Dementia Research and UK Membership to the European Union

Topic: Areas of consideration for UK membership to the EU for the dementia research environment.

This information is intended to provide issue-area expertise to inform policy development and ensure the UK remains a world leader in dementia research.

UK membership to the EU is a broadly favourable relationship for the dementia research environment across a number of important factors. Further, changes to the status quo as a result of the UK leaving the EU would be extremely disruptive of the current research environment and advances in dementia research would potentially be delayed and avenues of inquiry abandoned as a result of lost access to European research funding.

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Funding

The UK is a world leader in dementia research, funding more in the area relative to other disease areas than other EU member states.[1] However, EU funding has become an important source of support for the research environment in the UK, which enjoys a net gain in public R&D investment.[2] In the historically underfunded field of dementia research, this investment is particularly critical. Funding through just one of the strategic budget areas of the EU in 2013 produced over 20,000 publications in prominent peer-reviewed journals, including 909 in the area of neuroscience.[3]

From 2007 to 2013, the EU research investment strategy, called the "Seventh Framework Programme" (FP7), awarded €947 million to UK academic researchers; more than any other member country.[4] Horizon 2020 is the EU's framework programme for 2014 to 2020, strategically funding €80 billion in research and innovation, including an estimated €7 billion for health.

FP7 included a funding stream for brain research with a particular emphasis on the translation of basic discoveries into clinical applications. In the first three FP7 calls, 30 neuroscience projects were funded totalling €135 million. Projects ranged from basic to clinical research, including the identification of genes and molecules present in brain diseases, the pathophysiology of diseases, and the development of new therapies and diagnostic tools.[5] Research relevant to neuroscience was also funded in other health priority areas, leading to an additional €247 million dispersed to an additional 49 research projects. By comparison, UK funding for dementia research has increased rapidly in recent years, but continues to lag EU sources at £66 million (€84.4 million) annually.

Dementia researchers in the UK have been successful in leveraging significant addition investment from the EU for cutting edge dementia research projects. Some of the strategic collaborative funding from the EU research funding frameworks include:

- Prof Simon Lovestone is the co-coordinator of the €48,000,000 Innovative Medicines Initiative - European Medical Information Framework on combinatorial biomarkers for dementia prodromes, prediction, pathology and progression.

For more information on the Innovative Medicines Initiative and other EU strategic projects for dementia, please see Appendix 1.

- Prof David Allsop is investigating alpha-synuclein in plasma as a possible diagnostic marker for synucleinopathies funded by the EU-wide project NEUROSCREEN - Early, differential and progressive blood and cerebrospinal fluid test for neurodegenerative dementia – and Marie Curie Training Network NEURASYN - Alpha-synuclein-related brain diseases - worth a total of €7,570,000.

1 Alzheimer's Society Research Report. Table B3. 2015.
https://www.alzheimers.org.uk/site/scripts/download.php?type=downloads&fileID=2767
2 Seventh FP7 Monitoring Report. RESPIR data for FP7. Table 43. 2013.
http://ec.europa.eu/research/evaluations/pdf/archive/fp7_monitoring_reports/7th_fp7_monitoring_report.pdf
3 Ibid.
4 UK research and the European Union. The Royal Society. 2015.
https://royalsociety.org/~/media/policy/projects/eu-uk-funding/uk-membership-of-eu.pdf
5 European Commission. Major and Chronic Diseases. Website accessed February 2016.
http://ec.europa.eu/health/major_chronic_diseases/diseases/dementia/

- Dr Richard Wade-Martins, using a cutting-edge microscope for live cell imaging and a plate reader, secured a total of £1,252,360 from the European Commission to work on stem cells as models for biological assays of new drugs and predictive toxicology.

Even if there were net savings as a result of the UK withdrawal from the EU there is no indication that additional funds would be directed to medical research to support losses to current EU-funded projects. Further, centralised EU-level funding facilitates international collaborations and centres of excellence that are a complement to UK funding streams, but which could not be easily replaced if the UK were to sever the existing relationship.

Collaboration:

Cooperation among researchers is increasingly important in addressing major health challenges and expanding knowledge, and the EU is an important catalyst for medical research including neuroscience. As of 2011, 35% of European research publications included international collaborators[6] , but for UK dementia researchers more than 40% of publications involved at least one international contributor.[7]

Cross-border collaboration allows researchers to share new ways of working as well as important resources and techniques. Additionally, these research partnerships have been shown to increase research impact.[8] However, collaboration among scientists is further bolstered by access to the same funding streams, aligning administration and other considerations for research grants. Through the EU, UK researchers have been provided with a world-leading platform for international collaboration.

Research institutions in the UK collaborating with other EU centres of research benefit from improved measurable results as well as a straightforward collaborative relationship by working within the same funding scheme. Investment from the EU through FP7 has funded UK participation in nearly 90,000 collaborative links across the EU, in a wide range of projects[9], and this enabling has benefitted the UK dementia research environment immeasurably.

Resources for Research

Health data from across Europe, such as has been used in a number of studies investigating dementia in the EU, offers promising avenues for research. A portion of the diseases that cause dementia are rare or ultra-rare (each affecting less than 0.1% of the UK's population[10]) and the ability to study large population groups has numerous benefits. Large data sets that advanced the study of genetics and cancer have begun to unravel complex risk factors for dementia, informing public health initiatives across Europe.
The EU has prioritised addressing some of the technical, linguistic and cultural barriers that exist in research, making previously unavailable data sets and resources accessible to UK scientists. The availability of EU survey data facilitates longitudinal studies, which have a

6 Knowledge, networks and nations: Global scientific collaboration in the 21st century. The Royal Society. 2011. https://royalsociety.org/topics-policy/projects/knowledge-networks-nations/report/
7 Alzheimer's Society Research Report. 2015. https://www.alzheimers.org.uk/site/scripts/download.php?type=downloads&fileID=2767
8 Expert Group of the Interim Evaluation of Framework Programme 7. Bibliometric analysis – final report. Thomson Reuters. 2010. https://ec.europa.eu/research/evaluations/pdf/archive/fp7-evidence-base/experts_analysis/j.%20adams_-_bibliometric_analysis.pdf
9 The House of Lords Select Committee on the European Union: Internal Market, Infrastructure and Employment Sub-Committee Inquiry into the Effectiveness of EU Research and Innovation Proposals Evidence from The Russell Group of Universities. The Russell Group. 2013. https://www.russellgroup.ac.uk/media/5062/25hol-eu-select-inquiry-into-eu-research-and-innovation-evidence-from-the-russell-group-11-february.pdf

critical role in understanding long term conditions like dementia. Access to clinical trial data is necessary for meta-analyses and ensuring the validity of findings, and for over 10 years all clinical trials conducted in member states of the EU have been registered in the EudraCT database and monitored by the European Medicines Agency. Several initiatives to improve data sharing are currently underway, with some receiving EU funding, including multilingual platforms and data archives, and several European datasets that are used for health research have developed methods for sharing access among researchers. While alternative data sets and population groups exist outside of the EU, there would be a period of disruption to the medical research environment as a whole, including researchers studying dementia, if researchers were to no longer be able to access EU resources of this type.

In instances of dementia research where cell, blood and tissue samples, or animal models are necessary, the EU enforces minimum standards for regulation across member states and allows for a streamlined process for acquisition and transport. Studies employing cells and brain tissue make up a significant portion of dementia research, and logistic considerations for research materials impact the cost and feasibility of research. EU regulation in this area has supported a high standard of processing for these materials, as well as reducing the barriers to access for researchers, making the EU a preferable market to non-EU countries. Changes to the existing collaboration between tissue authorities in the UK and the rest of the EU would likely have immediate impact on current research projects, as well as long term effects on cost and viability.

The UK also benefits from Europe-wide information sharing on the management of dementia from a public health perspective. The EuroCoDe project (European Collaboration on Dementia), coordinated by Alzheimer Europe, gathered information on dementia prevalence, diagnosis and treatment from across the EU[11]. This critical information gathering supports knowledge and best practice for health services for people currently living with dementia, including those in the UK.

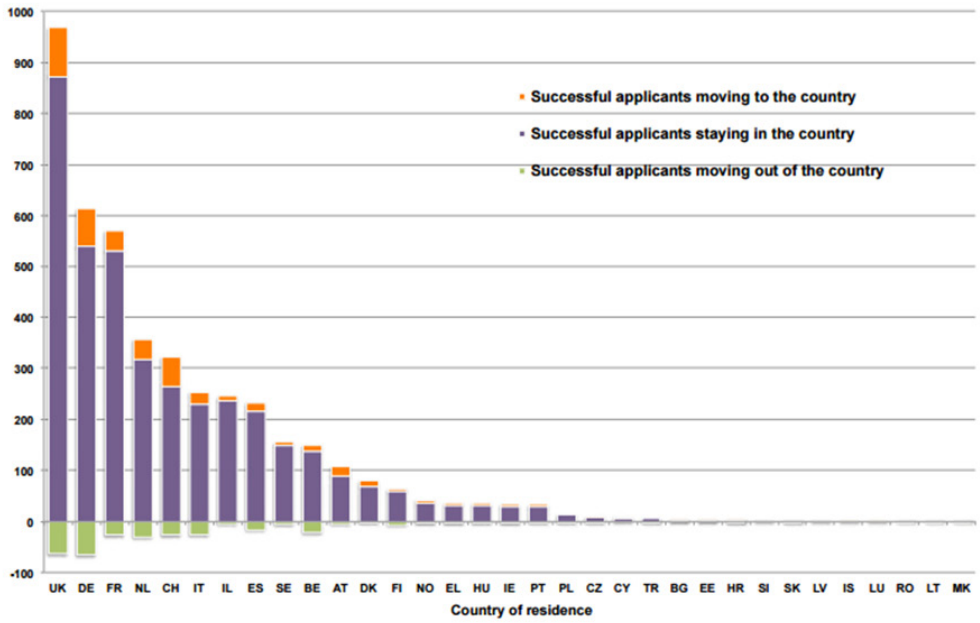
People in Science

People are key to the success of research, and the movement within the EU has attracted some of the most talented and innovative researchers to the UK, particularly in areas where the UK has world-leading research, like dementia. By volume, the UK attracts the largest number of EU-funded researchers coming from other EU member states.[12]

The freedom to recruit scientists from across the EU strengthens the quality of research institutions across the UK. Similarly, UK scientists are particularly competitive for positions at leading research institutions in Europe over non-EU applicants.

10 The UK Strategy for Rare Diseases. Department of Health. 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260562/UK_Strategy_for_Rare_Diseases.pdf
11 2006-2008: European Collaboration on Dementia (EuroCoDe). Alzheimer's Europe. Website accessed February 2016. http://www.alzheimer-europe.org/Alzheimer-Europe/Our-work/Completed-projects/2006-2008-EuroCoDe
12 Annual Report on the ERC activities and achievements in 2014. European Commission. 2015. https://erc.europa.eu/sites/default/files/publication/files/erc_annual_report_2014.pdf

Distribution of European Research Council grants by country of residence in 2014[13]



Some 26% of academic staff in UK universities are non-UK nationals,[14] filling 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. Extending these issues to include the current EU workforce within the UK would have wide-ranging implications for the research sector and negatively impact the small dementia research field.

Regulation

One of the most compelling aspects of EU membership for the UK is pharmaceutical market access and harmonisation in regulation. It enables research to move to business applications, such as drug development, avoiding delays, potentially prohibitive costs and duplicative efforts to satisfy a range of regulatory environments.

For the biomedical industry, the UK is only 3% of the global market, whereas Europe is the largest single global market.[15] The EMA collaborates closely with MHRA in conversation with other regulators around the world to support advancing treatments for dementia. However, the EMA is positioned to take forward conditional licensing and parallel review processes alongside the US Food and Drug Administration that would bring increased efficiency to the European market, making licensing authorisation attractive to industry.

13 Ibid. Figure 3.8
14 Immigration: Keeping the UK at the heart of global science and engineering. Campaign for Science and Engineering. 2016. http://www.sciencecampaign.org.uk/caseimmigrationreport2016.pdf
15 EU Impact on Life Sciences. Fresh Start Project Inquiry with George Freeman MP. 2014. http://www.eufreshstart.org/downloads/lifesciences2.pdf

Treatments for dementia are still in the development stage, but drug development experts and others in the field anticipate specific challenges for the licensing and uptake of the first generation of disease-modifying treatments because of the expense and difficulty in showing efficacy. Delay and expense in accessing treatments could be caused by a departure from the EU that separates the UK Medicines and Healthcare products Regulatory Agency from the close working relationship it maintains with the EMA.

Influence in the EU

The world-leading research taking place in the UK has occurred within the legislative framework of the EU, rather than in spite of it. However, where potentially detrimental legislation has been considered, the UK has effectively influenced the direction of EU policy.

Following complications to the conducting of clinical trials in Europe after the implementation of the Clinical Trials Directive (2001/20/EC) was approved in 2001, stakeholders in the UK successfully contributed to the development of a new Clinical Trials Regulation (EU No 536/2014.) This new piece of legislation, coming into effect in May 2016, streamlines the application process and harmonises the assessment criteria among member states, including deadlines. Researchers in the UK supported the changes to overcome the bureaucratic barriers that had a detrimental impact on clinical trials, and their concerns were addressed through the EU legislative process.

Medical research charities in the UK successfully raised concerns regarding proposed data protection regulations from 2012, ensuring that health data remains available for research purposes. Similarly, efforts in the EU to ban the use of animals in medical research have been countered by the UK medical research community with the dissemination of accurate information to EU policy makers that both highlights the necessity of some research on animals, the benefits to medical and veterinary research, and the standards of good practice in the UK recommended for adoption across the EU. The use of health data and animal models have important implications for dementia research, where the slow progression of diseases in the brain present unique and difficult challenges to the development of treatments. In both cases, the UK has been a leader in good policy and been effective in influencing EU regulation to responsibly support the dementia research environment.

Appendix 1: EU initiatives and programs of note for dementia research

Innovative Medicines Initiative (IMI) Alzheimer's Disease Platform

The cross-border approach of the EU's Innovative Medicines Initiative (IMI), Europe's largest public-private partnership, has been the foundation for a multi-strand focus on Alzheimer's disease. The IMI Alzheimer's Disease Platform is working to deliver clinical proof of concept in neurodegenerative diseases in five years, working closely to support the UK Dementias Platform and other initiatives that will drive forward the development of treatments. Half of the IMI budget comes from the Horizon 2020 EU funding framework, which is channelled alongside industry resources (e.g. researcher time or facilities) to support novel projects like the development of adaptive clinical trial approaches for Alzheimer's disease. For drug development across disease areas, and for dementia in particular, the IMI positions the UK as an international hub for research.

European Prevention of Alzheimer's Dementia Initiative (EPAD)

EPAD involves 35 partners from the academic and private sectors and has been funded largely through the EU for an initial period of five years. It will establish a European-wide cohort of 24,000 people deemed at high risk of developing dementia, studying the presence of biomarkers to investigate the earliest stages of the condition, and enrolling candidates in trials of preventative interventions. This project is led be researchers at the the University of Edinburgh and involves partners from the Universities of Cambridge, Leicester, Oxford and Cardiff. The discoveries made as a result of EPAD will drive progress in the dementia research field, reinforcing the global leadership of the UK in this area.

Marie Skłodowska-Curie actions (MSCA)

This EU grant program provides grants is open to researchers at any career stage to encourage "transnational, intersectoral and interdisciplinary mobility." The program is specifically tailored to support researchers seeking to work in foreign countries and to facilitate staff and knowledge exchanges among research bodies.