breadth of science and innovation (including new and emerging fields) will be essential to delivering an industrial strategy that enables growth. However, for UK science and innovation to continue to advance and make breakthroughs, we must enable researchers, entrepreneurs and innovators from across the world to come to the UK to live and work in both the short and long term. These people bring ideas and knowhow at the frontiers of discovery and application, enable the UK to establish new capability, and train the next generation of researchers and innovators.

12. **Crucial role played by regulation in delivering the industrial strategy by balancing support for innovation with protections for the environment and human health.**

Implementing the industrial strategy during the UK's negotiations to exit the EU offers the chance to examine overarching issues in a holistic way. One area that must be examined in the UK's negotiations to exit the EU is regulation. Regulation has the ability to support the effective implementation of the overarching Industrial Strategy and sector specific strategies that will lead to successful outcomes.

It provides clarity and guidance for industry and society, by providing an effective means of enabling innovation and trade, whilst providing appropriate safeguards for human health and the environment.

As identified in our response to House of Commons Science and Technology Select Committee,[46] there may also be opportunities for the UK to make changes to its regulatory regime. However, any changes must be examined in light of factors that include scientific evidence, socioeconomic factors, political priorities, health and environmental protection goals, public acceptance and trade concerns.

Agreeing standards on measurements, processes and techniques to evaluate goods will also be critical to forming trading relationships going forwards with countries outside the EU. Delays and uncertainty in our regulatory framework could impact our ability to manufacture and trade goods.

A key issue in developing the UK's future regulatory path will be accessing and/or generating appropriate data that underpins regulation. This includes everything from clinical trial data through to physicochemical data on the chemicals that act as building blocks for new consumer products and medicines.

Robust data is a key element of the scientific evidence base needed to inform regulation. The standards for and types of data that are required to underpin EU regulation are defined by the relevant EU agency.

For example, for the regulation of chemicals, such as REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), the European Chemicals Agency (ECHA) defines the data requirements. Data collection must be performed to agreed standards: for toxicology data using globally harmonised OECD test guidelines and good laboratory practice (GLP); for chemistry data by accredited analytical laboratories such as the UK Accreditation Service (UKAS). These types of standards and principles related to data generation operate across all chemical regulation. Currently the UK has access to data that is mainly owned and submitted by industry, but held by EU agencies to inform regulatory decisions. It is unclear whether the UK would be able to access the central repository of data held by ECHA (or other relevant agencies) in the same way as we do now, after we exit the EU.

For drug manufacturing, key markets for the UK are the USA and Europe. The Food and Drug Administration (FDA) in the USA has discussed a mutual recognition programme for drug manufacturing sites that have been audited by EU Regulators to improve the speed of drug manufacturing approvals.[47] In this programme the FDA can take the findings of the European regulator and endorse the site of manufacture without visiting the site themselves.

It is not yet clear whether the UK will continue be included in this programme after it leaves the EU or considered a stand-alone country like India and China. We have been made aware that some life sciences based companies are factoring this uncertainty into their decision-making process now when outsourcing drug manufacturing and favouring mainland Europe or US for their manufacturing over the UK.

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in our response in more detail. Any questions should be directed to Dr Mindy Dulai, dulaim@rsc.org, 01223 432674, and Dr Anne Horan, horana@rsc.org, 01223 432699.

About us

With over 50,000 members and a knowledge business that spans the globe, the Royal Society of Chemistry is the UK's professional body for chemical scientists, supporting and representing our members and bringing together chemical scientists from all over the world.

Our members include those working in large multinational companies and small to medium enterprises, researchers and students in universities, teachers and regulators.

Appendix – Case Studies from the Chemistry community showcasing Translation & Innovation in the Life Sciences

1. Royal Society of Chemistry and Emerging Technologies Competition[48]

Emerging Technologies is an annual competition run by the Royal Society of Chemistry that aims to accelerate the commercialisation of innovative technologies across the areas of health; energy & environment; food & drink; and materials & enabling technologies. The competition is open to small companies (with fewer than 20 employees and an annual turnover of less than £2 million) and universities across the UK and Europe. Successful entrants are invited to pitch their work to industry leaders who evaluate entries on the basis of the scientific feasibility of the technology, its potential market opportunities and the approach to commercialisation.

Prizes are awarded to two winners in each subject field (eight in total). Alongside a cash prize, the winners are offered tailored business support from our partner multinational companies including advice on product strategy and market insights, and access to their laboratories. The winners are also provided with intensive business training, intellectual property advice and tailored financial mentoring, as well as broader exposure for their company through our networks and media.

2. Medical Research Council – 2014 Emerging Technology Winners[49]

The Medical Research Council (MRC) team working on IHAT (a nanoparticulate form of iron) technology were winners of the Emerging Technologies competition in 2014. The team had completed early clinical work but had been unsuccessful in securing the funding needed for a clinical trial. They entered the Emerging Technologies competition to achieve greater visibility for IHAT and to receive strategic advice from key players in industry on how to progress.

Winning the competition gave the IHAT team a chance to be mentored by pharmaceutical giant GSK who could advise them on target markets, product development, business strategy, regulatory aspects, and the implementation of medicines in developing countries.

GSK also provided input in a number of funding bids to finance clinical trials with IHAT and, in 2015, the team successfully secured $1.7m from the Bill and Melinda Gates Foundation. The grant, awarded under the Gates Foundation’s Grand Challenge New Interventions for Global Health Pilot Awards Scheme, is funding a field trial to test the efficacy and safety of IHAT in young children living in the most deprived areas of the Gambia. The trial will run until the end of 2017 and results are expected in early 2018.

The publicity generated from winning the competition led to increased commercial interest in IHAT and the team were contacted by several companies interested in knowing more about the technology. As a result, the IHAT technology is currently being reviewed by a number of companies with a view to potentially licencing the technology and associated intellectual property (IP).

If IHAT is successful in the trial, there will be the opportunity to secure further funding from the Bill and Melinda Gates Foundation. This will be used to conduct the trials needed to support a market authorisation and to help place IHAT as an oral iron supplement in not-for-profit markets, where the need for a safe iron supplement is most pressing.

3. Open For Business – University Business Engagement in Chemistry Departments[50]

Our *Open For Business* report[51] is based on a survey of 25 university chemistry departments around the UK showing how they engage with businesses on research collaboration and enterprise and skills development. Our analysis found

- Over 1000 research collaborations with companies, an average of 40 per department.
- The number of collaborations per department ranged from 5 to 192.
- 34% of research collaborations were with small and medium enterprises (SMEs).
- Collaborations with SMEs focus on applied rather than underpinning research; the opposite is true for collaborations with larger companies.

- Life sciences and pharmaceutical companies made up over a third of the collaborations with both large and small companies undertaken by chemistry departments.

The top four barriers for universities to undertake research collaborations with businesses are: difficulty in identifying partners; access to funding; negotiations about contracts and intellectual property; and pressures on academic time.

We also developed a series of case studies[52] as a way of sharing good practice across our community that highlight partnerships that aim to overcome some of the barriers described above around facilities, skills and advice and support.

4. Engaging with local SMEs[53]

As part of the development of its new chemistry department, Lancaster University has set up a centre to facilitate knowledge transfer and build close links with local industrial partners.

Match funded through the European Regional Development Fund (ERDF), the Collaborative Technology Access Programme (cTAP) is a technology facility that enables businesses to access cutting-edge instrumentation, infrastructure and expertise. Interactions are fostered at all levels from simple one-off analysis/consultancy through to fully-funded research partnerships between an industry client and the chemistry department at Lancaster University.

The facility aims to provide a cost-effective option of engaging with academia for local industry in the North West. There are a significant number of technology-based SMEs in the region involved in products that are either directly related to chemistry or linked to chemistry through associated disciplines such as materials. The initial bid for the ERDF included the REACH Centre – a chemical regulatory services SME based on the Lancaster University campus – as an industrial partner for the scheme.

Links to companies are formed through interested companies directly contacting cTAP and through proactive publicity and marketing of the cTAP scheme. This activity is strongly supported by the university's Business Partnerships and Enterprise team within the faculty of science and technology, with referrals through the REACH Centre. Lancaster University has also been able to support feasibility studies through its Impact Acceleration Account (funded by the EPSRC), which has already been a rich vehicle through which to initiate research relationships and programmes with industrial partners.

Since its establishment in late 2015, the cTAP has facilitated the department's engagement with around 30 SMEs and 20 large companies, with a growing number of funded projects across a range of industries in the North West.

5. Staff training in enterprise[54]

BizzInn, an initiative hosted by the University of Birmingham and run by their Enterprise Acceleration team, provides the Medici Enterprise Training Programme. The course aims to help entrepreneurial academics and researchers to exploit the commercial value of their research. The programme has been running for 14 years and has provided training to over 400 attendees from across the country.

The training introduces delegates to a wide range of business areas, giving a better understanding of the business world. This gives them more confidence and awareness when approaching commercialisation of their research. Delegates also go on to use the training to enrich their teaching and research.

The programme explores the various routes available to academics to commercialise their research so they can make the best choices in how to develop their product. The course also covers skills such as networking, dealing with intellectual property, financial skills, marketing and pitching ideas.

6. Adapting to new business opportunities

We have been made aware of one large-scale business in the north of England that encountered problems with adapting their large scale plant to a new business opportunity, due to a lack of expertise and infrastructure further down their (UK) value chain. In order to fulfil the needs of a new market potential, expertise from organic chemists, fermentation scientists and engineers was required to help develop a pilot plant level solution into a pre-commercial demonstrator. They were unable to find a fermentation scientist within the UK with the right level of expertise (at the mid-to-higher technology readiness levels, e.g. TRL 5-7) and suitable yeast and microbe resources at an internationally competitive level. As a result, the opportunity to develop IP that would have been deployed internationally moved out of the UK.

This example illustrates the need for expertise that spans a breadth of disciplines, but also expertise that understands the challenges within a discipline at the different stages of translation. Whilst novel research may originate in e.g. academia in the biosciences, the skills and expertise to turn this into a product on a large scale requires input from chemists, physicists and engineers that have experience of working at pre commercial technology readiness levels.

7. LifeArc – Support for Translational Research

Bridging the "valley of death" between basic research and patient impact is a key aim of LifeArc,[55] a UK based medical charity, planning to invest over £500 million in the next 5 years in areas such as antimicrobials, neuroscience, personalised oncology and respiratory medicine. They have recently announced translational awards for academic scientists to progress drug discovery projects, and importantly have prior experience of leading successful collaborations culminating in four marketed drugs and a test for antimicrobial resistance.

8. Astex Pharmaceuticals[56]

In the 1990s, Professor Chris Abell and Professor Sir Tom Blundell at the University of Cambridge, funded by the BBSRC, began investigating enzyme inhibition in relation to drug development. An interest in developing a structure-based approach to enzyme inhibition led to a collaboration with Dr Harren Jhoti, former head of structural biology and bioinformatics at Glaxo Wellcome (now GSK).

The novel approach to drug discovery involved looking at the way small parts of drug molecules behaved. Drugs work by binding to proteins in the body and activating or inhibiting their behaviour, resulting in a beneficial therapeutic effect. However, due to their size, studying this interaction in a typical drug molecule is complex and time consuming. The researchers focused their attention on much smaller fragments of the drug-like molecules, drastically increasing the efficiency of the design process.

The collaboration led to the establishment of the company Astex Technology Ltd in 1998, backed by City investors interested in supporting biotechnology start-up companies. Astex built upon the university's fundamental research by combining fragment-based drug discovery with high-throughput methods and roboticised data collection.

Since their formation Astex has created 8 potential drugs that have progressed to clinical development; four being developed in-house and four through collaborations with Janssen, Novartis and AstraZeneca. In 2013 the company was acquired by Otsuka Pharmaceuticals for $886 million, Astex continues to build a rich product portfolio with many drugs in clinical development. Most recently, Kisqali, a breast cancer drug developed with Novartis was granted approval for use in the EU last month.[57]

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