

House of Lords Select Committee on Science and Technology inquiry into Life Sciences and the Industrial Strategy

Response from Alzheimer's Research UK September 2017

About Alzheimer's Research UK:

Today, over 46 million people worldwide are living with Alzheimer's or another form of dementia; complex brain diseases that leave them unable to think, move or communicate with the people they love most. Dementia will soon become the leading cause of death in the UK and without effective treatments, one in three children born today will die with it.

Alzheimer's Research UK is the world's leading dementia research charity dedicated to causes, diagnosis, prevention, treatment and cure. Our singular focus on research means that we can channel our expertise and energy with maximum benefit, to make the greatest difference to people affected by dementia and their families.

Our mission is to bring about the first life-changing dementia treatment by 2025 and we're doing this through four clear goals driven by passionate scientists, supporters and staff:

- Understand - To fund world-class researchers to unravel the science behind the complex diseases that cause dementia.
- Diagnose - To work at the forefront of technology to ensure an accurate diagnosis for everyone at a time that's right for them.
- Reduce risk - To accelerate the science of dementia risk and empower people to make informed decisions about how they live their lives.
- Treat - To build on 100 years of scientific of scientific discoveries to translate breakthroughs in the lab into life-changing treatments.

By driving progress across these important strands of work, we'll bring about breakthroughs that will transform lives.

Science and Innovation

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?

Alzheimer's Research UK has been doing ground-breaking work forming innovative partnerships between charities and industry. These could be reproduced by other charities and disease areas via mechanisms such as the ISCF. Alzheimer's Research UK is part of the Dementia Discovery Fund: a close collaboration between charity, industry and the government, to provide much needed investment in innovative dementia research. It is a partnership between the Department of Health, Alzheimer's Research UK and 7 world-leading pharmaceutical companies including Biogen, GSK, Johnson & Johnson, Lilly, Pfizer and Takeda. The fund is managed by SV Life Sciences, a venture capital firm, providing the investment management skills needed for the project to meet its goals and succeed financially. The fund has now invested in Alector LLC and Gen2 Neuroscience Ltd as its first two investments for novel dementia treatments.

Alzheimer's Research UK's Dementia Consortium is an innovative funding model based on international charity-industry partnerships, which is accelerating the development of therapies for novel dementia targets. Bringing together Alzheimer's Research UK, Medical Research Council Technology and the pharmaceutical companies AbbVie, Astex, Eisai, Lilly and MSD, the consortium aims to close the gap between fundamental academic research and the pharmaceutical industry's drug discovery programme to develop a new dementia treatment. The consortium provides funding, expertise and resources to support target validation studies of new drug targets emerging from academic research that hold the promise of patient benefit. The first five projects are underway and are scrutinising novel targets in a range of areas including inflammation, protein clearance and repair mechanisms.

Alzheimer's Research UK's Drug Discovery Alliance is a unique drug discovery venture in dementia research, tackling the lack of dementia medicines by embedding industry standard drug discovery in world-class academic institutions. The £30m Alliance unites three Drug Discovery Institutes at the Universities of Oxford, Cambridge and UCL and is one of the largest coordinated initiatives in the world to accelerate the search for new treatments for dementia. The aim of the Alliance is to grow and maintain a healthy pipeline of validated targets to take forward, bridging the gap between fundamental academic research and the pharmaceutical industry's drug development programmes.

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?

Alzheimer's Research UK welcomes the Government's increased investment in research and development. However, the UK's investment of 1.7% of GDP in public and private R&D is below the OECD average of 2.4% and far behind leading backers of innovation (e.g. South Korea, Israel, Japan, Sweden, Finland and Denmark).

The Life Sciences Industrial Strategy recognises that a key challenge for life sciences is around translating leadership in science into commercial outcomes. The Government recognises that the UK has too often pioneered discovery but not realised commercial benefits. While the way we distribute funding across different stages of R&D is not out of line with other European countries, in leading innovation nations, such as Israel and countries in Asia, a greater proportion of total R&D investment is on later-stage, experimental development. China, for example, currently spends twice the share of the UK. This may amplify the industrial impact of such countries' funding commitments to R&D.

We recognise that there is a win-win opportunity from pioneering discovery and then realising commercial benefits. Alzheimer's Research UK has a unique offer to contribute to the Strategy on funding models. We are aiming to close the gap between academic research and pharmaceutical drug discovery, with the wider goal of accelerating research towards patient benefit. We do this through innovative public-private funding models that work particularly well to stimulate investment and research into under-funded disease areas. We believe that closing this gap between discovery and commercial benefit should be a priority for R&D investment.

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?

While the recent increases in funding for dementia research and charity-led initiatives are expanding capacity in the UK dementia research landscape, we see clear evidence that long-term sustained investment is required to result in a greater step change to support the next generation of research leaders and entrepreneurs. In Alzheimer's Research UK's recent report

“Keeping Pace: Progress in Dementia Research Capacity” (March 2017) we make a number of recommendations to Government to support research in the future. They are:

1. Enhance Investment: We call on all current dementia research funders (government, charity and industry) to continue to increase investment in dementia research. This should include strategic investment in people, projects and supporting infrastructure to grow the research base. Initiatives such as the Dementia Discovery Fund and the Dementia Research Institute start to address the much-needed step change, however stark differences in investment remain compared to other disease areas. For example, for every £2 million of disease costs there were 10 cancer researchers for every 1 dementia researcher. To address this gap we need to increase dementia research investment given the significant impact on people and the economy.

2. Enable Collaboration: We call on the UK Government, through and post Brexit negotiations, to ensure that the UK continues to participate in EU research programmes and venture capital schemes. Once the UK has left the EU it is vital to dementia research that the UK maintains and enhances its ability to collaborate with colleagues globally. In future the Government must ensure the UK’s immigration system attracts high quality researchers, innovators, entrepreneurs, pharmaceutical R&D, legal and regulatory experts, skilled technicians and students. It is only through attracting and retaining this world-leading expertise, in conjunction with international collaboration, that we can grow dementia research and the UK can retain its standing as a global leader in medical research.

3. Increase Sector Support: We call on the UK Government to support dementia research and broader medical research landscape through the industrial strategy and future policy decisions, so that the UK remains an attractive place to conduct research for the benefit of people. This could be done by increasing the Charity Research Support Fund; involving medical research charities in public R&D funds such as the Industrial Strategy Challenge Fund; maximising opportunities for research with patient data and ensuring the NHS is a world leader in medical research.

Recent and ongoing changes to the Higher Education sector may also impact on the dementia research landscape. It is important that the Government’s reforms to higher education are mindful of the need to support dementia research capacity by promoting postgraduate education and early career research.

With the introduction of the Government’s new Apprenticeship Levy, Alzheimer’s Research UK will shortly begin contributing to the new tax. However, a number of overarching challenges may prevent us from making the most of the Apprenticeship Levy, contributing to upskilling the workforce and giving people the opportunity to undertake in-work training.

Much of our research work takes place in UK universities and hospitals; being able to transfer levy contributions to fund research apprenticeships in these settings would allow us to better utilise our levy contribution and to further our charitable objectives.

The current 10% limit on the levy funds which can be transferred from one organisation to another should be raised to allow medical research charities such as Alzheimer’s Research UK to more fully utilise our contributions within universities and other research partners.

The nature of our medical research means that, if we were able to use our levy contributions to fund research apprenticeships, we would need high level (level 8, PhD level) apprenticeships standards to be developed.

4. How does the UK compare to other countries in this sector?

The UK is a world-leader in dementia research. Dementia research in the UK has increased the most compared to research in other countries, and compared to other disease fields in the UK. The number of UK researchers has risen by 91% in dementia, by 42% in cancer, 41% in coronary heart disease and by 69% in stroke between 2008/09 and 2014/15.

Industrial Strategy

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 progress that has been made in dementia research in the last few years has largely been due to the Prime Minister's Challenge on Dementia 2020. As a result of this strategy, we have seen significant progress in the journey towards the first life-changing treatment for dementia. This demonstrates that where there is a clear and focused strategy around a sector, it acts as a catalyst for investment, collaboration and growth.

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'?

We welcome the vision laid out in the Life Sciences Industrial Strategy, as this significant level of investment will help us in our mission to bring about a life-changing treatment for dementia by 2025. With the strategy, there is a clear and determined plan to ensure that the UK continues to build on its world-leading life sciences sector, which will help grow our economy and accelerate positive outcomes for people impacted by serious health conditions, like dementia.

At Alzheimer's Research UK, we champion collaborations between charities, industry and government. For years, we have been focused on bridging the gap between academic research and pharmaceutical drug discovery to deliver the breakthroughs we so desperately need for those impacted by dementia and this collaborative approach can be replicated in many other health areas.

We're glad to see that the benefits of cross-sector working have been recognised in the Strategy. We would urge the Government to continue involving medical research charities, and drawing on their unique expertise, as the Strategy moves forward and a sector deal for life sciences is established.

7. Where should the funding come from to support the implementation of the strategy?

Please see Question 1 for examples of innovative funding models that we believe could be applied more widely to support the sector.

NHS Procurement and Collaboration

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?

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?

Government should implement the recommendations of the Accelerated Access Review (AAR), including the recommendation to involve patients in horizon scanning and prioritisation along the innovation pathway, including establishing a common set of principles describing good partnership working with patients. Working with patients will be critical to the success of the Accelerated Access Review, and patients' families, carers and the charities that advocate for them should also be included in this partnership working.

Mechanisms to improve horizon scanning such as the proposed Accelerated Access Partnership should be a priority. This could help foster early engagement and better prepare the NHS for new treatments and diagnostic tools coming through the pipeline, ensuring that these can be adopted by the NHS as quickly as possible.

Early engagement is essential in order to overcome access and uptake challenges for new treatments, including affordability challenges and how risk can be better understood and managed, as early as possible. There will need to be preparation, cooperation and compromise across a number of key stakeholders including the Government, the Department of Health, NICE, NHS providers and commissioners, and the pharmaceutical industry (*Treatments of Tomorrow*, ARUK 2016). A balance will need to be struck between setting a price that rewards and incentivises innovative research, but is also affordable to the NHS. The Strategic Commercial Unit proposed in the AAR could help facilitate early discussions and support the development of a range of innovative funding models.

As of 1st April, a new 'budget impact test' applies to cost effective new treatments that meet or exceed the cost of £20 million during any of the first three years. These changes to arrangements for evaluating and funding drugs and other health technologies could result in unacceptable delays in patients accessing new treatments, especially new treatments that could benefit large patient populations and those with significant levels of unmet need, such as dementia. The test could also present a significant risk to the life sciences sector by creating barriers to the uptake of innovation in the NHS.

There are 850,000 people living with dementia in the UK today, a number expected to exceed one million by 2025, and there have been no new drug treatments approved for dementia in over ten years. There are no treatments that can change the course of the most common diseases that cause dementia, we cannot yet slow their progression or delay their onset. There have been no new drug treatments approved for dementia in over ten years.

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?

Opportunities for conditional access to new treatments alongside the collection of real world evidence to understand longer term effects will be important for long term conditions. This will support early access to safe and innovative treatments for conditions such as dementia, where the slow progression the disease leads to challenges to measuring gradual change over the relatively short duration of a clinical trial, especially in the early stages of the disease. The NHS has unique potential in terms of collecting data, and with the right mechanisms and systems in place the NHS, and therefore the UK, could be positioned as the go-to place for doing research and launching new treatments. A "research-ready" NHS should be used as a selling point to attract investment into the UK.

Responsibility and Accountability

13. What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

We believe that the role of the UK Government should be one of prioritising the sector, acting as catalysts for collaboration and partnership and attracting inward investment to the UK.

As well as attracting global life sciences companies to the UK, the government must work to make the UK an attractive place for people from all over the world to live and work. This includes challenging negative views about migration, making workers feel welcome here, addressing housing and transport issues and considering the needs of employees' families.

Post-Brexit, part of the Government's role to attract and retain life sciences companies to the UK must be to ensure that the UK has an immigration system that is fit for purpose, attracts highly skilled people to the UK and allows for the development of a talent pipeline. Any new immigration system cannot be too simplified. A salary cut-off system, for example, could restrict important skilled technician workers or new graduates who are vital to ensuring the UK remains a global leader in life sciences.

Recent developments in funding models and collaboration mean that the roles of the academic, charitable and business sectors are more interconnected than ever before, which is leading to new sector collaborations seeking to address key healthcare challenges such as dementia by sharing risk and knowledge.

15. Does the Government have the right structures in place to support the life science sector? Should the Government appoint a dedicated Life Sciences Minister?

The Government should appoint a dedicated Life Sciences Minister to drive forward the strategy, particularly given the uncertainties around Brexit and the potential threats to the UK's position as a global leader in life sciences. A dedicated minister would ensure that there are the right structures in place to support the sector, and that government bodies such as the Office for Life Sciences are effective and delivering against the strategy.

Brexit

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?

The future has new uncertainties and challenges for the research landscape. The impact of Brexit on the research community is unclear. There is understandable concern that as a net beneficiary of EU funding, the UK research field could lose significant levels of funding in the future. A recent survey of dementia researchers by Alzheimer's Research UK indicated that 60% of respondents had great concern that Brexit would result in a loss of access to EU research funding. There is uncertainty about how UK scientists can be involved in EU grant applications, and EU scientists who are currently carrying out valuable research in the UK may be concerned about their futures.

The UK currently plays a leading role in many EU research projects – for example the UK has the highest number of managing entities of any EU country within the Innovative Medicines Initiative. This demonstrates the significant leadership role and contribution of UK institutions to the broader European research landscape.

Our “Keeping Pace” report highlights the current UK dementia strength in the range and diversity of international collaborations. European collaborations represent a significant component of these relationships, and support will be needed to ensure they are maintained after Brexit. However, there are numerous collaborations that extend beyond Europe, and which potentially could be strengthened due to Brexit. Ultimately international collaborations are likely to be a key aspect of finding a treatment or cure for dementia, and as such, need to be nurtured and supported regardless of the political landscape. See Figure 1, below, for a network map illustrating the growth in collaborations between countries within UK dementia publications between 2009 and 2015.

Some 26% of academic staff in UK universities are non-UK nationals, providing essential functions within the research environment. Academic and industry employer groups have voiced serious concern over current immigration policy for non-EU citizens, particularly in light of skilled worker caps and issues within the existing visa system. The UK must support mobility for those who contribute to the advancement of science and research to maintain the UK’s world-leading environment. While there is an opportunity to address migration issues for both EU and non-EU staff in research settings, it must be achieved with minimal burden or disruption for those EU nationals already engaging in research in the UK.

Talent and expertise from outside the UK contributes to building the UK’s skills pipeline, while time spent abroad can be vital in the development and training of UK researchers who ultimately return. Retaining and attracting well qualified researchers and health professionals must be prioritised.

The UK’s decision to leave the EU provides an opportunity to re-address the immigration system. To unlock the full potential of the UK life science sector, an immigration system that recognises the collaborative nature of science and supports the thriving research and innovation base in the UK is necessary. The system must be fair, transparent and efficient, and sufficiently flexible to allow for the UK’s changing skills needs and research priorities in the years ahead.

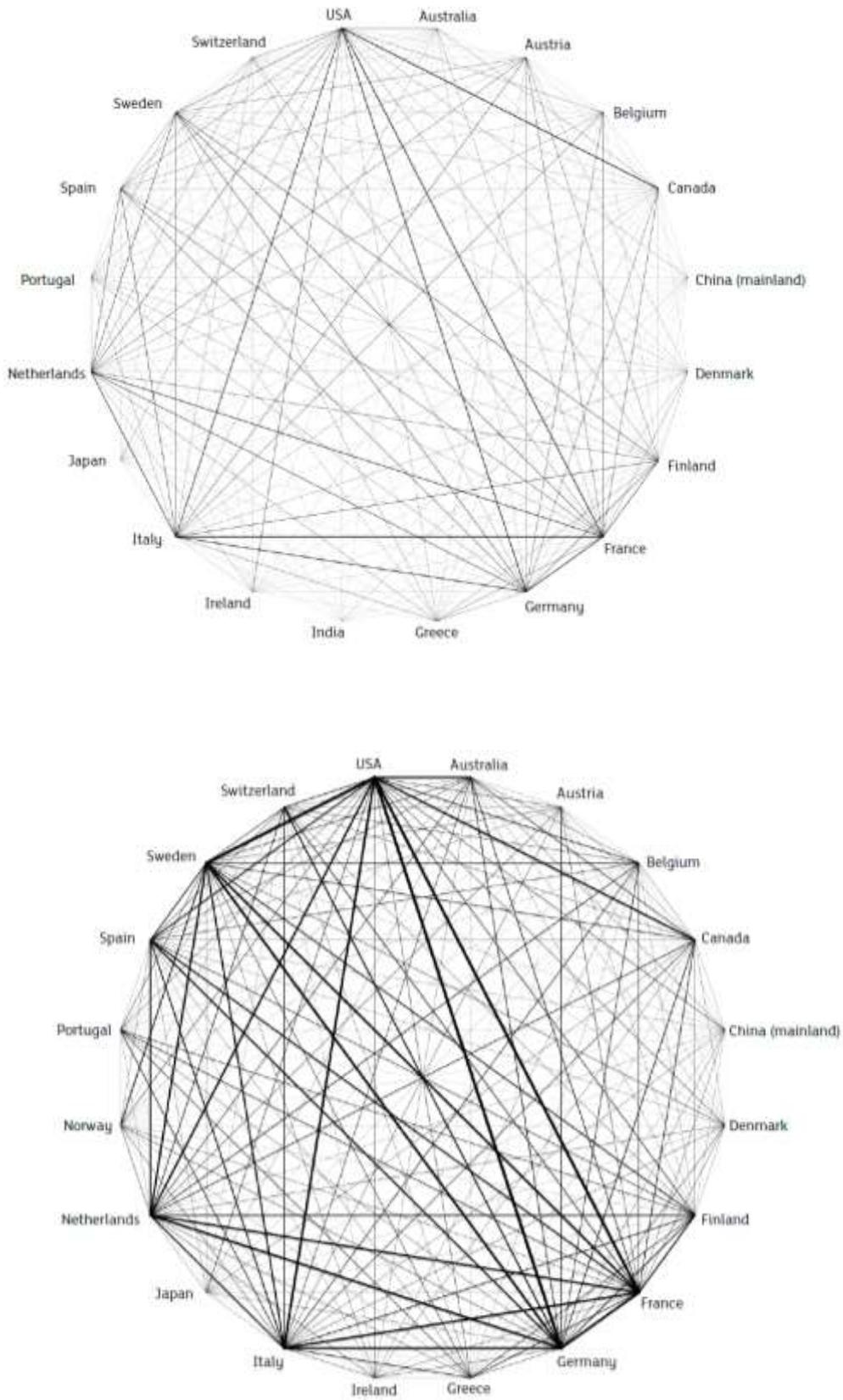


Figure 1: Network diagram of collaborations between countries within UK dementia publications in 2008-9 (top) and 2014-15 (bottom)

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

When the UK exits the EU, the Medicines and Healthcare Products Regulatory Agency (MHRA) may be able to develop accelerated regulatory frameworks for emerging and innovative areas of research. It may be helpful to review the MHRA guidance on risk management of clinical trials to enable an accelerated and innovative approach.

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

EU regulatory frameworks help build consistent research standards between countries, facilitating the exchange of ideas, research samples and data. This is particularly important in the case of rare and ultra-rare diseases – some of the diseases which cause dementia are categorised as such – where studies across multiple nations are the only way to access large enough patient groups for robust research. The availability of international data can also facilitate longitudinal research studies, which have a critical role in understanding long term conditions like dementia. The Government must ensure that a future regulatory framework facilitates international collaboration both with the EU and beyond, and allows the UK to lead international research projects such as clinical trials.

Contact Details

For further information please contact Helen Davies, Head of Public Affairs at Alzheimer's Research UK, on Helen.Davies@alzheimersresearchuk.org or 01223 896637.