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Summary

- The Academy of Medical Sciences believes that leaving the EU without a deal would be an extremely poor outcome for medical research and patients.
- The UK's scientific excellence is fundamental to our nation's health and wealth, and has benefitted from decades of close engagement with European research programmes and infrastructure. A "no deal" outcome would halt this relationship in its tracks, jeopardising crucial research collaborations and clinical trials and access to vital funding.
- Furthermore, our relationship with EU disease monitoring systems would be weakened and our participation in rare-disease networks would end.
- The UK's scientific workforce is highly international and mobile. It is a prized asset in the global competition for talent. There is a grave risk that EU nationals and others may choose to leave in the wake of a "no-deal" scenario.
- In the event of a "no deal", and in the absence of an implementation period, we do not believe that the necessary changes to the existing immigration system could be implemented in time to respond to the estimated trebling of the number of researcher visas that would need to be issued.
- The combined effect of this could be a talent deficit that could disadvantage the country for years to come.
- The UK Government has made welcome commitments for the continuity of funding UK researchers are entitled to up until EU exit. However, we have not yet seen confirmation from HM Treasury that funding will be available to cover all the necessary contingency arrangements if the UK were to lose access to the European Research Council and the Marie- Skłodowska-Curie Actions.
- The Academy of Medical Sciences believes that the UK research and innovation community would be best served by the closest possible association with the EU's next Framework Programme, Horizon Europe. We are concerned that leaving the EU without a deal would make this goal significantly harder to achieve.
- The MHRA has made pragmatic plans for the continuity of clinical trials where the legal sponsor is outside the UK, however we remain concerned that currently active clinical trials with a UK sponsor will be impacted in the event of a no-deal.

Introduction

1. 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.

2. The Academy, alongside the wider research and innovation community, has consistently raised our grave concerns regarding the threat of leaving the EU without a ratified Withdrawal Agreement.^{1,2,3,4}
3. The Academy views the key risks of a “no-deal” exit from the EU falling under three themes, loss of researchers; access to collaboration and funding; and barriers to clinical trials and research into rare diseases.

Loss of researchers from UK

1. UK medical research relies on the expertise of its global workforce. Almost 1 in 6 academic staff at UK universities in the disciplines of medicine, dentistry and health are EU-27 nationals.⁵
2. In December 2018, the UK Government confirmed that in a no-deal scenario a similar procedure for granting permanent residency would be put in place in the event of a “no-deal” Brexit.⁶ The subsequent announcement that the UK Government will waive the administration fee, removing any financial impediment to the right of EU citizens to remain in the UK, is welcome.⁷
3. However, these commitments would not include a transition period until December 2020.⁸ The Government’s Immigration White Paper lays out proposals for a future skills-based immigration system, however this system is not expected to be ready until after the planned implementation period.⁹
4. In the absence of an alternative system, we estimate that bringing EEA nationals in line with the rest of the world could treble the number of science and research visas being issued annually. It is not clear that the existing system and universities and businesses are equipped for this increased burden.¹⁰
5. We believe that this may have a negative impact on the ability of the UK to attract and the non-UK researchers that make such an important contribution to the UK’s excellence in science and innovation.
6. In addition, a no-deal exit may compromise the position of UK researchers in EU Member States.

¹ <https://acmedsci.ac.uk/more/news/no-deal-brexit-jeopardises-uk-medical-research>

² <https://royalsociety.org/~media/policy/Publications/2018/royal-society-brexit-no-deal-factsheet.pdf>

³ <https://russellgroup.ac.uk/news/warning-against-no-deal-brexit/>

⁴ <https://www.independent.co.uk/voices/letters/brexit-second-referendum-final-say-no-deal-theresa-may-a8732561.html>

⁵ <https://www.hesa.ac.uk/data-and-analysis/staff/cost-centres>

⁶ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762222/Policy_paper_on_citizens_rights_in_the_event_of_a_no_deal_Brexit.pdf

⁷ <https://hansard.parliament.uk/commons/2019-01-21/debates/0FBF8F8F-E4B4-47A2-BD0A-958EFC89BD7E/LeavingTheEU>

⁸ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762222/Policy_paper_on_citizens_rights_in_the_event_of_a_no_deal_Brexit.pdf

⁹ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/766465/The-UKs-future-skills-based-immigration-system-print-ready.pdf

¹⁰ <https://acmedsci.ac.uk/file-download/23154179>

7. The European Commission has encouraged Member States to “take a generous approach to the rights of UK citizens in the EU” however there is no legal certainty that they will be uniformly adopted by Member States.¹¹
8. In her Statement to House on 21 January, the Prime Minister noted that some EU Member States have confirmed reciprocal rights for UK citizens. The UK Government must ensure that efforts to extend these commitments to all EU Member States so that the rights of the many UK researchers living and working in the EU-27 are protected.

Disruption to productive collaborations and loss of access to funding

Collaboration

9. The EU has been uniquely supportive of multilateral collaboration, with the UK leading and participating in the major research projects that are needed to tackle the greatest challenges to society.
10. These collaboration are put in significant jeopardy by leaving the EU without a framework for our future research collaboration with Europe. For example, we are concerned that the resultant impediment to the transfer of patient data within health studies between researchers in the EU and UK will inhibit collaborative research.¹²

Funding

11. Leaving the EU without a deal will immediately exclude UK researchers from applying for prestigious and lucrative European Research Council (ERC) and Marie Skłodowska-Curie Actions (MSCA) awards.
12. In 2016 alone, UK researchers in the life sciences won over £85 million in funding from the ERC.¹³ Between 2014 and June 2018, MSCA awards enabled over 800 of the most promising researchers in the medical and life sciences from around the globe to come to UK institutions.¹⁴
13. However, the value of the ERC and MSCA to the UK research effort is not simply financial. In order to win EU funding from the prestigious ERC, UK-based researchers must compete against international researchers from across the MS and associated countries. This international competition drives up standards and provides an opportunity for UK-based researchers to benchmark themselves against the best in Europe.
14. In addition, ERC grants provide awardees with flexibility to be mobile as they can move with the recipient between institutions in MS/associated countries. Between 2007 and 2016, the UK was the most popular destination for ERC awardees to move to (with 20% of all researchers that moved countries coming to UK).¹⁵

¹¹ http://europa.eu/rapid/press-release_IP-18-6851_en.htm

¹² <https://www.gov.uk/government/publications/data-protection-if-theres-no-brexit-deal/data-protection-if-theres-no-brexit-deal>

¹³ <https://erc.europa.eu/projects-figures/erc-funded-projects>

¹⁴ https://ec.europa.eu/research/mariecurieactions/sites/mariecurie2/files/msca-country-profile-unitedkingdom-2018_en.pdf

¹⁵ <https://acmedsci.ac.uk/file-download/32381033>

15. Meanwhile the Marie Skłodowska-Curie Actions (MSCA) provide access to training support for researchers at all career stages.
16. The MSCA Individual Fellowships support the most promising individual researchers from anywhere in the world to undertake research in an institution in any MS/associated country. These awards are highly prestigious and competitive. Successful applicants have flexibility in choosing where to conduct their research and at present the UK is the top destination for MSCA fellows, with around 11% of the awardees in FP7 choosing to work in the UK. Five UK institutions were among the top 10 in terms of the number of MSCA fellowships under FP7.¹⁶ These MSCA fellowships draw excellent global talent to the UK, as well as allowing UK researchers to further their careers in other MS/associated countries.
17. MSCA Innovative Training Networks (ITNs) support joint research training and/or doctoral programmes that are conducted in partnerships of universities, research institutions, and non-academic organisations in Member State (MS)/associated countries. Participation can have an important added benefit building international cohorts of early-career researchers.
18. MSCA Research and Innovation Staff Exchange (RISE) supports exchange of research and technical staff employed in MS/associated countries.¹⁷ These exchanges may take place between MS/associated countries as well as a number of non-EU/non-Associated Countries. This programme has been particularly highlighted as a means of supporting global networks of rare disease research within the EU and beyond its borders
19. Furthermore, leaving the EU without a deal may inhibit the ability of the UK in securing an association agreement to Horizon Europe, the EU's next major research programme.

Barriers to clinical trials and research into rare diseases

20. All clinical trials taking place in the EU must have a legal representative in a Member State. In the absence of a deal, any pan-European trial that is currently underway, and where this legal sponsor is located in the UK, would be required to appoint a new legal sponsor inside the EU-27 by March 2019.¹⁸ This would pose a significant challenge to hundreds of currently active trials, causing delays and potentially disrupting the care of the significant number of patients taking part in the research. This requirement would have negative effects on the ability of the UK to lead pan-European clinical trials until any new regulations come into effect.

European Reference Networks

21. Rare diseases, of which there are an estimated 6000 to 8000, may affect up to 30 million people in the EU. These conditions often lack means for diagnosis and therapy. This is largely due to small and dispersed patient populations and fragmented research expertise.

¹⁶ <https://acmedsci.ac.uk/file-download/32381033>

¹⁷ https://ec.europa.eu/research/mariecurieactions/actions/get-funding/research-and-innovation-staff-exchange_en

¹⁸ https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante

22. Pan-EU support has been instrumental in coordinating rare disease research through the formation of the European Reference Networks (ERNs).¹⁹ ERNs bring together experts to address the unmet health needs and are funded by a several EU funding programmes, including the Health Programme, the Connecting Europe Facility and Horizon 2020. The networks have had a major effect on research and care by linking thematic expert centres across the EU.
23. Leaving without a deal could restrict UK access to essential clinical platforms for dealing with rare diseases, and would preclude UK institutions from applying for funding for these networks.^{20, 21}
24. The Academy considers that rare disease research in the UK, and the EU, would be negatively affected by a reduction of UK participation in the Framework Programmes. This would ultimately impact directly on outcomes for patients with rare diseases.

European Centre for Disease Control

25. The European Centre for Disease Control (ECDC)'s is an agency of the European Union and its main role is to strengthen Europe's defences against communicable diseases.²² The data collected also provides an important resource to understand the spread of communicable diseases. Membership is limited to EU Member States, with EEA States acting as Observers.
26. In the event of a no-deal exit, the UK's membership of the ECDC would end reducing data exchange between UK and European health protection agencies and researchers. This will negatively affect research into disease prevention, and, importantly, impact on the effectiveness of disease control across borders.

Government and non-departmental public bodies no-deal preparations

Funding

27. In the event of a "no-deal" exit, HM Treasury committed the funds to cover committed to underwrite Horizon 2020 funding for all successful UK bids submitted before exit. This guarantee has also been extended to cover UK participation in all Horizon 2020 calls open to third country participants from the date of exit to the end of the programme.²³
28. In addition to these guarantees, the Department for Business, Energy and Industrial Strategy (BEIS) have recognised that further measures would be necessary to compensate for the loss of access to ERC, MSCA and the SME instrument in the event of a no-deal exit.²⁴ We have not yet seen confirmation from HM Treasury that funding has been allocated to cover these measures. We believe that clarity must be provided at the earliest possible opportunity that the funding to cover these contingency plans will be made available if required.

¹⁹ https://ec.europa.eu/health/ern_en

²⁰ Specifically from the 3rd European Health Programme http://ec.europa.eu/chafea/health/annual-work-plan-2018_en.html

²¹ https://ec.europa.eu/health/sites/health/files/programme/docs/wp2018_annex_en.pdf

²² <https://ecdc.europa.eu/en/about-us/ecdcs-mission-and-main-activities>

²³ <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-07-24/HCWS926/>

²⁴ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/766510/horizon-2020-government-overview-december-2018-update.pdf

29. Together with the other National Academies and UKRI, the Academy of Medical Sciences has engaged with the BEIS on contingency planning with regard to both Horizon 2020 and Horizon Europe – all the time emphasising the strongest preference for the closest possible association with Horizon Europe.

MHRA and clinical trials

30. The MHRA have proactively consulted on no-deal preparations, holding an open consultation on proposals relating to the regulations of clinical trials, access to Investigative Medicinal Products (IMPs) and a range of other issues.
31. The Academy supports the MHRA's proposed approach for the sponsor or legal representative to be established in the UK or a designated country. We are pleased that the MHRA will not require an additional legal representative to be located in the UK as long as a representative is located in a designated state.
32. This pragmatic approach should minimise the administrative burden for trials which are currently underway in the UK, but where the sponsor or legal representative are located outside of the UK.
33. However, we are concerned that this arrangement is currently not reciprocal and that the multinational trials where the legal representative are located in the UK, will be required to appoint a new legal representative in an EU Member State by exit day.
34. It is not clear that these trials would be able to continue as some trials, particularly those with charitable sponsors or academic sponsors, may find it challenging to appoint an alternative sponsor in an EU Member States before 29 March.

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