

Cancer Research UK response to the Science and Technology (Commons) inquiry: Brexit science and innovation Summit February 2018

- 1. Cancer Research UK (CRUK) is the world's largest independent cancer charity dedicated to saving lives through research. It supports research into all aspects of cancer and this is achieved through the work of over 4,000 scientists, doctors and nurses. In 2016/17, we spent £432 million on research in institutes, hospitals and universities across the UK. We receive no funding from the Government for our research and are dependent on fundraising with the public. Our ambition is to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.
- 2. We welcome the committee's call for evidence to identify actions needed now to mitigate risks and exploit opportunities for UK science, research and innovation after Brexit. As we move to phase II of Brexit negotiations, it is vital that patients and research are prioritised in discussions about the UK's future relationship with the EU.
- 3. We support the Parliamentary and scientific committee "Science priorities for Brexit" reporting which reflects priorities from across the science community. Our response builds on evidence we have submitted to Brexit-related inquiries and to the Royal Society/Wellcome Trust Future Partnership projecting. We consider updates in the external environment, including the recent UK/EU joint agreement on progress made during phase I of negotiations which provides some clarity on citizen rights and EU funding programmes.
- 4. Key messages: Our priorities for patients and research as the UK leaves the EU:
 - a. The Home Office must design a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality. The research workforce is fundamental to our ability to understand disease and develop new treatments and interventions for patients.
 - b. The UK must seek regulatory alignment with the EU in the following areas:
 - i. <u>EU Clinical Trials Regulation (CTR):</u> greater clarity is needed on plans to ensure the UK aligns with the CTR post-Brexit, particularly as this will not fall in the remit of the EU (Withdrawal) Bill. Alignment with the CTR will better support clinical research in the UK and is crucial for patients with rare and childhood cancers where collaborative cross-border clinical trials are needed. Specifically, we need to understand the mechanism for the UK access to the EU portal and database key parts of the new regulation.
 - ii. <u>EMA drugs licensing:</u> The UK should explore an agreement with the EU to ensure we can continue to take part in the EMA's centralised procedure for drugs licensing. Any future drug licensing system must not exacerbate delays in access to the most innovative treatments for patients in the UK and across the EU.
 - c. The UK must strengthen its world-class science base by building on and developing new funding programmes and global collaborations, like the future EU Framework Programme 9.
- 5. The best outcome for patients and research could be achieved through:
 - The development of a **framework** for the new relationship between the UK and the EU. This should address the fundamental, underpinning aspects that support research collaboration such as an agreed legislative framework and principles for a mutually



- beneficial relationship in the long term. This would lay the foundation of a continued close collaboration for research and innovation, and for the development of individual partnerships.
- The development of **individual partnerships** for specific initiatives. Partnerships are generally created for a specific purpose within a given timeframe, and would require bespoke arrangements to ensure success. An example of a specific partnership would be the UK's interaction with Framework Programme 9.
- 6. Further details on our suggestions for this framework and partnerships can be found in our response to the Wellcome Trust/Royal Society Future Partnerships project^{vi}.
- 7. Last year CRUK, alongside other funders, published a report 'The impact of collaboration: the value of UK medical research to EU science and health'*ii. This report identified key areas where the UK has made significant contributions to the EU:
 - The UK's participation in pan-EU clinical trials, providing notable leadership for rare disease and paediatric clinical trials. There were over 4,800 UK-EU clinical trials between 2004 and 2016, and the UK has led or participated in the largest number of pan-EU trials for rare disease and paediatric treatments.
 - The UK's development of new therapies and medical technologies that benefit EU
 patients, backed by a thriving pharmaceutical and biotechnology sector. Around 25% of
 the world's top 100 prescription medicines were discovered and developed in the UK.
 - The UK's training of early career researchers from across the EU, to develop their skills and launch their research careers. Around 16,000 students from other EU countries are registered on UK biomedical courses.
 - Contributions to advisory bodies, networks and policies that underpin research across the EU and its member states
 - Co-ordination and hosting of some of Europe's unique large-scale infrastructures for medical research
- 8. The overarching message from this report is that scientists have a greater impact when they collaborate internationally. Patients and research across Europe and beyond will benefit if the UK maintains its world-class research reputation and if close scientific cooperation with the EU continues. Although collaboration will continue after Brexit, any limitations on the ability of researchers and institutions to work together could diminish the impact of science both in the UK and the EU.
- 9. We welcome the Government position paper on science and Brexit^{viii ix}. It is reassuring that emphasis is placed on continuing close collaboration for medical research and we are pleased that our priorities are reflected in the paper. The move to phase II of Brexit negotiations represents the time for Government to provide more detail on how these priorities will be taken forward in negotiations and in domestic policy. The Government's Industrial Strategy also provides positive messages in highlighting a desire to collaborate internationally by increasing the number of scientists in the UK and continuing to collaborate in EU funding programmes^x. Further reassurances are still needed on the detail of these arrangements and on regulatory alignment for clinical trials and approval of medicines.

Ensuring we have a skilled science workforce

10. The research workforce is at the heart of breakthroughs that benefit cancer patients in the UK, in Europe and worldwide. Our top priority is to ensure the UK Government designs a



future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.

- 11. CRUK funds postgraduate students and researchers from an international pool to ensure that we are working with the very best minds to conduct the highest quality research. Half of our PhD students and 46% of our research fellows are from outside of the UK^{xi}. The flow of talent globally is an essential part of the research environment and international movement is a feature of most researchers' careers and professional development. 72% of UK-based researchers spent time at non-UK institutions between 1996 and 2012^{xii}.
- 12. In consultation with our research community we have developed a detailed position on researcher mobility to ensure the UK remains an attractive place to undertake research^{xiii}. Our full recommendations cover three areas:
 - a. The status of EEA nationals in the UK
 - b. The current non-EEA immigration system
 - c. The UK's future immigration system

The status of EEA nationals in the UK and UK nationals in the EEA

- 13. We are pleased there have already been reassurances that:
 - The specific cut-off date from when EEA residents will no longer be entitled to stay in the UK is the date the UK leaves the EU this level of clarity is welcome.
 - Those currently with permanent residency permits will automatically be transferred to settled status: these individuals have already gone through a rigorous process to receive their permits and should not have to go through this process again.
- 14. However, we still need further clarity on:
 - Setting a minimal cost of application: this should be minimal and no more than the cost of Permanent Residency (£65)
 - Developing effective systems to process these applications, building on Government data such as National Insurance and tax contribution data: any increase in capacity needed at the Home Office to do so should be prioritised.
 - Ensuring interpretation of EEA nationals' continuous residence is not affected by periods spent abroad for study or research: more than half of the EEA nationals who answered our survey had spent time outside of the UK in 2016 for work (either trips less than 3 months or trips lasting between 3 months and 1 year). This should be a key consideration when developing the additional criteria required for EEA nationals to apply for settled status.

The current non-EEA immigration system

- 15. While the UK should design a comprehensive immigration strategy for the UK following Brexit considering both EEA and non-EEA migration (see section 3), the Home Office should make efforts in parallel to implement solutions and recommendations in the current system.
- 16. Tier 1 (exceptional talent/promise):
 - Cancer Research UK's fellowships should continue to be fast-tracked for Tier 1 through
 the Royal Society: the Tier 1 (exceptional talent) visa route enables the research sector
 to recruit global talent and ensure their eligibility for this visa from the start of their
 application.



17. Tier 2 (General – Skilled worker):

- Exemptions and priority for PhD level roles should continue in the Tier 2 route: the research sector invests significantly in domestic skills development, but PhD level roles can often only be filled by international talent despite this investment. These PhD level roles make up a large part of our funded research workforce. The recruitment of global talent to these roles is enabled by the current exemptions and priority for PhD-level roles in Tier 2. Global talent in these roles are also vital for the upskilling of the UK workforce through their training and educational contributions.
- There should be no increase of Immigration Skills Charge (ISC) for the research workforce: specifically, PhD-level occupations should continue to be exempt and there should be no increase in the Immigration Skills Charge for charities and higher education institutes. Using the higher education sector as a proxy for the entire research sector (which includes independent and government funded research institutes), the ISC would cost the sector £4.9 million for each year of the issued Certificates of Sponsorship; based on the upfront cost of the charge (£1000), this would be £24.5m per year. This £24.5m figure is equivalent to 1.5% of total funding from the Research Councils, The Royal Society, British Academy and The Royal Society of Edinburgh in 2013-14xiv.
- The Home Office, BEIS and DfE should work with the research sector to develop an
 appropriate mechanism which allows a significant proportion of the Immigration Skills
 Charge funds to return to the sector: this will enable continued research capacity
 building required for the future of UK research.
- Any changes to salary thresholds should not negatively impact charitable research funders' budgets: if the minimum thresholds are increased and roles requiring PhD-level qualifications were not exempt, it is likely that CRUK-funded research institutes would need to increase the salaries of postdoctoral researchers junior scientists that make up the largest single group of staff within these institutes which would impact on their budgets and reduce the amount of research they would be able to fund. This scenario is likely to apply to other academic organisations. To protect the volume of academic research funded in the UK, pay thresholds should be kept at the 10th percentile for new entrant workers and 25th percentile for experienced workers.

The UK's future immigration system

- 18. The top priority for CRUK is to ensure that the UK Government designs an immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.
- 19. Current Home Office immigration policies are based on reducing immigration to the UK through non-EEA migrants to the UK. However, once we leave the EU, the UK Government will be able to design an immigration system which considers both EEA and non-EEA flows of migration. As part of the development of a new immigration system, the Home Office should ensure the following features are included:
 - Mechanisms to recruit international staff with minimal cost, delay and uncertainty: the
 Home Office should not simply roll out the non-EEA immigration system for EEA
 nationals. The current system is expensive for the researchers we fund and resourceintensive for the employers who recruit these researchers (such as research institutes
 and universities).



• The most effective measure of skill and benefit of migrants coming to the UK: we recognise the previous recommendation of the Migration Advisory Committee to continue to restrict non-EEA migration by salary thresholds. However, salaries in the academic sector do not adequately reflect skill level or benefit of the work being undertaken. Some roles in the research sector are highly valued due to the niche expertise they bring from outside the UK, but they would not meet the current Government salary threshold.

For example, one of our group leaders in Oxford recruited a postdoc researcher from Japan to lead one part of their research project due to the unique expertise of the Japanese lab in a technique vital to progress their research. The Home Office must therefore consider how to reflect different sector needs while developing a comprehensive strategy for all industries. This should also include an assessment of the different salary levels across the UK.

- Policies to enable partners and dependents of the research workforce to live, work and
 use public services in the UK: over 75% of our survey respondents said that this is a key
 consideration when moving to another country. For the UK to continue to attract global
 talent, we must ensure their families are able to come with them to the UK and stay
 once they're here.
- Support to ensure that international students in the UK can take up firm job offers:
 CRUK funds more than 500 PhD students per year and 46% of these are not from the UK.
 These students drive research forward and are an important part of the research
 pipeline. It is vital for the UK scientific base that these talented students can stay in the
 UK and continue to contribute to the research that they have been working on once
 they have completed their PhD qualification. We are concerned that restrictions put on
 students once they finish their studies would impact how many of them would stay in
 the UK.
- Flexibility to enable extensive short- and medium-term movement of the research
 workforce: nearly 50% of all UK cancer research involves international collaboration^{xv}.
 CRUK collaborates extensively with European and international partners. In 2016, the
 survey respondents had travelled more than 1000 times outside of the UK for
 collaborations (such as clinical trials), training of staff, use of equipment, verifying data
 and sharing knowledge.
- Recognition and support of the dependencies between skills development and the
 international research workforce in the UK teaching environment: our global research
 workforce is involved in teaching and training students in the UK. To ensure we are able
 to upskill the domestic workforce, we must ensure the UK teaching environment is
 world-class, which includes continuing to collaborate internationally, attracting global
 scientific talent and enabling students to travel for education.
- Mechanisms to support non-UK research group leaders to bring members of their research group with them when they move to the UK: we want to ensure that we attract talented international group leaders. Some of these will already have established research groups outside of the UK. Their group members will be key to the success of their research. The UK Government should consider mechanisms for attracting these



group leaders with their group members which UK research institutions are currently not able to do.

Ability for the Home Office to capture and publish more detailed migration statistics to
inform future immigration policy development: increasing reliance has been placed
upon migration statistics to develop immigration policy, particularly post-Brexit. The
available measures, such as the International Passenger Survey and Home Office migrant
journey report, are not comprehensive and adequate reflections of the value of
migration to different sectors, such as research and innovation. Current statistics
captured by the Home Office also do not cover short-term travel (less than one year)
and data on EEA nationals. A future immigration system must capture data on this.

Ensuring an aligned and optimal regulatory environment for clinical trials

- 20. As a priority, the Government should provide greater clarity on plans to ensure UK adoption and alignment with the EU Clinical Trial Regulation when we leave the EU. Specifically, we need to understand the mechanism for the UK access to the EU portal and database key parts of the new regulation^{xvi}.
- 21. As the UK exits the EU, it's vital that cancer patients have timely access to clinical trial opportunities. CRUK supports over 250 clinical trials across the UK, recruiting around 25,000 patients each year. Of the 200 trials CRUK directly funds, more than a quarter (28%) involve patients from at least one other EU country^{xvii}.
- 22. The current EU Clinical Trials Directive (CTD) is due to be replaced by the new EU Clinical Trial Regulation (CTR). The UK played a pivotal role in the development of the CTR and CRUK believes it is a positive step forward in regulation of clinical research. For example, it will harmonise the assessment and supervision process for all clinical trials via a central EU portal and database, currently being set up by the European Medicines Agency (EMA). Ultimately, alignment with the CTR will better support clinical research in the UK and facilitate pan-EU trials.
- 23. Pan-EU or international approaches to trials are particularly crucial for paediatric and rare cancers. Collaborating across borders enables enough participants to make evidence from trials meaningful. The UK has led or participated in the largest number of pan-EU clinical trials for these types of disease^{xviii}. Researchers are also increasingly stratifying patients according to the genetic profile of their cancer, reducing the number of eligible patients in a single country. Therefore, to get sufficient clinical trial data to inform interventions, multicountry trials may become increasingly important for all types of disease.
- 24. Due to technical difficulties, implementation of the CTR has been delayed until 2019 after the UK leaves the EU, meaning the Regulation will not be covered by the EU (Withdrawal) Billxixxx. Alignment with the CTR will therefore be subject to negotiation on the UK's future relationship with the EU.
- 25. Any delay in aligning with the EU CTR could leave the UK behind, without access to a harmonised regulatory system. This could significantly impact our ability to do clinical research and lead world-class studies. It is crucial that an agreement is made before the EU CTR is implemented.



26. We welcome UK Government plans to seek regulatory alignment with the EU to protect public health and safety^{xxi}. We support their ambition to put patients at the heart of regulation, provide long-term stability and ensure the UK is a leader in medical innovation. But greater clarity is needed about how the UK will be able to align with the CTR so patients across Europe are able to benefit from taking part in UK-EU clinical trials.

Ensuring the UK is an attractive market for companies to launch innovative treatments

- 27. The UK should explore an agreement with the EU to ensure we can continue to take part in the EMA's centralised procedure for drugs licensing. Any future drug licensing system must not exacerbate delays in access to the most innovative treatments for patients in the UK and across the EU^{xxii}.
- 28. Cancer drugs play a crucial role in many patients' treatment. Before drugs come to national bodies like the National Institute for Health and Care Excellence for decisions about whether to be routinely prescribed to patients, they first need to be licensed. In the EU, licensing is primarily carried out through a centralised procedure, led by the European Medicines Agency (EMA). It is vital that we avoid creating further delays in access to medicines by diverging from the EMA's centralised licensing process post-Brexit. Such a divergence could lead the UK to become a lower priority market: the EMA covers an area responsible for 25% of global sales, whereas the UK accounts for just 3%xxiii.
- 29. The MHRA is recognised as one of the leading national authorities in its field^{xxiv}. Between 2008 and 2016^{xxv}, the MHRA acted as Scientific Advice Coordinator in at least 20% of centralised EMA medicine approval procedures and provided data in about 50% of medicine approval procedures.
- 30. The MHRA has also been instrumental in pharmacovigilance and designing the regulatory environment across the EU for clinical trials, ultimately driving patient safety and faster access to new medicines for patients across Europe^{xxvi}. This was referenced in a joint letter by UK and EU industry leaders^{xxvii}. The MHRA has also made its desire to stay involved clear, in a statement immediately following the Brexit vote^{xxviii}.
- 31. Our preferred option would therefore be for the UK Government to seek an agreement with the EMA, which would allow EMA decisions to apply in the UK, and would allow the MHRA's continued participation in decision-making and shaping the regulatory environment. This would help ensure that the UK remains an attractive launch market for pharmaceutical companies bringing drugs to market, and therefore that UK patients are able to access innovative medicines quickly.
- 32. Crucially, continuity would also benefit patients across Europe, by maintaining expert input into decision-making and regulation, and ensuring the process is not delayed. This has been referenced by EFPIA, the membership body for the European pharmaceutical industry, who have argued that a break in regulatory continuity would represent 'an unacceptable risk to patient health'xxix.
- 33. We recognise and support the UK Government's commitment to maintaining swift patient access to medicines in the recent position paper on Science and Innovation^{xxx}. But we would welcome further detail on the specific nature of the desired future relationship with the EMA.



<u>Investment in UK science and global collaborations to strengthen our research base</u>

- 34. UK Government should continue to develop the prestige and global recognition of its research grants and consider how these may facilitate and promote international collaboration and drive international research consortia.
- 35. UK Government should develop international collaborations and ensure UK access to infrastructure and funding that supports these. For example, the EU Framework Programme 9, which will replace Horizon 2020. The UK should shape the future of such programmes to ensure they align with UK priorities and are awarded on scientific excellence.
- 36. We welcome Government's focus on science and research in the Industrial Strategy, including additional investment in research and development. We are supportive of the Strategy's vision to increase the proportion of GDP spend on R&D to 2.4% by 2027 and 3% in the longer term and to produce a roadmap outlining how this will be achieved^{xxxi}. This roadmap should include measures to effectively market UK science globally and strengthen our research collaborations internationally.
- 37. The EU contributes significantly to science investment in the UK. In addition to their financial contribution, EU grants promote global recognition of UK science and support important pan-EU research collaborations. In 2015, the UK received £40 million pan-EU research in cancer research from the EU. Although CRUK does not receive any direct funding for research, in 2016/17, CRUK's institutes across the UK received £6 million income from EU grants; this was more than 2.5% of their total research funding panels. Furthermore, universities where CRUK has centres are supported by EU grants, totalling more than £110 million in 2016 to 10 million in 2016 to 10 million in 2016 to 20 million in 20 million in 2016 to 20 million in 20 millio
- 38. Cancer research is one of many fields of UK research that benefit from the financial support provided by the EU. In 2014/15, the UK received £120million of funding for clinical medicine from the EU and £90million for the biosciences^{xxxv}. This represented approximately 6% and 13% respectively of the UK's total funding for these disciplines^{xxxvi}.
- 39. It is reassuring that the UK is continuing to contribute to the EU's budget until the end of 2020, and UK participants are eligible to take part in EU funding programmes until this time. This provides some stability to UK-based researchers who will be able to participate in Horizon 2020 until the end of the programme. There is still no indication of whether UK-based researchers will be able to participate in the next Framework Programme (FP9) and what this participation will look like.

Short-term uncertainty and facilitating a smooth transition to new arrangements

- 40. We believe a transition period would help ensure patient safety is protected and may help mitigate some of the uncertainty during the negotiation period.
- 41. The current landscape in terms of the Brexit negotiations is very complex. For example, the implications of the delay in implementing the CTR are not yet fully understood, and this is just one piece of regulation. A huge amount of work is still needed and therefore a transition period would be sensible.



42. In addition, the EMA has indicated that their activities will be impacted by their relocation. This includes a reduction in, and delayed timelines for, their activities. Putting in place transition arrangements for their relocation may help reduce the impact of their relocation on their work.

For further information please contact Zoë Martin, Policy Manager on zoe.martin@cancer.org.uk or 0203 469 5337

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^{IV} Future Partnership Project https://royalsociety.org/news/2017/11/wellcome-rs-future-partnership-project-consultation/
^VJoint report from the negotiators of the EU and the UK Government on progress made during phase 1 of negotiations under Article 50 TEU on the UK;s orderly withdrawal form the EU (2017) https://ec.europa.eu/commission/sites/beta-political/files/joint_report.pdf

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^x Industrial Strategy: Building a Britain fit for the future

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- xiv According to HESA data
- xv https://www.ohe.org/publications/exploring-interdependencies-research-funders-uk
- xvi Cancer research UK policy statement on alignment with the Clinical Trial Regulation (2017)

http://www.cancerresearchuk.org/sites/default/files/dec2017 cruk policy statement eu clinical trial regulation.pdf xvii Statistics from CRUK's internal databases and include clinical trials from our Clinical Research Committee, New Agents Committee and Centre for Drug Development.

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xx Letter from Robin Walker (DExEU) to Norman Lamb (Chair of Commons Science and Technology Select Committee) (September 2017) http://www.parliament.uk/documents/commons-committees/science-technology/170921-Robin-Walker-to-Norman-Lamb-DExEU%20letter.pdf

xxi The UK wants to continue to work with the EU on medicines, Jeremy Hunt and Greg Clark joint letter, Financial Times (July, 2017) https://www.ft.com/content/a94326ac-5dbd-11e7-9bc8-8055f264aa8b?mhq5j=e5

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- xxxii This includes all grants given to cancer-specific and cancer-related research. NCRI analysis using data derived from the Global Grants Award Database and corresponding Dimensions Software platform, provided by UberResearch.
- xxxiii Funding data reported directly to us from CR-UK institutes, including the Francis Crick Institute
- xxxiv Self-reported data from universities at current CR-UK centre locations. Includes total award of active grants in August 2016
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