



University of Nottingham Response to House of Lords Select Committee on Science and Technology Call for Evidence: Life Sciences and the Industrial Strategy

15 September 2017

This response is submitted on behalf of the University of Nottingham and represents the views of a number of people across the university who have wide expertise in research, knowledge exchange and technology transfer in the life sciences both in the university and NHS contexts.

Science and Innovation

Question 1: How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector? Does the research base have the necessary infrastructure to be world-leading?

The role of venture capital (VC) investors is to make a return on investment for their clients. Life sciences, and drug discovery in particular, is high risk and expensive in comparison to other technology areas. Investment in life sciences is also discouraged by the long maturation time (often 7-10 years) for technologies and high attrition rates which is why “Patient Capital” (where investors are willing to make a financial investment in a business with no expectation of turning a quick profit) is emerging as a specific class of investment capital. The Government is currently exploring the issue of Patient Capital funds and this is a very important class of investment capital with respect to supporting the life sciences.

Government initiatives to promote investment should increase the attractiveness of life sciences over more conservative opportunities. Tax incentives such as EIS (Enterprise Investment Scheme) and SEIS (Seed Enterprise Investment Scheme) have really helped to increase the amount of investment available from Business Angels however the amount of investment available from this source is generally considerably less than that available from VC investors unless there are multiple Angel investors involved, which brings its own problems in terms of management. Increased availability of translational funding for universities will reduce the risk profile of technologies, making them a more attractive proposition for investors. Sources of funding such as the NIHR and MRC Developmental Funding Pathway Schemes have been invaluable and should be expanded.

Specific ideas to promote investment are:

- **Seeding the development of new life science businesses:** The Seed Enterprise Investment Scheme (SEIS) is considered to be a strong attraction to private individuals investing in technology businesses. Although only applicable to investments up to £150,000 it is important in enabling a high-risk opportunity to become established. Companies must be less than two years old to be eligible for SEIS investment, which works adequately for technology companies but it creates challenges for life sciences companies which can take longer to become investment ready. Increasing the company age limit from 2 years would enable life science companies to benefit more fully.
- **Encouraging university spin-outs:** It generally takes a long time for Life Science companies to mature to the point when they offer a financial return to investors. When faced with the choice of whether to license a technology or spin it out into a company, a research institution would often choose the licensing route as this provides the potential for quicker returns even though that may mean the technology would transfer out of the UK. A mechanism to make spin-outs more attractive than licensing would help redress this balance. One possibility would be to set

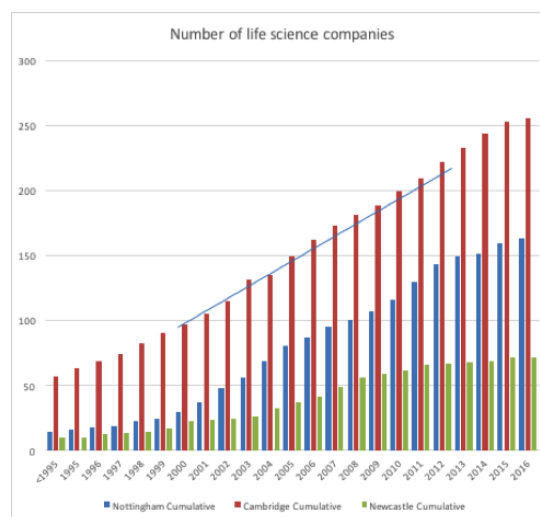


up a central fund which could buy the university shareholding at a price driven by a third-party investment round. The university could choose to sell some or all of its shareholding and so would have a route to gaining value at an early stage.

Geographic distribution of life science investment in the UK is a particular issue. Research Infrastructure is good in the Golden Triangle but as a country we need to ensure all regions have access to funding and facilities. Each year BioCity Nottingham undertakes an analysis of UK life science start-ups, collecting data since 2006 on location, type of company, source and investment. The data consistently shows that investment in the sector is heavily weighted towards London and the South East despite strengths across the rest of the UK. Of UK life science companies started in the period 2012-2016, 54% were located in London, the South East and East of England and 46% in the rest of the UK. The academic research base in relevant fields such as biological sciences, clinical medicine and chemistry is split approximately 50:50 between London, South East & East and the rest of the UK (as measured by 2014 REF Research Power). However, 87% of the investment into those start-ups over the 2012-2016 time period went into companies in London, South East & East- i.e. half the life science start-ups in the UK are receiving just 13% of the investment funds.

We would argue that the issue is not a shortage of investment in life science companies in the South East corner of England, but rather a lack of investment in companies in the rest of the UK. If the investment in start-up life science companies outside the South East was brought to the same level an extra £620M would have been invested over the past 5 years. We would not advocate policies that seek to shift investment from the South East, but rather to stimulate additional investment in the rest of the UK. This could include additional tax incentives for investments made outside the South East. Additionally, incentives for investors to establish headquarters in the regions could help as one of the issues is that most investors are based in London and rarely travel far. Finally, utilising the existing network of life science incubators to facilitate investment would also be simple and cost effective. Redressing this geographical balance would make a significant contribution to improving investment in the UK life sciences sector.

Life science incubators can also be the catalyst for stimulating growth of a local life science industry. The chart below shows the growth in the number of life science companies in Nottingham, Cambridge and Newcastle:



(data source: BEIS Strength & Opportunity Database- filtered for life science R&D companies only).

BioCity Nottingham was created in the early 2000's and it can be seen that since then the rate of company formation in Nottingham is roughly parallel to that of Cambridge. By contract, Newcastle is a



city of similar size and academic pedigree to Nottingham, but it has had no life science incubation facility of substance. There the sector has not taken off. We would advocate the government supports the growth of existing bio-incubators, the establishment of new ones where there is potential demand and utilizes the existing network of life science incubators as an efficient mechanism of improving investment into life science companies.

An example of such a development underway in the Midlands is proposed Medical Technologies Innovation Accelerator (MTIA) being developed by the consortium of Midlands Innovation universities (<http://midlandsinnovation.org.uk>) and their collaborators in industry and the NHS. MTIA will harness the Midlands' unique industrial base, patient population and academic-NHS innovation environment to create pan-regional collaborative working of scale; meet clinical demand more quickly; develop a thriving product and service industry base; and provide greater economic benefit. MTIA will drive the UK's leadership in the development, evaluation and adoption of Medical Technologies, supported by major match investment.

MTIA's key objective is to coordinate and develop the Midlands' Medical Technology cluster to support business growth regionally and nationally. Central to this is building a fully integrated multi-sector stakeholder network, designed to more rapidly target, develop and deliver innovative solutions for defined clinical needs, driving further investment and growth. MTIA will achieve this by:

- Growing our network of Life Science/Medical Technology Parks to form an innovative, connected infrastructure aiming to accelerate SME start-up, scale-up and growth
- Enhancing innovation, design and prototyping capabilities for Medical Technologies and devices through the development and integration of specialist 'hubs' across the region
- Coordinating the network in order to address critical industry roadblocks for new Medical Technologies, product and service development, and their subsequent adoption
- Translating the unique regional position in Defence Medicine to enhance innovation and accelerate adoption and dissemination of innovative Medical Technologies in civilian care

In addition, consideration needs to be given to equipment and other medium-to-large infrastructure which is too costly for single institutions to invest in but is needed to underpin the future of life sciences. For example, in a recent response to a MRC consultation the Midlands Innovation consortium identified two key priorities relating to imaging - MRI and Cellular. It is important that consideration to the costs of accessing and collaborating using large infrastructure items is made so that the equipment is accessible to a range of stakeholders and thus the full benefits of the investment can be realised.

Question 2: 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?

There are a number of key activities which could be undertaken in order to improve translation and entrepreneurship in the life sciences including:

- **Training more clinical academics:** Clinical academics provide the bridge between universities and the NHS and are also the people that can link life science industries into the NHS.
- **Improved training in entrepreneurship for bioscientists:** All PhD students should receive training in entrepreneurship, particularly in techno-economic modelling that translates the science into an investment analysis. The Haydn Green Institute for Innovation and Entrepreneurship at the University of Nottingham is a clear step in the right direction, providing enabling tools necessary to spinning out SMEs from academic research.



- **Align incentives across the tertiary education sector:** for example, the University of Nottingham apportions a large fraction of any commercial reward associated with patents to the academic inventors.
- **Establish an explicit funding vehicle for filing provisional patents prior to publication:** The costs of filing provisional patents is negligible compared to the costs at the national filing stage. More provisional patents should be filed within Universities to protect priority dates, which increasing scrutiny of commercial potential as the national filing deadline approaches. For example, should a patent not pass a scrutiny stage gate, the patent should be abandoned prior to incurring national filing costs.
- **Greater collaboration between SMEs and Universities:** The current grant funding framework draws SMEs and academia together, but does not necessarily facilitate cohesion and duplicates overhead costs during early exploration of an invention's commercial potential. Approaches for establishing greater collaboration such as 'spin in' opportunities should be pursued. For example, Nottingham's Synthetic Biology Research Centre (SBRC) has spun in companies into the University, which allows exploitation of infrastructure, which would be a greater overhead burden to a SME without this incubatory support. InnovateUK could be encouraged to support more such activity within Universities.
- **Universities should be encouraged to focus beyond technology readiness levels 1-3:** The engagement risk to industry is much reduced after technology demonstration (TRL levels 4 -5) Support for academic research at technology readiness levels 4 – 5 should be funded prior to requiring a financial commitment from industry as within the current InnovateUK funding model.
- **Promotion of multi-disciplinary research:** Translation of inventions to innovations typically requires contributions beyond the life sciences, e.g. engineering, chemistry and business sciences. The University of Nottingham's Beacon of Excellence initiative is an exemplar towards inspiring multi-disciplinary research with clear impact pathways.
- **Promotion of holistic, parallel research activity:** The UK's funding bodies should fund projects more holistically, looking beyond funding only research activities. Grant funding should be cast within a larger commercialisation endeavour, avoiding disjointed investment into ideas, where funding is also provided for integration of new research with existing technologies to provide holistic solutions to societal and industry challenges. In particular, early investigations into aspects that are key to later TRL concerns is crucial to ensure shorter development cycles through more parallel research activity.

It is important to also consider whether or not filing fewer patents is indeed under-performing or is simply indicative of a culture in which a more prudent approach is taken to patent protection. The patent prosecution landscape in the US, for example, is somewhat different and allows more flexibility such as the option to change a patent specification beyond the 12 month window. Patent protection can be extremely expensive, and in the drug discovery space potential licensees require wide geographic coverage further increasing the cost prior to out-licensing. This further encourages a prudent approach to patent protection in universities.

The current increase in HEIF funding for universities is welcomed but further intervention such as patent costs being covered for the duration of an RCUK translational award would be welcomed. Patents costs are currently not eligible costs under the Research Councils but the possibility of changing this policy position should be explored.



Question 3: 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?

It is critical to maintain or, if possible increase, investment designed to provide capacity in the sector through Research Council and NIHR/Department of Health funding streams. The recent Biomedical Research Centre (BRC) competition supported by NIHR has the potential to further increase the research base for clinical translational research at least until 2022: it is essential funding is ring fenced to continue this beyond 2022. Re-organisation and changing priorities in the UK Research Councils through the creation of UKRI may be a threat but also an opportunity. Post-Brexit we need to ensure we have adequate governance systems in place (e.g. for clinical trials), and do not complicate the regulatory environment further.

There are specific skills needs that need to be addressed in order to build a world-class life sciences sector. These include:

- ***In vivo* research methods:** One of the major skills shortages in the UK is in *in vivo* research methods, in both physiology and pharmacology (see ABPI 2015 assessment of skills <http://www.abpi.org.uk/our-work/library/industry/Pages/101115.aspx>). The only way to ensure that this, and other identified skills gaps is to ensure that financial support for such high cost skills training is prioritised by both Government and by industry.
- **Data and Informatics skills:** It is important that the Life Sciences begins to develop centres with expertise in analysis of big data/large data sets with digital and data/informatics analysis specialists. This is an expert resource needed to support much of the future Life Sciences agenda.
- **Enhanced entrepreneurship and collaboration skills for students and researchers:**
 - Four year PhD programmes with integration and time based in industry (e.g. BBSRC's Professional Internships for PhD Students programme) as well as the opportunity to interact with Industry during research/study.
 - Industry clubs with researcher and student meetings so communication routes are established. This helps to determine training and research needs.
 - PhD Plus programmes: 1/1.5-year period post-PhD for training and interaction with Industry.
- **Investment into other areas where skills are lacking:** this currently includes key areas such as bioinformatics and mathematical modelling; crop sciences; and physiology. This needs continuous evaluation and fluidity to ensure that new skills needs are able to be addressed as they arise.
- **Linking with International opportunities:** this enables the building of training networks, expertise and sharing of resources and training. Training networks such as BBSRC's Doctoral Training Partnerships can be part of this.
- **Close proximity and liaison with the NHS:** Applied life science research into new innovations in treatment and cures can lead to the birth of new companies if the relevant entrepreneurial knowledge is acquired by academics on this process of commercialisation of their products. Liaising closely with the NHS will be key in keeping new treatments and cures relevant to the clinic. Building research labs from University with industrial collaborations adjacent to NHS labs is a key way to facilitate such work.
- **Access to critical resources:** This includes facilities such as the UK Biobank and pathogen banks. Prompt access to real life pathogens (such as antibiotic resistant pathogens causing difficult to treat infections) rather than model strains, enables more relevant research into current epidemics to take place.



The future success of UK life science will also depend on attracting and retaining world-class researchers in the sector. The current life scientist career path requires an undergraduate degree, followed by 4 years of doctoral study, and, typically, at least 3 to 6 years of postdoctoral training on fixed term contracts, before an individual researcher is considered qualified to pursue their own research programme (in public or commercial sectors). This training path leads to an extended period of uncertainty and financial constraint, often requiring individuals to defer the start of their independent careers until their mid-thirties to early forties. Such a career trajectory is only likely to be attractive to world-class students if they perceive sufficient opportunity to secure a fulfilling career at the end of this pipeline. Traditionally, these rewards are seen as the satisfaction of applying research skills to important problems, with additional financial rewards in commercial settings, and personal autonomy being prized in academic settings.

Current trends are putting this system under strain. Job losses and restructuring in the commercial sector have destabilised this career route, and job insecurity, salary depreciation and increased workloads have eroded the appeal of the academic sector. These trends have resulted in a “leaky pipeline” problem, where the number of long-term positions in research is a small fraction of the number of students being admitted to graduate study. This has two negative outcomes: first, many highly qualified and capable researchers are lost from the sector after years of investment in their training, and second, top-performing students will not even enter the pipeline, perceiving it as a second rate career choice to other sectors such as finance, law or business. The sector would also benefit from strengthening opportunities to return to work for people (frequently women) who have had a career break. For example, focused fellowships, which may be full or part-time.

Addressing these issues of skills wastage, and lack of appeal to high performers, is essential to improving the sector’s future. Increasing investment in research funding will shore up the research sector, with prioritisation of schemes such as personal fellowships, enterprise schemes for translation, and early career awards to target the current career bottleneck. A review of academic and NHS salaries is also likely to be essential to attract ambitious and motivated individuals.

Industrial Strategy

Question 5: What can be learnt from the impact of the 2011 UK Life Sciences Strategy? What evidence is there that a strategy will work for the life sciences sector? How can its success be measured against its stated objectives?

The 2011 Life Sciences Strategy contained some good things but also has seen some negative impacts. In particular, since 2011 several major life science industry players have relocated much of their R&D from the UK (Pfizer, Astra Zeneca, and Novartis). It is important to consider how we can build further incentives to ensure these companies continue to invest in collaborations in the UK e.g. with universities despite the physical move of staff and facilities, and also ensure there are no further losses. The Accelerated Access Review led to a funding stream for introducing new therapeutic approaches into the NHS, but without a follow on from this incentives are reduced. Investment to support industry collaboration was rather restricted in the way it could be accessed, and the governance/review processes on funding allocation could be strengthened. Success will be measured by the level and value of academic/industry/NHS collaborations, and an increase in pharmaceutical (and other) investment into the UK.



Question 6: Does the strategy contain the right recommendations? What should it contain/what is missing? How will the life sciences strategy interact with the wider industrial strategy, including regional and devolved administration strategies? How will the strategies be coordinated so that they don't operate in 'silos'?

The Life Sciences Industrial Strategy is excellent and imaginative and should be strongly supported. However, there are several key omissions. Firstly, Universities are central and key to the whole agenda of delivering the industrial strategy. They bring everything together but they are hardly mentioned in the Strategy. Secondly, there is not enough on regionalism. With big regional groups now functioning and involving industry, universities, the NHS and local government such as the Northern Powerhouse and the Midlands Engine much more needs to be done to encourage and spread innovation and industry engagement with the Life Sciences nationally to the places where manufacturing and other industry are actually based. There is as much or more academic talent and good engaged industries and universities and excellent hospitals outside London and the south east as there is inside.

In addition, the Strategy is perhaps a little top down. The report had excellent contributors and makes important comments on the specific areas needing investment, but the authors do not have a monopoly on ideas and a bottom up approach to developing and funding the best innovation is needed.

Question 7: What opportunities for small and medium sized enterprises (SMEs) are there in the strategy? How can they be involved in its development and implementation?

Life Science companies need access to investment to grow and develop. Initiatives such as increasing the availability of Patient Capital and reviewing the tax incentives to Angel Investors should be considered.

There will be very few opportunities for standalone SMEs to develop and implement the Industrial Strategy, and we suggest that the Government make use of existing membership organisations such as the Chamber of Commerce, Federation of Small Businesses and Medilink in order to bring in an SME perspective to the development and implementation of the Industrial Strategy. There are two networks supported by this university which could contribute: the Nottingham Manufacturing Network and the East Midlands Chemistry Network, both of which will speak with some authority about their sectors and have some interest in developing the Industrial Strategy.

[NHS Procurement and Collaboration](#)

Question 10: How can public procurement, in particular by the NHS, be an effective stimulus for innovation in the Life Sciences Sector? Can it help support emerging businesses in the Life Sciences sector?

The NHS can be reluctant to buy new technology without a track record of successful operation. Innovative technology can often appear more expensive at the point of purchase but might have downstream cost savings. However, NHS Trusts often lack the expertise to assess, evaluate and implement new healthcare technologies and NHS procurement has historically found these opportunities hard to grasp: even with NICE recommendation, NHS Trusts have been reluctant to purchase some innovative technologies. Consideration of a funding mandate for NICE recommendation of medical technologies might help incentivise the NHS here but local Health Technology Assessment (HTA) teams can also play a significant role. Larger NHS Trusts should consider having Innovation & HTA teams with the relevant skills and experience (clinical engineers, ICT-device experts, human factors, health economics, and data analysts) that can appropriately assess and evaluate the impact of new technology. Such teams in larger



NHS Trusts could then act as hubs for regional adoption of new technology. However HTA teams are rare within the NHS as Trusts do not see the benefits of them and the skill sets are not generally available. In particular, there is shortage of senior clinical engineers and health economists with medical technologies experience which is a key deficit.

Coupled with this, industry (and particularly SMEs) find it hard to gather the evidence to demonstrate their innovations are better for patients and cost saving. More help needs to be given to industry to get both the clinical and financial evidence required to support the adoption of their technology. SMEs in particular can't generally afford to employ their own regulatory officer, compliance engineer, health economist, trials lead etc. Regional Innovation and HTA Centres (as above) could help promising technology by bringing together expertise and offering access to NHS data and patients (for trials etc). However such teams are relatively costly for the host NHS Trusts who do not always see the benefits. Government investment in this area would be beneficial.

Question 11: How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled?

The Accelerated Access Review suggests that "Tertiary academic hospitals that host Academic Health Science Centres (AHSCs) or Biomedical Research Centres (BRCs) should champion innovation and lead collaborations in their local health economies". This fits well with the idea of establishing Innovation and Healthcare Technology Assessment (HTA) teams in larger NHS Trusts (see Q10 above), perhaps particularly those with BRCs: Academic Health Science Networks (AHSNs) can support, resource and lead this.

Regional NHS Scientist Training Programmes (STPs) touch on the need for technology-led innovations and the Accelerated Access Review also supports this. However, the current NHS financial crisis is making the leap to new, cost-release/cost-saving technologies difficult as the initial investment is harder to unlock. NHS trusts, with AHSNs, BRCs and Innovation/HTA teams which are properly resourced, can play a role in unlocking this potential. Industrial partnerships are essential but industry, especially SMEs, need access to expertise, information and support. The Accelerated Access Review suggests incentivising NHS Trusts/AHSNs/BRCs with significant investment (£4m - £8m) which would make a significant difference.

Question 12: How can collaboration between researchers and the NHS be improved, particularly in light of increased fiscal pressures in the NHS? Will the NHS England research plan help in this regard? How can the ability of the NHS to contribute to the development of and adopting new technology be improved?

a) How can collaboration between researchers and the NHS be improved, particularly in light of increased fiscal pressures in the NHS?

There are a number of key issues that need to be addressed in order to improve collaboration between researchers and the NHS. These are:

- **Need for more clinical academics:** There is a need to increase the number of clinical academics i.e. doctors, nurses and other healthcare professionals who are also fully academically trained and also trained innovators and researchers. These people usually hold joint contracts in a



University and an NHS Trust and are often the people who run NHS research and innovation institutions such as NIHR Biomedical Research Centres. We need both more of them and for them to be better trained with regard to industry engagement.

- **Restricted time of key NHS experts (clinical and diagnostic staff) to collaborate with university researchers:** This is a key requirement since NHS staff can share real life requirements and examples of outbreaks and collaborative research between them and University scientists and industry is the way ahead. In the current climate, often services are too stretched and staff too overwhelmed to take time out of their daily working hours to do research.
- **Lack of research capacity:** Increased capacity for research in the NHS is part of the NHS mandate and locally, supported by all senior leaders, however, anecdotal evidence shows that blockages remain at middle level management level where managers are reluctant to release staff to carry out research (even if funding is available to backfill the position) as they won't be able to replace the exact skill set.
- **Lack of dedicated research time:** Many clinicians are busy with the day-to-day business of the NHS and most have no funded research time. Provision of dedicated research time for NHS clinicians and flexibility to allow more junior staff to undertake research degrees is essential to increasing effective collaboration with the research base. Recent increasing moves to support clinical academic careers (see: <https://www.nihr.ac.uk/funding-and-support/funding-for-training-and-career-development/training-programmes/nihr-hee-ica-programme>) are designed to address this need for NHS research capacity. However, whilst there is (limited) training funding, there is a growing issue of how to support the career development of practitioner-researchers. Joint NHS/University posts are the panacea, but there are too few of them, particularly for non-medical health care professionals such as physiotherapists, dieticians, midwives and nurses. Consequently, after PhDs (investment of £60K+ in training), practitioners are either going back into practice thus leaving research behind, or vice versa.
- **Risk to NIHR funding due to NHS financial pressures:** The NHS faces unprecedented financial pressures and whilst, at present, NIHR funding is ring fenced there is a real risk this might go which would jeopardise future translational research. It is essential this continues to be protected.
- **Need to build in NHS research support costs into grants:** often direct or indirect costs for NHS staff/organisations to be involved in research as stakeholders or participants aren't costed into funding. There are some limited sources which provide funding to cover these activities (e.g. the NHS Clinical Research Network and NIHR Research Capability funding) but if this is not forthcoming NHS Trusts either don't get involved in these kinds of research activities or they end up covering costs within service, thus taking them away from other areas. In addition, the UK Research Councils now make it much easier to buy out NHS clinician time within research funding applications which is very beneficial but this needs to be more widely publicised within the NHS.
- **Incentivisation:** Research collaboration in the NHS brings other benefits which are sometimes more difficult to measure and must not be forgotten: better recruitment and retention of staff to centres which are successful, increased staff satisfaction, improved patient outcomes for patients recruited into trials etc. However, for NHS staff, research is often seen as a luxury that can be cast aside in favour of more urgent, life-critical tasks. There isn't the capacity to see research as an investment for the future and research involvement needs to be incentivised.
- **Co-production of research:** the most successful research that gets implemented to make a difference to practice comes from the bottom up; is based on an identified clinical need; and then the intervention and research is co-produced between practitioners, commissioners and researchers. This is an ongoing, iterative process to ensure the outputs/outcomes are fit for



practice and intended use. Applied health research units, like the NIHR CLAHRCs are an important mechanism for supporting co-production.

- **Translation into practice:** research often doesn't translate well into practice with the "bench to bedside" sometimes taking up to 20 years meaning that evidence-based practice is often out of date or the service has moved on by the time the research evidence is ready. Solutions include:
 - Reassessing evidence requirements, for example, are randomised control trials always necessary
 - New and creative ways of sharing academic knowledge e.g. by supporting the 'translation' of evidence produced by academics into accessible forms of practitioners – either in the form of clinical summaries to aid decision making (see: <http://emahsn.org.uk/putting-into-practice/sparks-and-sparklers>) or producing 'how to guides' (for example, a guide to implementing change – see: <http://www.clahrc-em.nihr.ac.uk/research/our-approach-to-implementation.aspx>)
- **Funding for translational activities:** The MRC's Developmental Pathway Funding Scheme and the NIHR I4i (invention for innovation funding scheme) are excellent programmes for supporting translation of new technologies into healthcare. However they would benefit from additional funding and improvements as follows:
 - It would be beneficial to develop some "central" pool/library of expertise across relevant domains (IP, statistics and trial design, public engagement, design etc) to which newly funded projects could be directed), possibly through the AHSNs
 - Non-funding of animal work is problematic with the i4i programme and the development of medical devices. A mechanism needs to be in place if an otherwise strong proposal is thought to need animal evidence
 - Technology translation fellowships (2-5 years duration) could be created for clinicians, engineers and life scientists. For example MIT runs a programme that provides training and time to support translation of its technologies: <https://innovation.mit.edu/education-practice/affiliate-programs/translational-fellows-program>

b) How can the ability of the NHS to contribute to the development of and adopting new technology be improved?

- **Relieve NHS financial pressures:** the benefits of advances in translational research are often difficult to adopt into standard NHS practice because of NHS financial pressures. This is not helped by the commissioning model as there is little incentive to commission new tests or treatments as there is always an up-front cost before benefits accrue. The Accelerated Access Review also highlighted this issue, but at present there is no comprehensive solution being put in place.
- **Reduce complexity of route from basic science to adoption:** The route from basic science to adopted technology in widespread use in the NHS is long, diverse and complex. No single pathway exists: there are multiple routes depending on the type of technology; the health and wellbeing application; the market size; the maturity of the science. Even those who are within the NHS and experts in the adoption of new and innovative medical technologies find it difficult to keep pace with all the changes and be clear on this pathway; for those outside, even large companies, it can be almost impossible. Various attempts have been made at national and regional level to map this pathway but none have been particularly successful.
- **Increase resources for information signposting:** The NHS itself is a huge resource of information which could be of significant benefit to med tech developers. However, 'the NHS' is not a single body that can be approach for help, little if any signposting of where to find information exists,



and getting access to appropriate experts and advisers is difficult even for people inside the NHS. The proposed new 'digital information hubs' ecosystems, if resourced and well managed, might be able to help in this regard. The AHSN also has the potential to play an important role in bridging gap between universities clinicians and industry but is currently poorly understood by many clinicians.

In summary, translation of research and technology developments into the NHS and healthcare ecosystem is complex and a science in itself. This is not just about commercialisation and procurement but clinician behaviour, guidelines, supporting new care pathways and protocols as well as information systems that support this. This underlines the importance of applied health research and vehicles for supporting translation into the 'real world' of practice. The NIHR's investment in Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) is one of the few infrastructure investments into the complexities of getting this activity to happen.

Responsibility and Accountability?

Question 13: Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

Responsibility for implementation should rest with an independent non-political body that assesses implementation over the medium and long term and is made up of the wide range of stakeholders that have an interest in the Life Sciences Industrial Strategy.

The strategy should be enabling rather than prescriptive providing mechanisms that will shape and drive research agendas and accelerate the innovations that arise from these. The Government needs to have oversight of this approach but it will be vital that the stakeholders between academia, charitable and business sectors should be shaping the agendas and identifying the innovation pathways recognising that traditional innovation pathways may need to be supplemented by new models that take into account team-based, transdisciplinary science approaches (reference Report on *Improving recognition of team science contributions in biomedical research, March 2016, The Academy of Medical Sciences*). Accountability should be to a Minister (Minister of Life Sciences if appointed) given the importance of the Life Sciences Industrial Strategy for the UK and for the UK to be realising through effective research and innovation the opportunities and potential for the UK to be a leading Bioeconomy player.

Implementation will need to include a range of delivery partners which should include UKRI which should be funding research. There needs to be a recognition that an effective Life Sciences Industrial Strategy will be dependent on a well-funded research base that invests in infrastructure and equipment, people and mobility that draws on and links with the best research done globally, and with well-connected innovation pathways.

Question 15: Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Sciences Minister? If so, should that Minister have UK-wide or England-only responsibilities?

The structures need to be supplemented with an independent non-political body drawing on the wide range of stakeholders that can set an ambitious vision and objectives for the UK, targeting the realisation of the UK to have a productive, high value, high skilled Bioeconomy which delivers products and services



globally. The substantive basis for this must be continuing investment in the UK's world-leading research base in areas of life sciences.

Brexit

Question 16: What impact will Brexit have on the Life Sciences sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

Continued access to Horizon 2020 and its successor programmes after Brexit is vital for facilitating world-leading research and collaborations. The Life Sciences sector, like so many other sectors, relies heavily on global networks often facilitated by Horizon 2020 funding and the collaborations that this funding enables with the best researchers around the world. The framework provided by Horizon 2020 allows for a balance between collaboration and competition which allows cross-border collaborations which enable the full potential of research to be realised. Other European research initiatives such as the European Research Council programmes are also vitally important for supporting world-leading research in the Life Sciences as well as in other sectors.

In addition, the UK needs to be part of the process of shaping the FP9 Programme which will be the successor to Horizon 2020. The UK needs to negotiate hard to be included at this early stage on the assumption that UK will remain part of European research and development programmes as per the Government's recent position paper on Science and Innovation.

World class talent is also vital to the development of the Life Sciences sector in the UK. This does not just include skilled workers and skilled researchers but also PhD students, where we are already seeing a reduction in application numbers, and technical staff who may be excluded by an immigration system which uses salary as an indicator of skills level and thus rules out expertise that is needed for Life Sciences. A punitive post-Brexit residency and immigration system for EU nationals has the potential to discourage European researchers from coming to the UK, particularly if they have partners and families who also need to relocate and be able to work/settle in the UK. We are concerned that the UK Government's immigration policy is becoming more restrictive making it harder for skilled people to come to the UK and work in areas where the UK has a clear skills shortage. Additionally, some of the UK's statements may be dissuading people from coming here and encouraging those already here to leave. This is an issue for the whole of the knowledge-based economy and the educational system that supports it, but is as relevant to the Life Sciences as to any other sector.

Question 17: How should the regulatory framework be changed or improved after Brexit to support the sector?

In many respects the UK leads Europe with respect to policy and regulatory frameworks however it is likely to be more challenging for life science technologies to be commercialised in Europe post Brexit once there is no common framework and this will need to be addressed.

Key issues that need to be addressed as part of a post-Brexit regulatory framework include:

- **New drugs need to come to market in shorter timeframes.** The current lengthy clinical trial timelines drain the capital of investors and serve as a disincentive to investment. Sufficient consideration needs to be given to shorten clinical trial cycles without compromising patient safety. Combining and overlapping elements from the phases of clinical trials should be considered. For example, including patients alongside healthy volunteers should be considered as part of dose ranging during phase I. Dose ranging within the patient population is appropriate



given the purpose of the study. Early indications of efficacy during phase I, not necessarily statistically significant, would be of considerable benefit to launching into and informing phase II trials.

- The enormous benefit of the **UK research exemption** as set out in section 60(5)(b) of the Patents Act ('exempts from patent infringement acts done for experimental purposes relating to the subject matter of the invention') should not be underestimated. It provides a significant comparative advantage to the UK over countries such as the USA and such be preserved post Brexit.
- The UK should remain in step with Europe on the **stringent requirement for patent exemplification**. The US has drifted to granting patents without any semblance of exemplification which invites a land grab on ideas (a form of patent trolling), which destroys value for those who have an actual intention of investing in such ideas.
- **The process of granting patents has become outmoded as a vehicle to protect inventions in many areas of the life sciences**. The complexity, breadth and specialisation within a rapidly changing technology landscape makes it very difficult for patent examiners to assess the validity of patent claims. As a consequence, unsustainable litigation is likely to proliferate into the future, making the granting of patents ineffective as a vehicle for assigning property rights. A review should be undertaken to evaluate a more robust means of assessing the validity of claims within a complex and specialised patent landscape.

Question 18: To what extent should the UK remain involved with and contribute to agencies such as the EMA post Brexit?

The medical devices and technology field is highly regulated. These regulations help ensure that high quality technology is available to clinicians and patients which improves health and wellbeing and can increase healthcare efficiencies reducing NHS costs. We do not improve patient care by reducing the regulations and the standards to which we work. However, it is appreciated that compliance to these regulations and high standards can be difficult, expensive and takes time. The speed of uptake of new, promising technology is not achieved by reducing regulations, standards and quality: it is increased by providing expert support and advice to industry in order that they can meet the standards effectively and quickly whilst also generating the evidence to support the patient improvements and cost savings of their technology.

The fear is that Brexit could be seen as an opportunity to 'relax' UK adherence to EU med tech regulations – this might achieve rapid uptake of new technology, but not necessarily technology that increases patient outcomes and brings in financial efficiencies. Moreover, it risks allowing in cheaper, untested technology that ultimately costs more and places the patient at higher risk. Additionally, any move away from current and future EU regulation on med tech will place UK industry at a disadvantage in marketing to the EU (and to a wider world that often recognises EU regulations).

The UK should remain as involved as ever (or more so) with EU agencies: we are respected and influential now and any reduction in this would be disadvantage for UK medical technologies industry, academia and ultimate patients.