Cancer Research UK response to Scotland Chief Scientist Office consultation on Health Research Strategy - September 2014

Cancer Research UK recommends that the CSO:

1. Should clarify how this proposal for a Scottish trials database relates to the UK Clinical Trials Gateway (UKCTG). The CSO should avoid unnecessary duplication and cost of setting up its trials database where possible. Any information structure that is created should link to Cancer Research UK's CancerHelp UK clinical trials database for trials relating to cancer.
2. Enable GP data systems and cancer registries to be interoperable across Scotland and across the UK to enable one single data access point for healthcare professionals. The CSO should standardise R&D functions to reduce the need for trials to seek approval across the UK, but enable local flexibility on certain issues and for small-scale, single-centre trials.
3. Maximise the UK's investment in medical research by fully supporting the translation and uptake of innovative healthcare technologies. The CSO should highlight the importance of a research-active NHS and support the infrastructure needed to achieve this.
4. Consider ways to improve access to clinical trials for children and young people in Scotland as recommended by the NCRI report.
5. Continue to promote its support for excess treatment and support costs for research, to give the research community additional reassurance that their studies will be supported.
6. There is a need for new cohorts of samples from healthy individuals, ideally collected sequentially and linked to clinical data. An effective biorepository infrastructure is essential for the collection, storage and provision of such high-quality samples.
7. Protect the PCRCA, given the essential role of Primary Care Research in preventing and diagnosing cancer.
8. Review its smaller personal award schemes, with a view to aligning them with the rest of the UK, in order to avoid disparities.
9. Consider the longer-term outcomes and goals of the NRS Clinical Research Fellowship scheme with a view to increasing the capacity for research active clinicians within the health service.

Introduction

Cancer Research UK is the world's largest independent cancer charity dedicated to saving lives through research. We support research into all aspects of cancer: from exploratory biology to clinical trials, as well as epidemiological studies and prevention research. This is achieved through the work of 4,000 scientists, doctors and nurses.

In 2013/14, we spent around £34m on research in Scotland. We receive no Government funding for our research, however Government investment is critical to partnering and supporting our investment in research in Scottish universities and in the NHS.

Cancer Research UK funds a wide range of research projects in Scottish universities, as well as the Beatson Institute in Glasgow and the Cancer Research UK Formulation Unit at Strathclyde, which manufactures and prepares experimental anti-cancer drugs for clinical trials in the UK. In addition, we also fund the Edinburgh and Dundee Centres, which form a national framework to deliver world-leading research, improved patient care and greater local engagement.

We know that over the last 40 years, survival has doubled – today half of people will survive cancer. Our ambition is to accelerate progress and see three-quarters of people surviving the disease within the next 20 years. In order to achieve this, Cancer Research UK's ambitious new research strategy has committed to supporting and develop the very best researchers at all stages of their careers, continuing to discover and develop new therapeutics, surgery and radiotherapy treatments and optimising the chance of survival for every individual, through precision medicine approaches.

In drafting its health strategy the CSO should recognise areas of strength for Scottish life sciences including the collection and use of patient data, recruitment of patients to trials and the streamlining of regulatory processes. The strategy should recognise that the NHS is a uniquely valuable resource for medical research and an important asset to Scottish medical research. The CSO must ensure that the NHS is a research active health service to benefit both patients now and in the future.

Scotland must have a stable funding environment aligned to the rest of the UK, active patient participation in research, scope for international collaboration where relevant and the correct incentives to develop world-class clinical researchers.

Chapter Two - Partnership with Scottish Patients and the Public

Patient Participation in Research

All patients should have the opportunity to access relevant research studies. We know that cancer patients welcome the opportunity to participate in research. Evidence from the 2012 Cancer Patient Experience Survey in England found that 95% of respondents who had research discussed with them said they were glad to have been asked. Of those that were not asked, 53% said they would have like to have been asked. New methods to enable patients to participate more easily in future trials would therefore be welcomed by cancer patients while also benefiting clinical research. This can be achieved be promoting clinical research through mechanisms such as Cancer Research UK's CancerHelp UK (see below).

We support the requirement in the draft strategy that NRS Research Networks demonstrate evidence of public involvement, both in their work and through embedding patient involvement in their management processes. Public involvement helps to boost the accessibility of complex research studies to lay patients, design studies that take into account practical considerations for patients and inform research questions so that they are relevant to patients.

Having a metric for patient participation will also be useful in identifying which Trusts are most research active and incorporate patient participation. In addition, this type of involvement opens opportunities for people to contribute to research where they may not have been eligible to take part as a participant.

It is also important to acknowledge that all public involvement is not equal and does not necessarily represent the view of the wider public. There are difficulties, for example, with lay contributors becoming 'experts'. While such factors do not diminish the importance of the input, there should be sufficient flexibilities in guidance and minimal standards to take into account the potential variability of input and the context of the source.

The charity's Research Engagement Managers also have a role in informing and engaging others in our research through open days and lab tours. Senior Research Nurses are also heavily involved in this work. The CSO should ensure that it has sufficient resources and awareness to engage and promote the work of organisations such as Cancer Research UK.

The CSO should explore different methods for signposting patients to opportunities to participate in research. Cancer Research UK signposts patients through our CancerHelp UK clinical trials database[1]. Unlike trial registers, this database contains trial summaries that are written primarily for a lay audience. The database includes all types and phases of studies supported by a variety of organisations, including a growing number of pharmaceutical companies. There are currently over 500 trials listed and kept up to date with an average of 35,000 trial summaries are viewed every month.

The creation of a trials register requires a significant investment of resource to keep this database up-to-date. We are therefore unclear as to how this proposal relates to the UK Clinical Trials Gateway, a Department of Health project, of which the CSO is also a supporter. The UKCTG already links to CancerHelp UK's clinical trials database.

Recommendation One
Should clarify how this proposal for a Scottish trials database relates to the UK Clinical Trials Gateway. The CSO should avoid unnecessary duplication and cost of setting up its trials database where possible. Any information structure that is created should link to Cancer Research UK's CancerHelp UK clinical trials database for trials relating to cancer.

Trial Register and Patient Records

The capability for healthcare professionals to use eligibility criteria provided by research teams to search databases for suitable patients to inform them of upcoming research (e.g. a clinical trial) should be an essential component of a system. To work effectively this will mean that any GP systems will need to interoperate with one another, so that researchers (where appropriate) or healthcare professionals are able to have one single access point to data.

Recommendation Two
Enable GP data systems and cancer registries to be interoperable across Scotland and across the UK to enable one single data access point for healthcare professionals. The CSO should standardise R&D functions to reduce the need for trials to seek approval across the UK, but enable local flexibility on certain issues and for small-scale, single-centre trials.

It is essential that patients' interests are protected by proper safeguards on access to their medical records, however information stored in patient records is also a vital resource for research. Properly used this information will be the key to improving understanding and preventing cancer in the future.

The use of patient data collected in the NHS is crucial for population and epidemiology research, particularly in the context of large-scale national and international comparative research into

[1] CancerHelp UK database, available at: http://www.cancerresearchuk.org/cancer-help/trials/trials-search/

prevention, screening, early diagnosis of cancer and the secondary physical effects of treatment. Cancer Research UK's Population Research Committee provides project grants in this area, however, population studies rely on high quality data, often from cancer registries. These should aspire to match the data regime across the rest of the UK to ensure interoperability and ease for researchers.

Case Study – Cancer Registries

In the UK, regionally-based cancer registries have been collecting population-based cancer data for over 40 years. These registries are an example of how the collection and use of data has progressed and should continue to develop, in order to deliver on the promise of real time data.

The result of this is an invaluable resource for population researchers, which traces historic trends in cancer incidence and survival across the four nations. The UK cancer registries are global leaders, in terms of their comprehensiveness, their quality and the length of time over which they have been continuously working.

Cancer registries support a wide range of research. Examples include studies that benchmark UK health outcomes against the rest of the world, research into stratified medicine and large scale population studies, such as the Million Women Study that looks at risk factors for breast cancer.

Regulation and governance of Scottish clinical research

Cancer Research UK fully supports the efforts to improve and standardise the approvals process leading to faster set up and more efficiently run trials. Shorter trial set up times reduce the cost of undertaking studies to funders, reduce the regulatory burden on trials units and allow patients to participate in research sooner.

Although the principle of a Scotland as a 'single-research site' is helpful for large, population based studies, there is a need for research permissions also to work for smaller trials too. NHS permissions need to have an element of local tailoring to each host institute, but where possible common approaches should be taken at national (Scotland) level and across the UK.

We welcome proposals to streamline the Ethics Service and R&D, but care must be taken to ensure that the single integrated system shouldn't compromise the independence of the REC. For example, costing should not be part of influencing the REC decision, nor should it be influenced by scientific peer review or issues of resource allocation.

Research culture in the NHS

The CSO's proposals must adequately address the difficulty of incentivising specialists to participate in clinical trials. Although clinicians can benefit from the promise of career progression and the publication of their research in journals, these rewards are not available for 'co-investigator' staff that work under the lead researcher in facilitating and managing trials, or supporting services, such as diagnostic radiology for participating in research. There is therefore a challenge in recognising the work of these staff, and incentivising them to support clinical trials.

Cancer Research UK welcomes the appointment of Professor Cameron as Scottish Cancer Research Champion. Given that research is increasingly an international activity, the appointment of a Cancer Research Champion in Scotland will provide a useful link to the UK-wide research community and help facilitate access to wider patient populations for future studies.

Government's continued support for the clinical research environment is crucial and we wish to see it maintained and strengthened. The UK is world-leading in the number of cancer patients that participate in research: nearly 57,000 in 2012, 1 in 5 of all UK cancer patients[2]. Participation in research has dramatically increased since 2001, largely due to the formation of the National Cancer Research Network (NCRN) in 2001 and the National Institute for Health Research (NIHR) in 2006.

Cancer Research UK is a leading funder of clinical research in the UK, supporting around 250 clinical studies and providing core funding for seven Clinical Trials Units. Over 33,000 patients join our trials each year. Cancer Research UK's early and later phase trials are critically dependent on a strong research infrastructure in the NHS. Continuing the development of this infrastructure will be necessary to ensure that the UK can efficiently run clinical trials; attracting investment from industry and charities and providing innovative treatments to patients faster.

Cancer Research UK partners with the NHS in order to bring treatments to patients. Our Centres[3] drive local partnerships and high-calibre collaborations between universities, NHS Trusts and other cancer charities under a united strategy to accelerate the translation of research into the clinic. We also fund the Experimental Cancer Medicine Centre (ECMC) network[4] in partnership with NIHR and the Departments of Health in Scotland, Northern Ireland and Wales (see below for further details). The ECMC network provides the infrastructure for both academic and industry early phase clinical trials. Academic trials often receives support - in the form of free drugs and finance - from pharmaceutical partners.

Recommendation Three
Maximise the UK's investment in medical research by fully supporting the translation and uptake of innovative healthcare technologies. The CSO should highlight the importance of a research-active NHS and support the infrastructure needed to achieve this.

Children in clinical research

We are supportive of the CSO's focus on promoting childhood research. There are concerns that children and young people across the UK are not benefitting from access to clinical trials. A recent report[5] funded by the National Cancer Research Institute (NCRI), found that applying age restrictions to cancer clinical trials was 'irrational' and highlighted other studies which found these rules were 'barriers to inclusion', particularly in the case of recruiting teenagers and young adults into cancer trials. The research also found that trials designed with broader age limits resulted in more

[2] http://www.ncri.org.uk/wp-content/uploads/2013/11/2013-NCRI-CSG-prospectus.pdf
[3] http://www.cancerresearchuk.org/funding-for-researchers/how-we-deliver-research/about-our-centres
[4] http://www.ecmcnetwork.org.uk/
[5] Fern, L, Lewandowski, J, Coxon, K and Whelan, J (2014) 'Available, accessible, aware, appropriate, and acceptable: a strategy to improve participation of teenagers and young adults in cancer trials' in *The Lancet Oncology, 15 (8),* p341-350

teenagers and young adults going on clinical trials. Age limits on clinical trials need to be more flexible to allow more teenage cancer patients the chance to access new treatments. In light of this study Cancer Research UK now requires researchers to justify age restrictions on new studies, and is one of the first major cancer funders in the UK to do so.

Recommendation Four
Consider ways to improve access to clinical trials for children and young people in Scotland as recommended by the NCRI report.

Treatment Costs

Clinical research supported by Excess Treatment Costs (ETCs) enables close collaboration between UK academics and the pharmaceutical industry. Since 2008 Cancer Research UK trials have secured the support of over 50 pharmaceuticals which provided £240m of support for access to free drugs and educational grants for patients across the UK whose treatment would otherwise have been paid for by NHS budgets. This should be recognised as a saving, enabling the NHS to support trials that don't get pharmaceutical funding.

We also agree that a trial's Support Costs, such as the provision of research nurses, are another common reason that research is not funded across the UK. It is required that both ETCs and Support Costs of Scottish non-commercial research are subsidised in compliance with the 'Attributing the costs of health and social care Research & Development' (AcoRD) guidelines, which apply across the whole of the UK.

Recommendation Five
Continue to promote its support for excess treatment and support costs for research, to give the research community additional reassurance that their studies will be supported.

Chapter Three - Targeted Deployment of Resources and Infrastructure

Formalisation of infrastructure planning is to be welcomed, although this should be provided with a level of flexibility to reflect research activity in Scotland. By leveraging funding from various sources, researchers have the ability to draw on a range of expertise and infrastructure support. This in turn provides the best collaborative environment to do science and eventually deliver treatments to patients. Below is an example of a critical piece of infrastructure to early phase cancer trials.

ECMC Network
Established in 2007, Experimental Cancer Medicine Centres (ECMCs) are jointly funded by Cancer Research UK and Government funding through the CSO and health authorities in other nations. There are centres in Edinburgh, Dundee and Glasgow. The ECMC Network is a collaborative UK wide initiative, bringing the leading figures in early-phase clinical research together with world class infrastructure, offering patients across the UK access to innovative, new treatment options.

Since the establishment of the network, ECMC funded staff have helped to support over 2000 studies, notably early phase trials of new biological therapies and small molecules, with a majority of early phase trials sponsored by industry. To date over 150 companies have collaborated with the Centres. Currently the Centres fund over 175 staff (2011/12).

The quinquennial review of the Centres by independent international experts concluded that the ECMC network represented a world class asset for the UK and provided a unique driver for locating early phase cancer studies here.

Future infrastructure investment

One area that requires further consideration is stratified medicine. Tailoring treatments to individuals (stratified medicine) in all areas (surgery, radiotherapy and drugs) is an increasingly promising area of treatment. By providing the right treatment to the right patient at the right time it is hoped that patients receive the best possible treatment.

Furthermore, the results of molecular diagnostics research need to link through to service delivery. In order to deliver targeted treatments the effective molecular pathology services need to be developed in order to characterise patients or their tumour's genetic makeup so that the correct treatment can be delivered. The service needs to perform this in clinically relevant timescales and to a quality that will give confidence to clinical decision makers.

We welcome proposals for the creation of a network for the supply of tissue for non-commercial and industry research. In regards the forthcoming review of NRS biorepository opportunities and investments, effective discovery and development of markers to detect cancer earlier is dependent on the collection of high-quality samples from an early, generally pre-symptomatic disease stage.

Recommendation Six
There is a need for new cohorts of samples from healthy individuals, ideally collected sequentially and linked to clinical data. An effective biorepository infrastructure is essential for the collection, storage and provision of such high-quality samples.

In addition to investments in large scale infrastructure, it is also important for the CSO to invest in the services and staff to enable further research into stratified medicine programmes. Researchers have highlighted the pathology imaging of tissue samples to the required standards, for example.

Chapter Four - Working in Collaboration

International Advisory Board

We believe that an International Advisory Board would enable a level of scrutiny from clinicians and researchers external to Scotland and enable an unbiased look at the effectiveness of research and make recommendations based on expertise of best practice from other countries.

Recent research commissioned by Cancer Research UK has uncovered the extent to which funders of cancer research are interdependent, both nationally and internationally.[6] Data show that two thirds of research publications acknowledging external support have relied on multiple funders, while just under half benefited from overseas funding, and almost a fifth are also supported by industry.

[6] OHE and SPRU, 2014, *Exploring the interdependencies of research funders in the UK*

The activities and funding of the charity, public and private sectors are complimentary and mutually reinforcing, rather than duplicative or merely substituting for one another. This can be seen in the investment that Government funding leverages from both charity and industry sources.

Interdependency is not only financial; the differing skills and knowledge offered by funders lead to more productive collaborations and helps to ensure that funding is complementary. The benefits of interdependent funding models, both financially and in terms of scientific outputs, are demonstrated by the Farr Institute.

Case study: The Farr Institute

The Farr Institute of Health Informatics Research, which includes a node at the University of Dundee and supported by the CSO, aims to build health informatics research capacity, and conduct research into the linking of electronic health data with other forms of research. The development of further infrastructure to facilitate informatics research to support the Farr Institute – part funded by Cancer Research UK - is to be welcomed, and it is important that clear governance and data protection arrangements are in place

At a time when the volume of data available to science is expanding exponentially and challenging ethical questions are being raised about its use, the Institute is working to address key issues in health informatics research. These include governance, computer science infrastructure, public engagement, and training and education. It will support innovation in the public and private sector, leading to advances in preventative medicine, healthcare delivery and drug and diagnostic development.

Chapter Five - Investing In The Future

Primary Care Researchers

Overall cancer incidence shows a positive association with socio-economic deprivation[7]. Cancer Research UK is concerned that losing the driving force of enthusiastic researchers in primary care could in particular be counterproductive to improved early diagnosis and prevention outcomes in deprived areas.

Recommendation Seven
Protect the PCRCA, given the essential role of Primary Care Research in preventing and diagnosing cancer

Researchers in Scotland have warned that developing and supporting clinical scientists is challenging, and have called for a rethink of the ways in which clinical scientists progress upon completion of their PhD. There is agreement from the research community that while NRS fellowships have been helpful, their success criteria are unclear.

[7] 'Cancer incidence by socio-economic variation', available at: http://www.cancerresearchuk.org/cancer-info/cancerstats/incidence/socio-economic-variation/

Researchers have also voiced concern that the need for NRS Career Research Fellowship schemes, in which NHS consultants bid for dedicated sessions in which to undertake clinically-relevant research, is a direct result of service-focussed NHS consultant contracts and that there is no thought as to what happens to researchers that complete the scheme. Some have called for Fellowships to be built into future job plans for a minimum of five years.

Others have emphasised the importance across the UK of allocating time for clinicians to conduct laboratory research, in addition to clinical trials. It is unclear whether NRS CRFs accommodate laboratory research.

In our new research strategy, Cancer Research UK has committed to continuing to build a strong community of highly trained, innovative and world-class cancer researchers. The charity has pledged to provide support at all career stages to develop and recruit the leaders of the future. In particular, we have announced plans to support mid-career researchers through the launch of a new multi-year funding scheme, which will enable applicants to compete for full programme grants.

Recommendation Eight
Review its smaller personal award schemes, with a view to aligning them with the rest of the UK, in order to avoid disparities.

Recommendation Nine
Consider the longer-term outcomes and goals of the NRS Clinical Research Fellowship scheme with a view to increasing the capacity for research active clinicians within the health service.

For further information, please contact Policy Adviser Phil Reynolds (Philip.reynolds@cancer.org.uk) on 0203 469 5374