The Academy of Medical Sciences

Response to Royal Society and Wellcome Trust consultation for the "Future Partnership Project"

January 2018

Introduction

The Academy of Medical Sciences promotes advances in medical science, and works to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost medical science experts drawn from academia and industry. This submission is informed by the expertise of our Fellowship and elements have been adapted from our previous work, including submissions to relevant Select Committee inquiries and joint work with the Wellcome Trust on EU Regulation of Research and Innovation.

Elements which underpin a successful partnership

The most successful models of collaboration are those which are driven by shared scientific interests and objectives. This "bottom up" approach supports the involvement of best people to deliver a project. Successful collaborations are built on mutual trust and respect between research partners which is best achieved by a self-organising approach.

This does not, however, preclude appropriate intervention by Governments and other actors. For example, it is the role of these organisations to create the conditions that facilitate collaborative and productive relationships. This can include a range of policies and practices, from immigration systems which support movement of researchers and their dependants, to the creation of collaborative partnerships, which bring together individuals to discover shared scientific interests. These facilitating factors, with specific examples where appropriate, are explored in more detail below.

Ease of movement of research personnel

A key facilitator of international collaboration is the ease of movement of researchers between participating countries. This must encompass researchers at all levels and career stages, from established world-leaders to early career researchers, PhD students as well as technicians and support staff. It must allow for short term visits between collaborators, secondments and placements, and long-term or permanent relocation. Whilst productive collaborations and scientific relationships do not necessarily require long-term residency, a permissive immigration system must form part of a concerted approach to ensure that the UK remains, and is seen to remain, open to researchers from both within and outside the EU. This must also include wider environmental factors such as access to healthcare and education systems.

A fair, transparent and efficient immigration system is required not only to support academic research, but also the highly international workforces of research-intensive private companies.

Alongside an appropriate immigration system, funding which supports movement of researchers at different stages of their career can have transformative effects, particularly on early career researchers. These opportunities can expose individuals to different research cultures, practices and ideas and can drive the establishment of lifelong collaborations. Existing EU programmes funded by the Marie Skłodowska-Curie actions (MCSA) such as Individual Fellowships and Innovative Training Networks

represent some of the most productive examples of these schemes.[1] UK-based researchers have been highly successful in securing these awards in recent years, for example UK universities host the highest number of Marie Skłodowska-Curie fellows.[2] Continued access to these or similar schemes should form part of the future partnership.

Funding and infrastructure that is accessible to all partners on equal terms
International research collaborations are supported by mutually accessible funding streams. EU Framework Programme funding facilitates a range of activities which cannot be supported at a national level, these include funding for multinational consortia, such as through the Future and Emerging Technologies programmes or the European Research Council (ERC), through its Synergy Grants, which support joint bids from between 2 and 4 Principal Investigators.[3,4] Schemes such as the Innovative Medicines Initiative (IMI) link academia and industry. IMI provides access to expertise of over 7,000 researchers across Europe and 55 public-private consortia, facilitating access to regulatory bodies, associations and patient organisations from around Europe. It would be challenging to replicate these examples on a national scale.

Alongside these consortia, ERC grants now provide a significant proportion of the individual grants awarded to UK-based researchers and are firmly established as an important stream of funding for UK researchers.[5] ERC grants provide important support at different career stages through Starting, Consolidator and Advanced grants. Recipients of these grants are able to recover up to 100% salary, providing increased flexibility for their recipients. In addition, Academy Fellows believe that these awards provide an important marker of international excellence that cannot be matched by national funding sources.

The Academy believes that the UK should seek to attain the closest possible relationship with future EU Framework Programmes, as an essential component for securing successful future partnerships with EU27. A clear commitment from the UK that we wish to continue to participate in EU Framework Programmes must be accompanied by ongoing financial commitments. The Government's pledge for financial contributions that will cover the continued participation in the remainder of Horizon 2020 is welcome, although certain existing programmes, such as IMI, extend beyond this date. There must be a seamless transition into the future partnership such that existing collaborations are not jeopardised or negatively affected by any period of uncertainty.

The future involvement of the UK in EU Framework Programmes should include the continued ability of UK-based researchers to participate on equal terms, including the ability to lead and shape specific programmes. At present, the UK is an attractive research partner due to its excellent research base and research infrastructure. This is enhanced by the ability of UK researchers to fully participate in EU framework programmes. Erosion of this ability to participate would be detrimental to the attractiveness of the UK as a research partner. As stated in the report of the European Commission's High Level Group on maximising the impact of EU Research & Innovation

[1] https://ec.europa.eu/research/mariecurieactions/about_en
[2] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033
[3] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/future-and-emerging-technologies
[4] https://erc.europa.eu/funding/synergy-grants
[5] Technopolis (2017). The role of EU funding in UK research and innovation https://acmedsci.ac.uk/file-download/70343877

Programmes, "Lab-Fab-App", the "full and continued engagement with the UK within the post-2020 EU R&I programme remains an obvious win-win for the UK and the EU".[6]

In addition, a future partnership should provide ongoing access to shared EU infrastructure. For example, European Research Infrastructure Consortium (ERIC), provide a special legal status to facilitate shared research infrastructures. At present 14 ERICs exist, including the Biobanking and biomolecular resources research infrastructure (BBMRI) ERIC, which pulls together biobanks from around the EU into a pan-European facility. This allows access to collections of partner biobanks and biomolecular resources, as well as their expertise and services.[7] UK access to existing ERICs should be protected and provisions made to consider participation in future consortia.

Harmonised Regulation

A continued close relationship in research and innovation will be greatly facilitated by regulatory alignment with existing EU regulations. The UK has employed a science-led, risk-proportionate approach to earn public confidence in the regulation of research and innovation. By employing this approach the UK has successfully promoted better research regulation in the UK and EU. Following EU exit, the UK's ability to influence future EU regulation will be diminished. However, the future partnership between the UK and EU27 should place a value on harmonisation to existing and incoming regulation. Regulatory divergence in the future, where deemed appropriate by the UK, would not be precluded by this broad approach.

At present clarity is urgently required for those operating under existing regulations, particularly within clinical research and the pharmaceutical sector. Illustrative examples of how this should be achieved are provided below.

Use of animals in research

Shared regulations for the use of animals in research, as governed by the EU Directive 2010/63 and implemented in the UK through the Animals (Scientific Procedures) Act (ASPA) 1986 Amendment Regulations 2012 have provided a common framework for research using animals across the EU. This harmonisation has raised the required standards of welfare across the EU, facilitating pan-European collaboration and enhancing the attractiveness of the UK for commercial research involving animals.

The UK should maintain the existing standards to protect animal welfare, ensure public support and permit collaborative research. In the longer term, ASPA must keep up to date with emerging science, and the UK's relationship to EU regulation should be monitored to allow the UK to diverge at a point in the future if necessary.

Clinical trials

The UK coordinates the third highest number of pan-European clinical trials and the highest number for rare and childhood diseases.[8] This collaboration is supported by harmonised frameworks for conducting multinational trials. As therapeutic interventions become increasingly targeted to individuals, research must be based on smaller patient cohorts making international collaboration essential. Thus, collaboration is not only

[6]High Level Group on maximising the impact of EU Research & Innovation Programmes (2017) LAB – FAB – APP, Investing in the European future we want https://ec.europa.eu/research/evaluations/pdf/archive/other_reports_studies_and_documents/hlg_2017_report.pdf

[7] http://www.bbmri-eric.eu/BBMRI-ERIC/about-us/

[8] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033

important for patients with rare diseases, but for patients across Europe. Therefore, harmonisation to the incoming EU Clinical Trials Regulation and access to the portal that it will create should be prioritised by the UK.

Licencing of medicines, medical devices and in vitro diagnostics
The European Medicines Agency (EMA) is able to issue a single approval licencing a product across the EU. This approval from the EMA provides access to approximately 25% of the global pharmaceutical market. The UK alone represents approximately 3% of the global market. Nevertheless, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) provides substantial support to the EMA, acting as Scientific Advice Co-ordinator in at least 20% of EMA medicine approvals and conducting a substantial amount of work in inspection and enforcement standards on behalf of the EMA.[9] Continued collaboration between the two agencies would be mutually beneficial.

Alongside the licensing of new drugs, the EMA also conducts post-marketing efficacy and pharmacovigilance studies across the EU. For example, the agency coordinates pharmacovigilance data from 28 member states through its EudraVigilance database. The UK has robust data collection which adds significant value to the data captured in this database. Recent trends to accelerate approval regimes, have seen innovative medicines enter the market at earlier stages in their development. These innovative licensing schemes further necessitate the need for evaluation of risk-benefit profiles on the basis of much smaller clinical trial data. Therefore, the rigorous collection, monitoring, and evaluation of post-licensing safety and efficacy data becomes increasingly important.[10] This is best conducted at an international level and is currently facilitated by the EMA.

New EU legislation to regulate medical devices and In vitro diagnostics (IVD) will come into force in 2020 and 2022 respectively. This legislation represents an improvement on existing regulation, providing a more robust regulatory framework for devices, including more emphasis on evidence generation around their effectiveness. There is strong support in the sector for maintenance of regulatory alignment for devices between the UK and EU. A survey by the Association of British Healthcare Industries found that only 3% of members who responded supported regulatory divergence with the EU.[11]

In addition, continuity in the CE marking system will ensure that products developed in the UK continue to be recognised in the EU and around the globe, and that products developed in the EU can continue to be recognised in the UK. This is important to maintain NHS patient access to innovative devices, and facilitate access for UK device companies to the EU and broader market. The system of Notified Bodies granting CE marks should therefore be maintained and mutual recognition of the existing UK Notified Bodies should be explored.

Challenges

Securing UK participation in future EU Framework Programmes will be subject to certain tensions, in particular the adherence to the principle of freedom of movement. It is promising that the recently published Lab-Fab-App report, called for future framework

[9] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033
[10] EL Jackson, P Feldschreiber, and A Breckenridge (2017), Regulatory Consequences of "Brexit" for the Development of Medicinal Products. Clinical Pharmacology and therapeutics, Vol. 102, no. 2
[11] http://www.abhi.org.uk/membership/members-area/updates/2017/july/impact-of-brexit-2017-member-survey-results/

programmes to be "open to the world", by opening association to the best and participation to all. [12] A globally facing Framework Programme 9 should allow full and continued participation of the UK.

Whilst it is likely that the ability of the UK to formally influence future research programmes will be diminished from outside the EU, active UK participation through non-governmental channels must continue. This should include contact through specialist societies, Academies and European umbrella bodies, such as the Federation of European Academies of Medicine.

Recent announcements have provided welcome clarity that the jurisdiction of the European Courts of Justice will continue during the implementation period. This is absolutely necessary to provide time to adapt to future arrangements. However, the transition period will only be useful if the future requirements are established early on in the negotiations. For example, in the pharmaceuticals sector uncertainty around the mutual recognition of qualified persons in batch testing of medicines is driving organisations to invest in facilities outside the UK. This is necessary to ensure that medicines manufactured in the UK can continue to be sold within the EU in the event that mutual recognition of qualified persons is not achieved. This would not be a desirable outcome, but indicates that pharmaceutical companies are being forced to make decisions in the absence of clarity on future relationship to ensure secure supply chains in the long-term.

Additionally, regulatory harmonisation will depend not only on enshrining of EU standards in UK law through the EU (withdrawal) bill, but the ongoing relationship with the relevant EU bodies and agencies, such as the EMA, the European Chemicals Agency and ultimately the European Courts of Justice. A pragmatic solution must be found enabling, for example, the MHRA to operate as a sovereign regulator, whilst maintaining an ongoing relationship and equivalence with the EMA. The recent concessions over citizen's rights and the ability to make technical referrals to the ECJ may offer a potential model.

Finally, the UK and EU negotiators might consider placing scientific collaboration and a shared research and innovation partnership at the forefront of negotiations. This mutually beneficial outcome would achieve an optimal outcome for research, innovation and patients across Europe as well, perhaps, as paving the way for a productive future partnership in other areas.

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[12] High Level Group on maximising the impact of EU Research & Innovation Programmes (2017) LAB – FAB – APP, Investing in the European future we want https://ec.europa.eu/research/evaluations/pdf/archive/other_reports_studies_and_documents/hlg_2017_report.pdf