Scottish Government Chief Scientist Office Health Research Strategy 2014: Medical Research Council response to consultation

7 October 2014

Introduction

The UK Medical Research Council (MRC) is one of the main agencies through which the UK Government supports medical and clinical research. Our mission is to improve human health and support economic growth through supporting the delivery of world class medical research. For over 100 years, we have worked to improve the health of people in the UK and around the world by supporting the highest quality science. We fund across the biomedical research spectrum from fundamental laboratory-based science to clinical trials and population and public health research.

In Scotland, the MRC spent £80.6m on research in 2013/14. MRC funding supports collaborations with universities, charities, the private sector and other research councils and Government bodies, including three units jointly funded with the Chief Scientist Office (CSO):

- MRC/ Chief Scientist Office Institute of Hearing Research, Scottish Section
- MRC/Chief Scientist Office Social and Public Health Sciences Unit, University of Glasgow
- Scottish Collaboration for Public Health Research and Policy (part CSO funded) University of Edinburgh

MRC units and centres leverage significant additional funding from other sectors including UK and international charities; they collaborate effectively with the private sector to commercialise research findings; secure income from patent royalties and create spin-out companies and jobs. All of this helps to sustain a competitive environment for world-class medical research in Scotland.

We welcome the CSO's ambition to increase the level of high quality research conducted in Scotland, for the health and financial benefits of the Scottish population, and further the recognition of the need to balance new and promising research modalities with long-term stable support for existing high-quality research streams.

We also welcome the opportunity to contribute to the development of the Scottish Government's strategy on health research, and in particular to help ensure alignment between MRC and CSO, to ensure funding is complementary and maximises the value of investments.

In responding to the consultation document, we have answered those questions of most relevance to the MRC.

Chapter 1 – Efficient R&D Support for Research

Question 4: To what extent should the joint planning of the deployment of infrastructure resources be formalised? Should there be a formal record of such discussions?

Question 5: Taken together, will these steps to both free up and promote the availability of NRS resources address current concerns over lack of time and support? If not, are there other steps CSO should take?

Question 6: Are there any further changes that should be made to improve the efficient delivery of patients to studies through the NRS Networks and Speciality Groups?

NHS Research Scotland (NRS) has provided a very effective mechanism for delivery of research in the NHS and is clearly recognised across the UK as a successful approach. It is outside the MRC's remit to comment on the detail of NRS structure and management, however, we welcome the recognition of the need for greater effort to ensure resource is deployed as intended to support research activity, and ensure optimal value for CSO in delivering its core aims. Regarding proposals 1.15 and 1.16, we support efforts to ensure protected time for research and promoting transparency as to the use of allocated research funds. In addition, consideration could be given to ring-fencing time in staff contracts for research; including research in job descriptions and annual reviews; and looking to engage NHS staff who may have little knowledge of research by including research in basic training.

Chapter 2 – Partnership with Scottish Patients and Public

Question 8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?

The MRC has a long-standing interest in the development and implementation of clinical trials, and is a major funder of academic clinical trials in the UK and internationally. We would support initiatives that aim to increase participation in clinical trials and better match patients with available trials, and thus broadly welcome the proposals for a trials register.

For many years the MRC has required MRC funded trials to be registered, and has strongly supported the position that clinical trial outcomes must be published in a timely manner, and that data should be appropriately shared to maximise the value of the data for research and for eventual patient and public benefit. As well as promoting transparency, clinical trial registries have an important role to play in facilitating and allowing monitoring of data sharing.

CSO should consider how any Scottish Clinical Trials Register would work alongside existing similar initiatives, such as the UK Clinical Trials Gateway, and how it would be promoted to researchers, healthcare professionals, patients and the general public.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible be a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

Using clinical systems presents an apparently ideal opportunity to alert patients about trials in which they might wish to participate. However, it is difficult to properly assess the proposal in the absence of further detail. At a minimum, it would need to be within an ethically robust framework to ensure patients are given time to make fully considered decisions about whether to participate in a trial, considering the potential risks and benefits. Care will be needed to ensure the invitation process is managed securely to protect patient confidentiality and that any incentives for recruitment do not pressurise

patients into participation. It would also be important to ensure the new system does not build in and exacerbate bottlenecks. Patients should also be given the option to opt-out of being invited to clinical trials. We would suggest consulting further with clinicians and patients to determine their preferences, including whether patients would prefer to be contacted initially by their doctor or a researcher, and clinicians' views of any impact of the proposal on the doctor-patient relationship.

Chapter 3 – Targeted Deployment of Resources and Infrastructure

Question 10: What proportion of CSO funding should be available for deployment in new research initiatives relevant to the NHS? In what areas should CSO seek to disinvest to free up resources?

We would support the need for regular review to ensure funds are deployed in the most efficient and beneficial manner to improve health. Although having a flexible resource to support emerging areas of strategic priorities and novel technologies is important, we would emphasise that it is also important for CSO to continue funding those initiatives that are performing well, as continuing support is essential to capitalise on the research and investment that has already been made. Studies have shown that the time lag between research expenditure and eventual health benefits is around 17 years (15 years for cancer research). This highlights the criticality of long term sustained underpinning investment in research[1].

Further, we suggest that any interrogation of the current research portfolio should be carried out in consideration of the broader context of national and international activity. Focus on a few key areas may help with economies of scale and, in consideration of the broader national and international landscape, could avoid duplication. As the CSO moves to further increase its partnership working, it may be that a focus on emerging priorities and technologies could be achieved through new partnership arrangements that do not require substantial disinvestment of current funds.

There is also a need for balance across the research portfolio - in terms of support for infrastructure, people and research costs. In seeking to free up resources for new initiatives, the CSO should also review this balance.

MRC's support for experimental medicine across the UK builds on investment in clinical research infrastructure and personnel from the UK's health departments. CSO might wish to review whether current investment is optimal to take advantage of MRC funding available for experimental and stratified medicine.

Question 11: Is the focus of the CSO response mode grant schemes adequately defined and understood by the research community? Should there be a narrower focus to complement and avoid overlap with other funding streams Scottish researchers have access to? What is a realistic upper level for CSO grants to allow worthwhile projects to progress?

It is important for the CSO to understand from their community how well the funding streams are considered, and identify any perceived gaps. The level of overlap should be considered with other funders and the CSO may want to avoid direct competition where possible, especially if considering a new funding stream. Ideally, CSO's funding schemes

[1] Health Economics Research Group, Office of Health Economics, RAND Europe. Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK. London: UK Evaluation Forum; 2008 http://www.mrc.ac.uk/news-events/publications/medical-research-whatsit-worth/
Estimating the returns to UK publicly funded cancer-related research in terms of the net value of improved health outcomes *BMC Medicine* 2014, 12:99 http://www.biomedcentral.com/1741-7015/12/99

should complement funding available through private, other Government and charitable providers. A degree of overlap is inevitable and should not be considered problematic, as it reduces the possibility for projects/areas of research to fall between funding gaps.

Determination of an upper level for CSO grants should take into consideration the breadth of portfolio, duration of funding, and availability of other sources of funding. Raising the upper level, for example to a level sufficient to cover large clinical trials, would reduce the number of projects that can be funded. Ultimately, the level of funding considered appropriate should be linked to the niche/area the CSO wish to fund.

Question 12: What should determine the creation and continued funding of a CSO unit? Should any new unit have a plan for CSO funding to be time limited?

As noted above, the MRC has three Units jointly funded with the CSO, and we value the collaboration highly.

The creation of a Unit should be backed by a 10-15 year strategic vision, and a long-term commitment to fund to meet an identified need. This does of course not preclude regular reviews to ensure the Unit is meeting desired levels of impact, but the initial intention and vision should be long-term and in our view there should not be a pre-determined time limit.

The Unit funding mechanism should only be used:

- where there is a long-term strategic need that cannot be addressed through more conventional forms of grant support, for example through long-term project or programme grants.
- where there is a need for strong scientific leadership (delivered through a Unit Director) built on a critical mass of academic expertise
- when the challenge requires an integrated and well-coordinated approach across a number of cognate disciplines
- where there is likely to be a requirement for agility and reprioritisation of scientific aims during the course of the award. In our view Units can also have a useful role as a vehicle for capacity building and training
- to promote translation, dissemination and application of research findings and as an authoritative source of advice and guidance on scientific matters

Funding of Units should only be continued if:

- the Unit continues to deliver cutting edged research as judged by regular international peer review
- the impact of the Unit's research is at least on par with other mechanisms of support
- there has been an appropriate return on investment in terms of intellectual and financial leverage; the scientific impact of the unit as a whole is greater than the sum of its constituent research programmes
- the Unit has fully discharged its mission and has shown agility in addressing emerging scientific or policy issues

If at the regular review it is determined that there is no longer a strategic need or a Unit is not meeting its aims, then it is important to consult with the Unit and any other funding partners to agree a wind-down period sufficient to allow valuable research projects to find other sources of funding.

Additional comments on proposal 3.15 A review of the NRS Biorepository opportunities and investments will be conducted in the course of 2014–15

We share the CSO's view that there is a need to maximise use of tissue resource through efforts to match resource to expected demand. The UKCRC Experimental Medicine Funders Group, which includes CSO and MRC, has adopted a vision for funded collections of human tissue and biosamples to: '*…maximise the value of human tissue samples and resources while minimising duplication of effort. This requires better characterisation of tissue samples…and increased linkage to accurate clinical data. Sample collections must then be made more easily discoverable and accessible for use in high quality, ethical research'.*

The CSO review should take account of the UKCRC Experimental Medicine Funders Group project, due to start imminently, which aims to make collections discoverable and improve harmonisation of collection and storage of samples across academia, the NHS and industry[2]. The partnership of funders will support a UK Centre that will:

- Develop a prototype and deliver a functional Resource Finder/Directory to enable researchers to discover, search across and contact multiple human tissue and biosample collections via a unified interface (taking account of existing systems) in order to facilitate sample access. The Centre will be expected to provide an evaluation of the system, in terms of usability, effectiveness in providing the ability to locate relevant samples, a demonstration of the benefits of the chosen approach, and an appraisal of potential options for a second phase of development, for example with increased metadata content and functionality;
- Provide coordination and guidance to increase harmonisation of standards across the entire biosample lifecycle;
- Build and manage engagement between researchers, biosample collections, the public, regulators and policy makers supporting evidence-based approaches to best practice in sample collection, governance and public engagement.

Additional comments on proposal 3.16: A review of the NRS Safe Haven opportunities and investments will therefore be conducted in the course of 2016-17.

We likewise welcome the CSO's focus on health and bio-informatics research, which is a strategic priority for the MRC. In the past two years we have invested over £100 million supporting research, infrastructure and building capacity in interrogating, analysing and linking large and complex health datasets. These initiatives include establishing the Farr Institute of Health Informatics Research, a collaboration with the CSO and others.

Our investments are underpinned by policies that both encourage data sharing and aim to safeguard the privacy and confidentiality of personal information held within these data and associated biological samples. It is vital that the public feels confident that any personal information used in research will be treated with respect and handled in secure environments that protect their privacy. At the same time, the management and control of any "safe havens" should also be risk-proportionate to prevent unnecessary delays or barriers to research activity. There is a compelling need not to introduce unnecessary or disproportionate barriers to the conduct of medical research, as highlighted in the Academy of Medical Sciences Report on Regulation and Governance of Health Research[3].

For more than 60 years, MRC-funded researchers have been managing and linking large health-related datasets that include personal information and, latterly, biomedical samples, and this work has led to significant public health and medical advances.

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[2] http://www.mrc.ac.uk/funding/browse/ukcrc-joint-funders-tissue-directory-and-coordination-centre/

[3] http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf

In recognition of the changes in the data protection landscape within the UK we have an ongoing dialogue with the Academy of Medical Sciences (AMS) and other research funding partners to further develop the principles for legal and ethical data use by accredited researchers within trustworthy research environments. Further, the MRC is aware of several other current initiatives exploring how personal and confidential information should be handled across the NHS, wider government and for research. We urge the CSO to ensure any governance and inspection arrangements flowing from the review align with these, as otherwise there may be potential confusion amongst data users, with a consequent risk to confidentiality.

Chapter 4 – Working in Collaboration

We applaud the draft strategy's focus on improving linkages and collaboration, and the CSO's plan to work in partnership where possible. The MRC's Strategic Plan 2014-19 notes that "partnerships are essential to bring the benefits of our research to people" and outlines plans to build on and expand relationships developed with industry, the National Institute for Health Research (NIHR) and health departments in the devolved administrations, the Department for International Development, medical research charities, universities, research councils, and the international community, in order to secure the impact of our research for the future. Similarly, the CSO's plan to increase partnership working with these stakeholders is welcome and has the potential to deliver the strategic priorities outlined in the Scottish Government's *'Health and Wealth in Scotland: a Statement of Intent for Innovation in Health'.*

Alignment with industry in research, training and translational investments is at the heart of the MRC's strategic and delivery plans; we are committed to developing and sustaining a wider range of close and productive partnerships with industry in the UK.

Question 13: Are there other key areas of partnership CSO should be seeking to build?

We note the CSO's recognition that partnership with the medical device and biotech sectors is less well established. The CSO clearly has a number of strong strategic partnerships with industry and good links with the ABPI; it will be important to build on these existing relationships and broaden to the bioindustry sector. Linkage with the BioIndustry Association will be important in this regard, while engaging more closely with the SME community will help broaden and drive innovation.

Given the CSO's stratified medicine and biomedical informatics objectives, partnership with the diagnostics and informatics industries will also be important. While diagnostics might be implicitly covered by the reference to medical device companies (in vitro diagnostics being a sub set of EU medical device regulation), making this goal more explicit could be helpful.

Question 14: Would the creation of a CSO International Advisory Board be a positive step in raising Scotland's research profile and supporting our ambition? What should be the make-up of such a Board?

The creation of an advisory board could have real benefit, providing that there is a clear remit and appropriate membership. Its make-up should not be exclusively academic but should also include representation from Government and industry.

Chapter 5 – Investing in the Future

Question 16: Is the Primary Care Research Career Award scheme suitably focused to attract suitable high quality applicants? If not, what would a revised focus be?

It is difficult to comment on the Primary Care Research Career Award scheme as up-to-date information does not appear to be available on the CSO's website. We broadly support the aim of promoting research within the primary care setting but we note that primary health appears to be covered within the existing, broader-remit schemes. Therefore, in order to attract additional applicants, this scheme would need focussed aims in terms of both distinct research areas it wishes to support and career stage.

Question 17: Are the current CSO personal award schemes targeted to meet our future needs? If not, should CSO conduct a wider review of its capacity building schemes?

The CSO's focus on supporting early-to-mid career researchers at critical career steps would seem targeted to meeting future need, but we would support the need for regular review of this alongside other available personal award schemes to confirm whether strategic needs are being met and whether there are any skills gaps that need to be specifically targeted. Consideration should also be given to reviewing the balance between salary and research/consumables costs, as currently the focus appears to be on supporting salary costs.

Additional comments on proposal 5.15: We therefore plan to publish the health and bio–informatics research strategy in 2014, and then move quickly to implement its key recommendations, so that the benefits of a more efficient system of governance and a strong, flexible federal network of safe havens begin to flow as soon as possible, and the returns on the investment in the e-HIRCS, Farr, ADRC and national data linkage service are maximised.

Further to our comments around proposal 3.16, we would welcome the development of a health and bio–informatics research strategy and governance arrangements harmonised with the rest of the UK.

The MRC has identified the following key principles for health and bio-informatics research:

- To build public confidence in medical research and researchers, in particular in relation to consent and confidentiality of personal information
- To help create a legal and regulatory framework that promotes and enables excellence and innovation in research while taking a proportionate approach to the risks to people and the research process
- To promote a research culture that recognises and rewards 'sharing' of research information
- To promote and enable collaboration for research across disciplines and between academia, government departments, industry and regulators
- To strengthen transparency, so that sources of research data and tissues can be 'discovered,' assessed for their potential for new research and accessed efficiently.

Additional comments on proposal 5.17: CSO will therefore fund a £ 1.2m NHS Stratified Medicine Applied Research Programme designed to evidence the value of adopting a stratified approach. Focused on evidencing the value of existing yet unadopted stratified approaches, rather than seeking to develop new ones, we anticipate that it will provide

the health economic evidence base for the subsequent adoption of the technology or process.

The question of overlap is relevant to this proposal. While generating the evidence base required to support the evaluation, commissioning and adoption of stratified medicine is critically important, consideration might helpfully be given to how the proposed support is distinct from that offered by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) HTA programme[4], which is open to Scottish researchers.

It should be noted however that, even if there is overlap, the proposed call could help stimulate activity in this field in Scotland, which could be of strategic value to Scotland. Experience from the MRC's stratified medicine consortia shows that industrial partners are impressed and attracted to teams who are tackling health economic issues within their consortia, as these issues are critical to industry and not often tackled by academic groups. Promoting this skill set in Scotland could therefore help further both the CSO's stratified medicine and collaboration goals.

[4] http://www.nets.nihr.ac.uk/programmes/hta