
The impact of the vote to leave the EU

Position Statement from
The Institute of Cancer Research, London

Summary

The Institute of Cancer Research (ICR) believes that the UK's planned departure from the EU risks causing serious damage to this country's position as a world leader in science and the ability of our researchers to work collaboratively with colleagues across Europe. It is essential that the Government secures a deal that keeps the UK's regulatory frameworks for science, and especially for clinical trials and drug licensing, aligned with the EU. Otherwise, Brexit is likely to prove a significant barrier to the ability of the UK's researchers to collaborate in clinical trials, and for our patients to access the latest cancer treatments. It is vital to maintain an immigration system that allows us to continue to attract and retain the brightest and best scientists from the EU and elsewhere, so that the UK can continue to be at the forefront of research into cancer.

Updated April 2019

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Background

On 24 June 2016, citizens of the UK voted to leave the EU by 52 per cent to 48 per cent. On 29 March 2017, the UK submitted its intention to withdraw from the EU via Article 50 of the Treaty on European Union. The UK was due to leave the EU on 29 March 2019 but the proposed withdrawal agreement reached between the EU and UK was rejected three times by UK MPs. EU leaders agreed to extend the Article 50 process further until 31 October.

It is still unclear exactly what the UK's vote to leave the EU will mean for UK science, but there are likely to be serious implications for the ICR's work and for cancer patients.

The UK operates under EU frameworks in many areas of science, innovation and drug access. While some of these regulations can be bureaucratic, operating under European-wide frameworks has many advantages for UK science. It reduces the regulatory barriers to working across European borders, and provides an attractive single market for drug licensing.

In September 2017, the Government published a policy paper¹ outlining the UK's objectives for a science and innovation agreement with the EU. It outlined issues that need to be addressed as part of an exit deal including collaboration, movement of skilled researchers and membership of EU agencies.

The Government's Brexit White Paper² was published in July 2018 and sets out its vision for the UK's new relationship with the EU including building a close partnership on data, science and innovation. It proposes that the future relationship provides for UK participation in EU research funding programmes, enables continued cooperation through joint participation in networks, infrastructure, policies and agencies, and establishes channels for regular dialogue between regulators, researchers and experts.

However, none of these proposals have yet been agreed, and as we move towards the UK's withdrawal from the EU, there is still much uncertainty over what the new relationship will look like.

In August 2018, the Government published a large number of documents on preparations for a no-deal Brexit, including outline regulatory procedures for clinical trials, drugs and medical devices. The Government has asked pharmaceutical companies to stockpile an extra six weeks of medicine supplies, and said the UK would seek to quickly align with the new EU Clinical Trials Regulation, and that the Medicines and Healthcare Products Regulatory Agency (MHRA) would take on all UK drug approvals.

¹ <https://www.gov.uk/government/publications/collaboration-on-science-and-innovation-a-future-partnership-paper>

² https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725288/The_future_relationship_between_the_United_Kingdom_and_the_European_Union.pdf

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Key ICR positions

- The ICR believes the uncertainty over the future relationship with the EU is damaging for UK science and unsettling for patients and their doctors. It's essential that the Government secures firm commitments for science and healthcare as soon as possible. A deal should avoid negative impacts on recruitment and collaboration in research, and allow patients to be able to benefit from research by continuing to access new treatments and clinical trials.
- While we welcome the fact that planning is under way to prepare for a no-deal Brexit, we believe such an outcome could be extremely damaging to UK research and patients. We believe the Government must do all it can to avoid such an outcome.

Collaboration

- It is critical that UK researchers can still collaborate freely with colleagues across the EU after Brexit. The biggest challenges in cancer research will only be met by scientists and clinicians working together in collaboration. The UK must closely align with regulatory frameworks across the EU, to avoid barriers to carrying out collaborative research.
- UK scientists will need continued access to EU funding and information resources that allow scientists to find potential collaborators. Otherwise, it will become much more difficult for UK researchers to participate in collaborations that receive funding through the EU.
- We are particularly concerned over the potential impact on clinical trials across EU states. Multi-centre EU trials are often vital to involve the necessary number of patients to generate meaningful data, particularly for rarer cancers. The new EU Clinical Trials Regulation will not be in force in the EU at the time that the UK exits the EU. The Government has said that where possible the UK will align with the new regulation without delay when it does come into force in the EU. However, the European Commission has issued statements^[1] making it clear that after we leave the EU, the UK will fall outside the regulation with no access to systems supporting the approval and safety monitoring of medicines across the EU.
- We are concerned that UK researchers will find it much more challenging to lead Europe-wide clinical trials after Brexit. It will be more difficult for UK organisations like the ICR to become trial sponsors and we may need to find an alternative legal representative in an EU

[1]

https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_brexit_clinical_trials_final.pdf

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member state. There is a risk that UK patients could miss out on the opportunity to join trials providing access to the latest treatments.

- We need to ensure that the UK can still access the infrastructure, systems and legal support required to deliver collaborative trials. As part of this, the UK will need continued access to large shared data sources, and must align with EU Data Protection laws to ensure that 'adequacy' requirements for data sharing with the EU are met.

Researcher mobility

- It is essential that any new immigration policies allow us to recruit the best staff and students from inside and outside the EU. For the ICR to retain its competitiveness we need to be seen as an attractive place to work and study for the best scientists throughout the world. We find it difficult already to attract staff with skills in certain disciplines where there are shortages such as big data and computational biology. Since the referendum in 2016, we have had staff leave the ICR or turn down offers of employment citing uncertainty because of Brexit.
- The Government needs to be much clearer about how movement of skilled researchers will work if as expected freedom of movement ends following the UK's departure from the EU. Simply assessing people by how much they earn does not work well for science, where highly skilled researchers are often not paid particularly highly. Many highly qualified technicians are in roles which may not be paid highly enough for them to be eligible for working visas. We have concerns that we may struggle to fill many technical roles with appropriately skilled staff if the proposals in the Immigration White Paper are implemented.
- The Government should also safeguard access to the clinical workforce needed to carry out clinical trials. The ICR's NHS partners employ trial coordinators and data managers who may fall below the proposed wage threshold in the immigration White Paper. Loss of these staff would curtail the UK's ability to set up and run clinical trials, and could deny patients access to the latest treatments.
- It is vital for the Government to secure a deal with the EU that preserves the rights of EU citizens to study within the UK, and for UK citizens to study within the EU. It would be extremely damaging to science and academic study more generally to erect barriers in the flow of students.

Funding

- We need further clarity on access to EU funding by UK scientists as soon as possible. The current uncertainty is already making it difficult for UK researchers to take leadership positions on EU-funded collaborations. We welcomed the announcement that the Treasury will underwrite funding for approved Horizon 2020 projects applied for before the UK leaves the EU, but there remains uncertainty over arrangements for the next Framework Programme. It is crucial to know which sources of EU funding UK scientists will be able to access and for

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how long, in order to be able to make long-term plans.

- It is important for the UK Government to strike a deal with the EU that as much as possible preserves access to EU sources of funding and facilities for UK scientists. The Government must act to prevent any funding shortfall to science once the UK formally leaves the EU. Funding from the EU plays an important role in supporting large-scale scientific initiatives, and its loss could limit the UK's ability to participate in these.
- We believe the Government must make every effort to secure continued access by UK researchers to large-scale European scientific research infrastructure. If UK scientists had to pay charges to access shared facilities after the UK leaves the EU, it would become prohibitively expensive and would severely damage the ability of our researchers to remain internationally competitive.

Access to medicines and medical devices

- It is crucial to ensure that there are no delays for patients in accessing the latest, best and most innovative cancer treatments. The UK will need close alignment with the EU on both the regulatory approval of new medicines and medical devices, and supply of treatments across borders. There is a serious risk that UK patients could suffer significant delays in accessing the latest cancer treatments if companies need to gain separate licences in the UK before marketing them here.
- We urge the Government to negotiate a deal with the EU that either preserves UK membership of the EMA or ensures close regulatory alignment for licensing of drugs or medical devices. There is a major risk that patients in the UK could miss out on the latest cancer treatments as a result of the decision to leave the EU. Under a no-deal Brexit, the Government would grant UK market authorisation to all drugs that have already been centrally licensed by the EMA, but would expect the MHRA to assess all new drugs. The UK represents only a 3 per cent share of the global pharmaceutical sales market compared with 25 per cent for the EU, so we believe that companies could prioritise the larger EU market ahead of the UK's in applying for authorisations.
- It is vital that the supply of medicines, medical devices and reagents is not blocked or disrupted once the UK leaves the EU. The Brexit Healthcare Alliance estimates that 37 million packs of medicine come to the UK from the EU each month. The Government must seek to avoid customs delays or requirements to re-test products after crossing borders. The ICR is working with suppliers to ensure we continue to gain deliveries of goods and services after the UK's departure from the EU. A no-deal Brexit has the potential to cause significant disruption to deliveries of drugs, reagents and laboratory supplies.
- We believe it is important that expert organisations like the ICR can continue to influence the development of scientific policy and regulation in Europe, to ensure it works as well as possible for our researchers. We

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have until now held an influential position in the development of EU regulations, and would want this to be preserved in any Brexit deal.