Cancer Research UK response to the Science and Technology Committee (Lords) inquiry: ‘Life Sciences and the Industrial Strategy’  
September 2017

Summary

1. Following the publication of the Life Sciences Industrial Strategy (LSIS), it’s vital the Government agrees an ambitious and well-resourced Sector Deal in order to cultivate the UK’s world-leading life sciences sector. The LSIS comes at a critical time for the UK, with our impending exit from the EU and the NHS facing challenges on many fronts. We have a strong history of medical research in the UK and it’s vital that we remain a world-class destination for the benefit of our economy and, most importantly, patients. We welcome the Committee’s focus on the life sciences and appreciate the opportunity to submit written evidence to its inquiry.

2. Cancer Research UK (CRUK) welcomes the Government’s focus on the science and innovation within the Industrial Strategy as an important UK industry. We particularly welcome the development of the LSIS as part of this broader framework. CRUK was represented on Professor Sir John Bell’s Advisory Board that guided the development of the LSIS and we support its recommendations.

3. It’s positive that the value charities bring to the medical research environment in the UK is recognised throughout the strategy. Along with Government and industry, medical research charities play a vital role in stimulating and investing in innovation. Charities have invested nearly £10 billion in life science and medical research in the UK since the sector started collecting data in 2008. In 2016/17 alone, CRUK spent £432 million on research in institutes, hospitals and universities across the UK. Our research covers all aspects of cancer and this is achieved through the work of over 4,000 scientists, doctors and nurses. We support over 250 clinical trials across the UK, recruiting around 25,000 patients each year. Our funding also leverages substantial inward investment through R&D collaborations and direct and indirect support for clinical trials. This demonstrates our strong commitment to improving patient lives through research and the important contribution of charities to UK life sciences and the economy.

4. Furthermore, medical research charities stimulate regional economies by funding research across the UK. Last year, CRUK spent over £23 million on research in the North West of England, over £41 million in East Anglia and over £33 million in Scotland.

5. We have structured our submission around the recommendations of the LSIS that we believe should be prioritised by Government either through development of a Sector Deal or in Brexit negotiations. Our top priorities are for Government to:
   - Establish the Health Advanced Research Programme (HARP) with a particular emphasis on taking forward the project to support early detection research
   - Reinforce the UK science offer by optimising medical research charity investment through increasing the Charity Research Support Fund
   - Ensure the UK remains a world-leader in life sciences research post-Brexit by:
     - Ensuring we have a skilled science workforce: designing a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.
     - Ensuring an aligned and optimal regulatory environment for clinical trials.

We have also provided comments on how we would like the Government to:
   - Enhance the clinical research environment in the UK
   - Ensure NHS collaboration commercialises research and brings innovations to patients
   - Harness the use of data to benefit patients
6. Now that this Sector Strategy has been published, it is vital for Government, in particular the Office for Life Sciences (OLS), the Department for Business Energy and Industrial Strategy (BEIS) and the Department of Health (DH), to provide clarity on how the Sector Deal will be agreed, resourced and implemented. Alignment with the wider Industrial Strategy is central to successful implementation as will be the case for subsequent sector strategies. Given the nature of the life sciences sector, responsibility sits across the remit of both health and business Government departments. The OLS plays a key role in bringing these departments together. It is essential the process for the Sector Deal has a clear owner and is conducted in a coordinated way.

7. The Governance and Implementation section of the Strategy provides a starting point by identifying key principles to follow during implementation. **CRUK and other organisations who will share responsibility for implementing parts of the strategy should be involved in the agreement of the Sector Deal.**

The Health Advanced Research Programme (HARP)

8. The flagship recommendation of the strategy is to create a Health Advanced Research Programme (HARP) where charities, industry, NHS and Government collaborate to fund higher risk “moonshot” projects. We strongly support the establishment of this initiative.

9. It is encouraging that charities are identified as being central to HARP. It is also acknowledged that success and scale is heavily dependent on involvement of the data-rich NHS, as well as Government committing resource to help coordinate and implement HARP. However, in taking HARP forward, we would strongly advise that it is created as a multi-funder independent initiative, as alluded in the LSIS.

10. A number of example projects that would sit under the HARP have been identified as having the potential to transform healthcare over the next 20 years. We are particularly supportive of the inclusion of the project to create a platform for the early detection of disease. CRUK put this proposal forward during the development of the strategy. This platform would allow multi-technology evaluation of early phase diagnostics and would expand on successful UK cohort collections of biological materials that help us understand why some people develop certain diseases, such as the UK BioBank. A revolution in early detection research would dramatically improve the chances of survival for cancer patients, create a more sustainable health system and set the UK apart from international competitors. This would seed a new diagnostics industry which has the potential to be world-leading.

11. We are also supportive of the other suggested projects, including the genomics in medicine project which supports the Chief Medical Officer’s “Generation Genome” vision. This includes a key objective in the NHS for routine whole genome sequencing of cancer samples that could have major implications for precision medicines research.

12. **Government should commit to supporting the establishment of HARP as a multi-funder independent initiative with a particular emphasis on taking forward the project focussed on early detection of disease.**

Reinforcing the UK science offer by optimising medical research charity investment

13. The UK’s science base is a national asset. We support the recommendations within the LSIS for Government to ensure that its investment in science serves to attract further investment in UK R&D from industry and charities. To do so, we believe Government should set an ambitious target and
roadmap for total public and private R&D spending in the UK to reach 3% of GDP. The target would be in line with other comparable countries and would send a clear signal globally that the UK is open for business.

**Increasing the Charity Research Support Fund (CRSF)**

14. In particular, we support the recommendation to enhance the Charity Research Support Fund (CRSF). This is a recommendation we championed with other medical research charities during the development of the strategy.

15. Government must provide universities with long-term confidence in its support for charity investment by committing to increase the CRSF. This commitment needs to be taken on by the Higher Education Funding Council’s successor organisation, Research England.

16. Universities rely heavily on funding from charities for exploratory and high-risk research. Promising results which arise from this research are taken forward by industry, having been “de-risked” by charity funders. To leverage further investment from industry and charities, it is crucial that a proportion of Government’s new investment in R&D of up to £2bn/year supports research in UK universities through quality-related (QR) research funding, which underpins the excellence of our science base.

17. The CRSF is an important component of QR research funding. Universities receive the CRSF from Government to cover indirect costs of research, such as the costs of maintenance of laboratories, which charities cannot pay because their supporters expect donations to be spent directly on research activity. However, ongoing failure to increase investment in CRSF, so that it keeps pace with charity spending, is impacting on the attractiveness to universities of medical research charity funding, with negative consequences for research anticipated in a wide variety of disease areas.

18. Within QR funding, the level of the CRSF has remained at £198 million per year since 2010; a real-terms decrease of £38.7 million over 6 years, and it will stay at £198 million in 2017/18. This has put pressure on universities and has led to some coming to view charity funding as being less valuable than other sources\(^x\). An increase in the CRSF to £264 million by 20/21 would be in line with inflation since 2010 and in proportion to changes in charity investment since 2010.

19. Evidence suggests investment in charity research by Government will see long term returns: each pound invested in cancer related research by the taxpayer and charities returns around 27 pence to the UK year on year\(^x\). It is therefore vital that the Government incentivises and provides long-term confidence for universities seeking charity investment.

20. **Government should commit to increasing the CRSF each year in line with inflation and in response to changes in charity investment.**

**Ensuring the UK remains a world-leader in life sciences research post-Brexit**

21. We welcome the publication of UK Government’s Brexit position paper on science\(^x\). Whilst the paper sends a positive message to the research community in the UK and EU, further detail is needed from Government on how it sees this scientific collaboration operating once we leave the EU. We are pleased the position paper, as well as the LSIS, reflects on our top priorities: the need for an immigration system that supports researcher mobility, and regulatory alignment to support clinical trials and medicines approval.
Ensuring we have a skilled science workforce

22. We strongly support the acknowledgement in the LSIS that a skilled workforce underpins the success of life sciences in the UK.

23. In light of the UK’s exit from the EU, the Strategy recommends establishment of an immigration system that allows recruitment and retention of highly skilled workers from the EU and beyond. During development of the Strategy we highlighted this as a fundamental requirement to our future success.

24. 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. 46% of our PhD students and half of our research fellows are from outside of the UK\textsuperscript{vii}. 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\textsuperscript{viii}.

25. Current Home Office immigration policies are based on reducing immigration through restrictions to the flow of 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. The Government’s priority should be to ensure that we can attract, recruit and retain global scientific talent at all professional levels regardless of their nationality.

26. In consultation with our research community we have developed our position on researcher mobility to ensure the UK remains an attractive place to undertake research\textsuperscript{x}. In summary, our recommendations cover:

- **The status of EEA nationals in the UK** – the Home Office should clarify the position of existing EEA residents in the UK and UK nationals in the EEA by:
  - Setting the specific cut-off date for when EEA residents will no longer be entitled to stay to the date the UK actually leaves the EU
  - Setting a minimal cost of application
  - Transferring those currently with permanent residency permits automatically to settled status.
  - Developing effective systems to process these applications
  - Ensuring their interpretation of EEA nationals’ continuous residence is not affected by periods spent abroad for study or research.

- **The current non-EEA immigration system** - the Home Office should make efforts to implement solutions and recommendations in the current non-EEA system:
  - CRUK’s fellowships should continue to be fast tracked for Tier 1 through the Royal Society
  - Continued exemptions and priority for PhD-level roles in the Tier 2 route.
  - There should be no increase of Immigration Skills Charge for the research workforce for Tier 2
  - Any changes to salary thresholds should not negatively impact charitable research funders’ budgets

- **The UK’s future immigration system** – the top priority for CRUK is to ensure that the Government designs an immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality. A future immigration system should include the following features:
  - Mechanisms to recruit international staff with minimal costs, delay and uncertainty
27. The Strategy also recommends creating a programme of combined Government and charitable funding to attract up to 100 world-class scientists to the UK. Charity research funders, including CRUK should be consulted during the development of a programme such as this.

28. Alongside the need for an immigration system which allows us to attract, recruit and retain global scientific talent, we also support the Strategy’s ambition to improve domestic skills development.

29. CRUK is committed to skills development and take an active role in this through funded programmes such as our PhD-level trainee schemes, training volunteers in multiple ways and internal career development schemes.

30. We welcome the focus on developing the Skills Action Plan and improved apprenticeship schemes for the life sciences – it will enable the sector to develop the workforce needed to drive forward the Government’s Industrial Strategy. Medical research funders, such as CRUK, should be consulted and engaged as part of the development of these programmes of work.

31. **Government should prioritise designing an immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality**

32. **Ensuring an optimal regulatory environment**

33. We are particularly concerned about the UK’s future alignment with the forthcoming EU Clinical Trial Regulation (CTR), due to replace the current EU Clinical Trials Directive. Over a quarter (28%) of CRUK’s clinical trials involve at least one other EU partner. The ability for our researchers to collaborate with European counterparts is key to conducting research for paediatric patients and those with rare diseases where cohort numbers are low.

34. CRUK played a key role in the development and adoption of the EU CTR which we firmly believe is a positive step forward in the regulation of clinical research. For example, the EU CTR will harmonise the assessment and supervision process for clinical trials via a central EU portal and database, currently being set up by the EMA. Ultimately, alignment with the EU CTR will better support clinical research in the UK and facilitate pan-EU trials.

35. The EU CTR was originally due to become applicable in 2018 and therefore expected to be implemented into UK law through the EU Withdrawal Bill. The EMA recently announced a delay to
implementation until 2019 due to issues with developing the portal. This delay could have significant implications for alignment between the UK and the EU CTR. In addition, there are elements of the Regulation that appear to require EU member status or other legal requirements being negotiated as part of the UK’s exit from the EU.

36. During development of the Strategy we highlighted that Government should take steps to ensure alignment with the CTR which the UK has played a key role in shaping for the benefit of UK research.

37. **Government should provide greater clarity on plans to ensure UK alignment with the EU Clinical Trial Regulation when we leave the EU**

Enhancing the clinical research environment in the UK

38. We welcome the acknowledgement in the LSIS that enhancing the clinical research environment, including encouraging innovative trials, is key to the success of the wider Industrial Strategy. CRUK supports over 250 clinical trials across the UK, recruiting around 25,000 patients each year.

**Streamlining clinical trials set-up**

39. During development of the strategy we highlighted the importance of streamlining set-up for clinical trials and increasing industry investment, through support for infrastructure. More specifically, we called for recognition of the importance of adequately resourcing the Health Research Authority (HRA) to assist with the streamlining of clinical trial set-up. The LSIS acknowledges that additional investment in the HRA is required.

40. We would also like to see the HRA work with funders and sponsors to develop effective end-to-end trial timelines that include metrics which span the whole system, starting from the moment of grant award. This would help our understanding of where trial set up is being impeded and inform strategies to address this.

**Early-phase clinical trial networks**

41. The LSIS recommends that further work is done by funding agencies to support early-phase clinical trial networks. The Experimental Cancer Medicine Centre (ECMC) network is rightly provided as one of the examples of a strong network that advances exploratory development programmes and we advocate adoption of this model of working. Government can support research and innovation strengths in local areas through continued investment in such initiatives.

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**The Experimental Cancer Medicine Centre (ECMC) network**

The ECMC initiative was launched in 2007 as a partnership between Cancer Research UK and health departments from all four UK nations, and forms a network of 18 ‘virtual’ centres across the UK designed to bring new treatments to cancer patients as quickly as possible. The network is a partnership between local NHS Trusts and universities, enabling world class health researchers and clinicians to work together to generate new approaches for beating cancer.

Around 1,500 new early phase trials over ten years in 35 cancer types have been reported within the Network, providing access to innovative treatments to 18,000 patients. In addition, 70% of the studies supported in the network are either sponsored and/or funded by industry; ECMCs have been able to leverage over £155 million (£73.5m in 2014/15 alone1) from industry towards clinical trials and pre-clinical research in experimental medicine.
Streamlined commissioning of Excess Treatment Costs (ETCs) for clinical research

42. The treatment costs that the NHS covers for non-commercial trials – Excess Treatment Costs (ETCs) - are a critical component of clinical research. Commissioners must meet ETCs for clinical trials as part of routine business, to avoid delays in setting up studies. However, delays in agreeing these costs have a knock on effect on trial set up. Addressing this would ensure optimal development and delivery of high quality clinical trials.

43. For certain therapies it is essential that we take a national approach to meeting the ETCs of studies, to fit with national priorities. In cancer this is particularly relevant in radiotherapy, where we have already seen the benefit of national ETC funding for stereotactic ablative radiotherapy (SABR) studies. The national cancer strategy called for £4.3m per year to provide ETCs for upcoming trials up to 2020\(^\text{ix}\).

44. The LSIS acknowledges that funds should be found to cover these costs to eliminate this impediment to trial participation. We are pleased that the DH is undertaking a piece of work to address this issue, to which we are contributing. We advocate for an output to this piece of work that reduces bureaucracy and clarifies roles and responsibilities for covering ETCs. DH should clearly communicate that it is a requirement of Commissioners across the country to meet ETCs.

45. **Government should take forward recommendations to streamline setup for clinical trials through investment in the HRA, and provide clarity on responsibility for ETCs**

NHS collaboration to commercialise research and bring innovations to patients

Accelerated Access Review

46. We welcome the vision and recommendations set out in the Accelerated Access Review (AAR) and support the LSIS’s recommendation to fully adopt the AAR. The AAR offers a pathway that will encourage the pull through of transformative medicines and innovation into the NHS, offering new possibilities to international companies. However, we must not forget about the other potential technologies that can make substantial improvements on patients’ lives, and we support the need for clearer pathways of adoption for all types of technology.

47. The AAR proposes a new Strategic Unit (SCU) in NHS England to consider affordability and wider value of accelerated access, such as early approval from NICE. This would include the generation of real-world observational data on top of clinical trials data. We agree that there is a real opportunity to consider this approach beyond those drugs designated as “transformative”.

48. We also agree that there is a need to encourage flexibility and innovation in payment arrangements between NHS England and pharmaceutical companies for new medicines. As the cost of cancer drugs continues to increase, we believe the new SCU should consider a range of flexible pricing models as part of a commercial dialogue with innovators. One way of achieving this is the establishment of outcomes based payments and multiple indication pricing. CRUK is planning to undertake a project to define the outcomes that should be collected as part of an outcomes based reimbursement scheme for cancer and see whether this is possible with current data collection mechanisms. Our aim is to pilot an approach in Greater Manchester depending on the outcomes of the initial stages of the project.

49. We agree with the AAR that transformative products, which show promise but where data remains immature, should be recommended by NICE for conditional recommendations leading to a period of managed access. This will increase innovation into the NHS and open up faster access for patients.
50. CRUK does not support the new Budget Impact Test. We are concerned at the potential for NHS England to delay the introduction of new innovative cancer drugs into the NHS, a position in direct conflict with the intentions of the AAR. If NICE has assessed a cancer treatment as clinically effective and represents value for money, then patients should receive it without delay. A system that could add up to a three year delay before patients can access these treatments is unacceptable. As we have already made clear, manufacturers should be encouraged to price drugs responsibly and there is absolutely a need to enable earlier and more flexible pricing negotiations. While we hope that implementation of the AAR will make this policy redundant, we also encourage Government to develop alternative ways to address affordability.

51. **Government should implement the AAR in full without further delay and consider alternatives to the new BIT**

Harnessing data to benefit patients

52. The UK health system has the potential to be a unique data asset. More complete and real-time datasets, effective quality assurance and stronger data linkage would be attractive to industry and stimulate economic growth opportunities. We welcome the Strategy’s aims to support and align with the National Data Guardian (NDG) recommendations with a strategic goal of establishing 2-5 national data hubs to rapidly engage researchers with a meaningful dataset.

53. During the development of the LSIS we supported the creation of local health economies for data, so we are pleased to see this reflected in the recommendations. Any data initiative must build on existing infrastructure, skills and relationships. Enforcing interoperability has been a weakness in past programmes and will be key in the implementation of this initiative. Greater Manchester would be a good choice for a health economy, given the existing strong relationships formed during ‘DevoManc’. The large amount of high-quality data available means that cancer could be an initial priority area; there is huge potential in linking genomic data to treatments and outcomes. The cancer vanguard in Manchester has a history of collaboration between organisations and a strong academic centre of excellence.

54. Although these local health economies should be encouraged to trial new innovations, it is important that nationally-determined datasets and standards are adhered to. This allows for accurate regional comparisons and for robust evaluation of local initiatives that could be translated into a national programme. This would also support work on rarer diseases, where it is unlikely that a population of 5 million would be large enough to capture enough data.

55. The implementation of the new NDG model will be central to ensuring the success of the ambitious vision for data set out in the Strategy. The new national opt-out and wider data programme must build strong safeguards and must communicate these effectively to the public, patients and health professionals. The work of the NDG and of Understanding Patient Data is central to this debate and must be progressed before any new initiative is launched. Patients are often supportive of their cancer data being used: 94% of people with cancer supported their cancer data being used for research and 89% supported their data being used for direct care. However, support does not override a desire to be informed: 83% believed it is important that people with cancer are informed about the cancer registry.

56. There are several outstanding decisions to be made about the implementation of the national opt-out. We have heard concerns from many, including NHS England and the Care Quality Commission, about the impact of applying the opt-out to national patient surveys such as the Cancer Patient
Experience Survey (CPES). This survey is vital for giving people with cancer a chance to have their voices and experiences heard. It allows patient experience to be included, for example, in the CCG Improvement and Assessment Framework, thus placing it on a par with clinical effectiveness. We would welcome assurances from the DH that CPES is not at risk and that this important survey can continue to be used in the future.

57. We are pleased to see that the Strategy has recognised the importance of national disease registries. The English cancer registry, run by Public Health England, underpins all efforts to improve outcomes for people affected by cancer and is at the heart of the 2015 Cancer Strategy for England. The information contained in this registry is the result of extensive work by registration officers and analysts to compile a wide range of clinical information and is world-leading in its quality and completeness.

58. **Government should ensure that care is taken in developing strong safeguards governing the use of data and building public trust. These are crucial components in the implementation of the new national opt-out and will underpin many recommendations in the Life Sciences Industrial Strategy**

**About Us**

Cancer Research UK 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. Cancer Research UK wants to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.

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