



Delivering Innovation through Research - Scottish Government Health and Social Care Research Strategy





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FOREWORD



In the six years since the Health and Healthcare Research Strategy “Investing in Research, Improving Health” was launched, we have seen a number of significant developments in the area of health research.

The dual role of the NHS in supporting the health and wealth of the population has never been more apparent or important. Health research is one of this country’s key strengths, and it is essential that we utilise this national resource to the fullest.

This document sets out our ambition for the next five years and how we can support Scotland to be renowned as a health science nation on the international stage.

I am pleased at the progress we have seen in NHS Research Scotland, both in terms of delivery and its ethos of partnership working. Colleagues in industry speak highly of the spirit of collaboration that exists and value the business-like approach to the management of a complex research environment. Having invested significantly in infrastructure posts over recent years, we now move to focus more clearly on delivery for that investment. This document sets out the next steps in this ambitious programme.

Equally ambitious is our plan to enhance our informatics capacity and capability. Perhaps the single biggest change since the publication of the previous Strategy has been the recognition of the importance of utilising NHS electronic data for research purposes. Scotland already leads the world on this front and we must remain in that enviable position. What is initially done

through research frequently informs the patient care of the future, and I am determined NHSScotland works in partnership with academics and industry to harness the full potential of health informatics to drive up quality, effectiveness and safety of health care. Ensuring Scotland remains at the forefront of new technologies is critical if we are to deliver an NHS that is both effective in delivering high-quality care, and efficient with limited resources. Informatics and personalised medicine are key to this ambition, and I am determined that, through research, the NHS will evidence the value of these new technologies.

Taken together, the aims in this document set out an ambitious agenda for change. They will require new ways of working and a new approach to how we go about our business. That is why we have called the new strategy “Delivering Innovation through Research”, recognising the key role research has in the identification and adoption of innovation. I am committed to supporting the Chief Scientist Office in achieving these aims. Since its creation 41 years ago, CSO’s role in that process remains of critical importance.



Ms Shona Robison MSP
Cabinet Secretary for Health,
Wellbeing and Sport

PREFACE



The vision of CSO is to support and increase the level of high-quality health research conducted in Scotland for the health and financial benefits of our population, so that Scotland is recognised globally as a “come to place” for health science.

“Delivering Innovation through Research” aims to provide clarity and coherence on what we need to do to achieve this vision, and identifies key areas where we can and should make a difference. In doing so, however, it is important to recognise the wider context of the research landscape. Our 2020 Vision for health and social care is that everyone is able to live longer healthier lives at home, or in a homely setting, supported by sustainable high-quality health and social care services in Scotland. Securing that vision remains a central theme of the Quality Strategy, but we are also looking to a longer horizon and have started a national conversation with the people of Scotland on the future of health and social care over the next 10 to 15 years. Research has a key role to play in supporting the delivery of that vision and in our planning for the longer term.

Looking forward in this context, we have identified six guiding principles that we believe will help maintain Scotland’s position at the forefront of health research internationally:

1. Build on the strong science infrastructure that exists across our Universities in Scotland;
2. Deliver collaborative partnerships with a tripartite mission of research, education and delivery of quality health care and public health improvement;

3. Exploit our ability to link information from health, social care and non-health sources using data to support better treatment, safety and research;
4. De-clutter the pathway for the regulation and governance of health research by taking a proportionate and streamlined approach to research governance;
5. Deliver collaborative arrangements with the biotechnology, pharmaceutical, informatics and medical devices industries;
6. Position Scotland as a single research site when it makes good sense to do so.

Since taking up post as Chief Scientist I have been impressed by the range of research activities funded or co-ordinated through the Chief Scientist Office. To seek to progress them all with equal vigour would be beyond our means and indeed impractical for a country of our size.

This Strategy therefore focuses on four key areas for action that we feel will make a real difference to delivery, and will lend direct support to the guiding principles.

In addition I would like to emphasise the use of data and its contribution to health research in Scotland. Informatics is key to making the provision of high-quality health care sustainable, perhaps the biggest challenge facing all healthcare providers and governments in the next 20 years.

It is just over 40 years since the first Chief Scientist Sir Andrew Watt Kay described CSO in the Health Bulletin as “a partnership within which science will have more influence on the Government’s central policy-making activities than before, and which will contribute more directly and more effectively to the task of making the best use of science and technology for the needs of the community as a whole”. We believe that ambition of making best use of science is even more relevant now. “Delivering Innovation through Research” is therefore an important statement of ambition as we seek to improve health outcomes and support the improvement of NHSScotland over the next 40 years.



Professor Andrew Morris FRSE FMedSci
Chief Scientist Health

INTRODUCTION – OUR NATIONAL AMBITION



Scotland has a proud heritage in the field of health research. Our previous Strategy set out our ambition of placing Scotland at the international forefront of clinical translational research and the development of systems medicine. That ambition is a reminder of how quickly the research landscape can change, with Precision Medicine and Informatics widely seen as the new areas where we must compete to be globally competitive.

This strategy anticipates a future where outstanding health science research is embedded within health systems as core business, generating new knowledge based upon a myriad of qualitative and quantitative evidence. It anticipates a future where clinical information and samples are integrated with informatics of individual genomes and other ‘omic’ datasets, eHealth records, imaging datasets, and personal health data to enable individualised therapy, and improved patient outcomes. It anticipates a future where the NHS, patients, universities and business work closely together for mutual benefit.

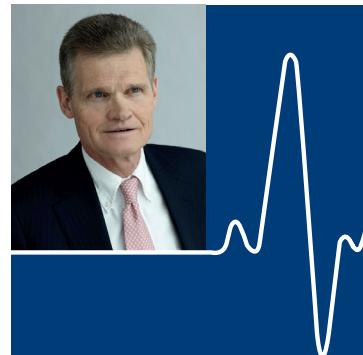
We already have much to be proud of. Scotland already attracts over 30% more of UK public research funds than our population share would suggest, but we want to do better.

The ambition of this Strategy is therefore to increase the level of high-quality research conducted in Scotland, for the health and financial benefits of our population. The Strategy focuses on four key areas that underpin success in the conduct of current and future research, aimed at supporting research across a vast number of disease areas. Our patients and public rightly expect a focus on their needs as well as the ambitions of our research community. While CSO will continue to support new and promising research modalities, it is essential to the long-term sustainability of our ambitions that opportunities exist for all high-quality research to be supported.

This Strategy identifies four areas critical to our future success:

1. Efficient R&D Support for Research
2. Partnership with Scottish Patients and the Public
3. Targeted Deployment of Resources
4. Investing in the Future.

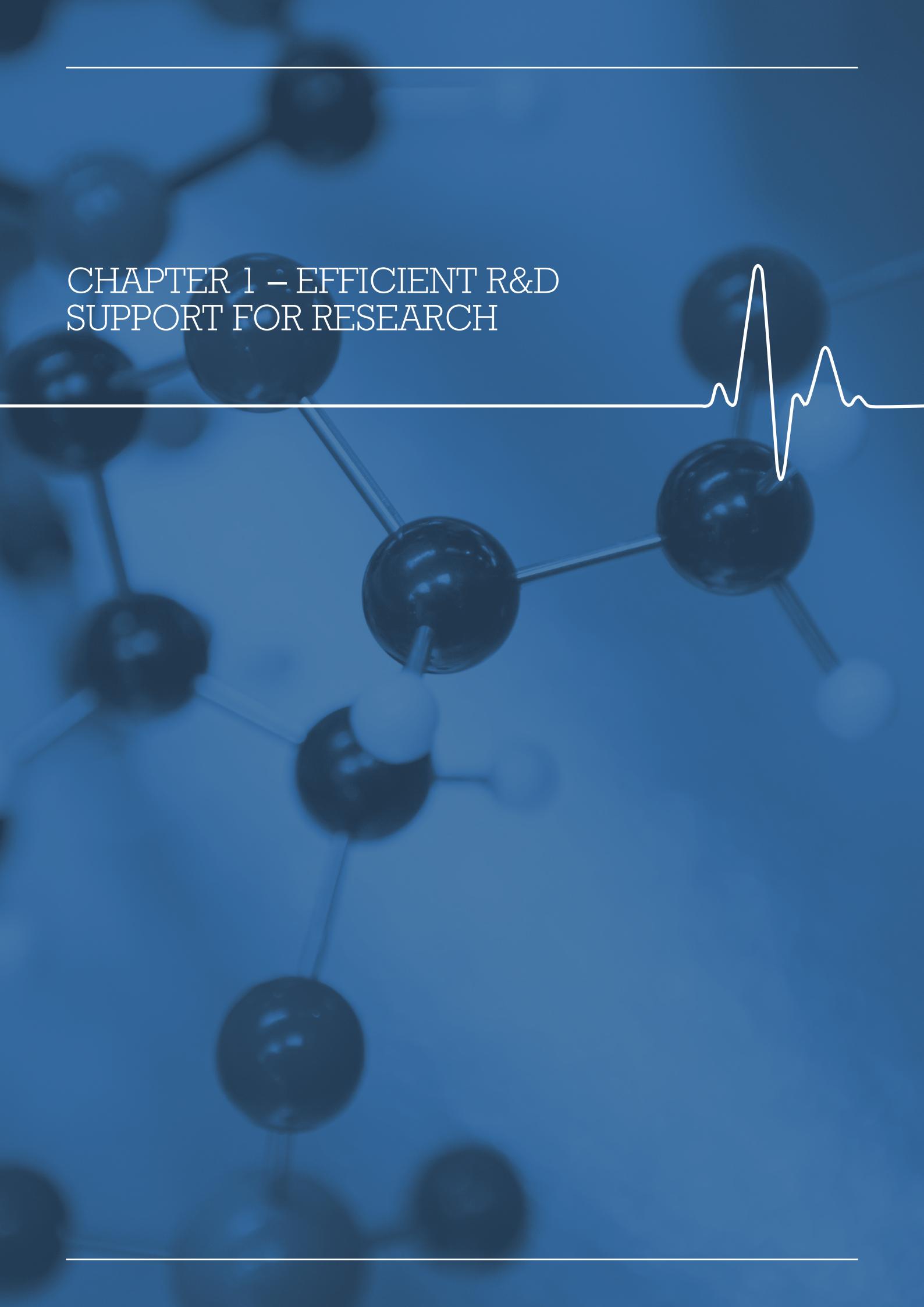
Each of these areas are critical to realising our national ambition. Working in collaboration with others is a theme that already applies across all these areas, and is one that we will build on as we deliver beneficial change over the next five years.



“Scotland’s Health Research Strategy reflects the considerable strengths of the medical research community in Scotland. The programme of research activity has generated outstanding outputs over many years, and this new strategy will ensure its continued productivity. Importantly the health science program in Scotland complements that in the rest of the UK, creating a powerful internationally competitive programme.”

Professor Sir John Bell – Regius Professor of Medicine, University of Oxford.

CHAPTER 1 – EFFICIENT R&D SUPPORT FOR RESEARCH



The background of the slide features a blue-tinted photograph of several molecular models. In the center, a model of a molecule with four spheres and connecting rods is visible. To the right, a line graph with a prominent peak and some smaller fluctuations is overlaid on the image.



It is critical to the success of our national ambition that research in Scotland is supported by efficient structures in the NHS – both for R&D governance purposes and for ethical approval. Since the publication of the last strategy NHS Research Scotland (NRS), a partnership between Scottish Health Boards and CSO, has continued to deliver efficient and prompt approval for study start-up. Further, the last few years have seen even greater efficiencies with the introduction of a single costing for all studies – commercial and non-commercial – now in place. As a consequence of this business-like approach, significant interest and support have been expressed from industry. This is evidenced by the strategic collaborations with some of the world's largest clinical trials contract research organisations and pharmaceutical companies. In the area of research ethics, our REC approval times remain among the fastest in the UK. It is our ambition to build on this success and deliver even greater efficiencies.

Management of NHS Research Scotland Activity

Central to the NRS ethos is working on a pan-Scotland basis. NRS operates in four regional nodes, with oversight and strategic direction achieved through the NRS Strategy Board that meets monthly to progress issues of relevance to the overall operation of NHS research in Scotland. The success of NRS relies substantially on the close working relationship between the Health Board R&D staff and CSO. This is a defining characteristic of NRS and it works well.

However the burden of managing NRS activity within the NHS falls disproportionately on the four nodal R&D Directors, and the successful delivery of NRS and CSO policy through them is critical. Having national R&D Directors of the appropriate standing and commitment is vital to its future success. It is therefore important to clarify both the key responsibilities of these national posts and the expectations on their successors.



"Excellence in clinical research requires having the right design, the right process and the right data to build evidence that can answer the right questions. NHS

Research Scotland (NRS) is developing the right research environment for our members to achieve this excellence in Scotland. ABPI companies welcome the leadership from the CSO in building a collaborative approach with industry to make this happen, and we welcome the significant improvements in approval times for commercial trials."

Dr Virginia Acha – ABPI
Executive Director of Research,
Medical and Innovation

CSO currently spends approximately £2m annually on R&D Office staff across Scotland. This is a significant investment of public funds. CSO allocates funds for this function based on the level of research each Health Board is undertaking, but currently allows complete flexibility in deploying those funds. Given the need for the R&D function to fit with different Health Board structures and scales of activity, central definition of all NRS posts would be counterproductive. Nonetheless there is a strong case for key functions to be delivered in the same way across different Health Boards, strengthening the Scotland wide nature of the services. The move to nodal staff taking on national functions for R&D permission makes the consistency of the delivery of those functions to national standards all the more important.

Action

1. CSO will define the job description of a nodal NRS R&D Director and become formally involved in the recruitment of new appointments to these posts.
2. CSO will define the functions of key NRS posts, particularly where they provide a nodal or national function. CSO will also more closely define the NRS services to be delivered locally and the associated delivery targets, but will not normally determine the grading or detailed functions of posts delivering those services.



NRS has operated well through the current system of generic issues being determined once on behalf of Scotland. However if we are to efficiently support the increased commercial activity being attracted to Scotland,

and use management information more effectively to drive improvements, further evolution is required.

From October 2014 CSO has therefore funded the NRS Central Management Team (NRS CMT) to provide greater co-ordination and oversight of national NRS functions. In a rationalisation of national functions to deliver efficiencies and declutter the Scottish research landscape, the NRS Industry Manager post, and another post to support partnerships of medical universities and their Health Boards in the field of clinical and translational medicine, have been relocated to the NRS CMT.

The successful delivery of these functions through the CMT is critical to the success of NRS.

Action

3. CSO will undertake a formal review of the NRS Central Management Team in April 2016 in order to ensure it is optimally delivering on its functions.

Management of NRS Investments

At the core of an efficient NHS R&D management system is close collaboration with NHS and academic researchers. While the strategic investments referred to in Chapter 3 are designed to meet national need and bridge some of the gaps between NHS and academic investment, most of the funds deployed through NRS are designed to ensure either that NHS researchers have the time to undertake research for the benefit of our patients, or the necessary NHS staff (e.g. nurses) are available to support that research.

Even though these investments have been ongoing for a number of years, not all researchers are aware of the significant investments in staff and researcher time to support their work. Feedback from our Networks and Specialty Groups also indicate a concern that resources will not always be available to support studies. As a consequence there is a risk that studies may be declined in the belief that the required support will not be available. It is therefore critical that the Health Boards regularly assess with their NHS and academic researchers how well the deployment of the funds meets their needs in terms of providing the necessary NHS support for all eligible studies.



"As a researcher leading a number of multicentre studies,

I can see how the infrastructure investments made through NHS Research Scotland have transformed the environment in which research is conducted. By allowing a significant degree of flexibility in the deployment of its resources, CSO has facilitated investment targeted on areas of local expertise while maintaining an effective national infrastructure for the co-ordinated delivery of studies."

Professor David Newby – British Heart Foundation
John Wheatley
Professor of Cardiology

Promoting these investments within the research community, and publicising CSO's condition of grant that the first call on the use of those funds is supporting eligible research, is an activity that may not have been afforded sufficient priority in the past. CSO also needs to ensure resources are deployed where the need exists.

Action

4. CSO will require that all Health Boards take adequate steps to promote the availability of resources to support research.
5. CSO will require formal consultation and joint planning of NRS Infrastructure investments with partner universities and NRS Network and Specialty Group leads as a condition of funding.

These steps, alongside the intention to make infrastructure funding fully activity based from 2016, will make the link between the research activity and the infrastructure allocated to support it more transparent.

One of the main barriers to undertaking more research is the availability of clinician time. Although CSO allocates £12.7m per annum to Health Boards through the NRS Researcher Support budget to meet the time of staff conducting research, how this funding is used to "buy out" researcher time is not usually understood by researchers. Although in recent years a number of Health Boards have taken steps to allocate this funding to clinical departments in line with research activity, in others it remains embedded in the wider NHS allocations and is not identifiable as a research resource, or managed by R&D Offices as such. CSO intends freeing up this resource so that it is fully deployed transparently supporting research activity.

Action

6. By the end of 2015 CSO will require the submission of proposals from Health Boards on how the NRS Researcher Support funds will be pro-actively managed and allocated for researcher time and associated activities by their NRS R&D Directors, from April 2016. Access to the NRS funding schemes will be conditional on CSO agreement to the Health Board proposals.

Management of NRS Networks and Specialty Groups

During 2013 CSO consulted on changes to the NRS Topic Networks and Specialty Groups to improve their impact on clinical research in Scotland. The consultation identified a wish on the part of the community to retain the current Network and Specialty Group structures but recognised a need for closer engagement between these groups and the underpinning NRS Infrastructure. Changes were made to deliver closer working in 2014-15.

Strategic oversight at a Scotland level is also required to ensure that the planned improvements in performance are delivered. To that end a new post has been appointed within the NRS Central Management Team to supply CSO and the NRS Boards with regular reports on progress. Additionally, CSO will hold regular meetings with Network Leads throughout the year at which performance against national objectives will be discussed. Taken together these changes, alongside the new joint planning proposal, should ensure that all eligible studies in Scotland have operational oversight of delivery and an escalation procedure to resolve problems.

Action

7. To ensure that the Networks and Specialty Groups remain the most efficient way of supporting our research activity, CSO will review the success of these revised arrangements in the second half of 2016.



"The Scottish Diabetes Research Network (SDRN) works to improve the quality and increase the quantity of Diabetes research in Scotland. The funding provided by CSO since 2006 has allowed the network to achieve this aim. CSO has supported the network in its development of innovative initiatives such as the Diabetes Research Register. The SDRN has benefited from the NHS Research Scotland infrastructure when engaging with potential commercial partners. This has led to notable successes including: the First Global Patient in a Sanofi study; First Global Patient for the IMPERIUM Study, lead UK recruiters for NOX, DEVOTE and LIXILAN-O studies and top recruiters for CARMELINA. Finally, the SDRN- Primary Care Initiative won the Diabetes UK award for service improvement in primary care for 2015."

Professor Rory McCrimmon
– Scottish Diabetes Research Network

The Research Ethics Service and NHS R&D Systems

A distinct feature of the Scottish research landscape is the close working between the NHS Research Scotland Ethics Service and the Health Board R&D Offices. This relationship, along with the appointment of ethics Scientific Officers, has removed some of the artificial barriers between these two functions and streamlined the process of obtaining the necessary approvals for study commencement. However it is imperative that Scotland continues to lead the agenda on streamlining the approvals process and reducing bureaucracy; and there is scope for further improvement.

A high percentage of ethics submissions across the UK receive a provisional opinion, requiring the submission of additional information and further ethics consideration before a full opinion is forthcoming. Many of these resubmissions could be avoided by the provision of advice to researchers prior to their submission of documents. Similarly in R&D permission early contact with, and support for, researchers can significantly reduce delay later on in the process. However much activity is focused currently on gatekeeping rather than assisting researchers, driven by the Research Governance Framework which focuses on responsibilities rather than outcomes. CSO believes that through the provision of early advice supported by a revised Research Governance Framework that recognises the importance of facilitating good research, greater efficiencies will be forthcoming in the handling of applications.



Action

8. CSO will seek to combine the Scottish Research Ethics Service and NRS R&D Offices into a single integrated service for researchers while retaining the independence of the REC decision making function.
9. CSO will arrange for shared access to study data for ethics and R&D staff through the Health Research Authority HARP database, streamlining access to electronic documents for R&D staff throughout Scotland.

Action

10. CSO will refocus the early contact of ethics and NHS R&D staff with researchers on facilitating study approvals, with named R&D contacts being given to support the researcher in obtaining those approvals.
11. CSO will work with the HRA to revise the Research Governance Framework and implement an efficient ethics and R&D permission system across the UK that both builds on the efficiencies already delivered through NRS and operates seamlessly for sponsors and researchers across the UK.

NRS Relationships and Academic Institutions

Scotland has a close relationship between its Health Boards and academic institutions, at a strategic as well as operational level. Joint offices are common and are to be commended. Routine co-sponsorship of research is a good example of the two organisations working closely together for the researcher's benefit.

However the prominence given to local collaborative working and systems in some websites gives the impression that R&D permission is a local function operating to local arrangements, rather than to a nationally determined set of documents and standards. As a consequence researchers are not always aware of the services they should be receiving or how NRS systems operate with other Health Boards, or NHS Trusts in England, to streamline multicentre studies. Further, some of the NRS strategic investments are not always identified as such, with the associated expectations of CSO not always understood by those seeking access to those resources.

Action

12. It is proposed that the NRS website will be the portal through which researchers access relevant information on NRS resources and services, with local sites being linked through that portal. This will greatly improve understanding of the national NRS systems, infrastructure and service standards that NHS R&D Offices deliver through NRS funding.

CHAPTER 2 - PARTNERSHIP WITH SCOTTISH PATIENTS AND THE PUBLIC



The Scottish public are at the heart of clinical research, both as healthy volunteers participating in early stage studies and as patients benefiting from improved diagnoses or treatments. Without patients enrolling to take part in clinical research, very little of the research conducted in the NHS would be possible. The insights and views of patients, carers and relatives are also immensely useful in ensuring the successful delivery of well-designed, scientifically valid research that has relevance to the people of Scotland.

CSO Public Engagement Group

Since 2001, CSO has involved the public in both grant funding and policy areas. We acknowledge that the CSO Public Engagement Group (PEG) plays a key role in representing the public's interest in CSO's work, providing a vital lay view of policy and research proposals.

We have recently carried out a fundamental review of public involvement activities both within CSO and the NRS Research Network structures. While there is much excellent work being undertaken by the Public Engagement Group we recognise jointly that there are opportunities to enhance its role in providing advice and support to CSO. As a consequence:

- There will be broader lay representation in the work of CSO, including participation at CSO policy and strategic committees;
- Lay involvement will be built into the planning and review of CSO investments such as CSO funded units, NRS bio-repositories and safe havens, and
- CSO will liaise with the other UK administrations to share and learn from best practice.

Our NRS Networks also heavily involve the public at steering group level as well as directly with research. However, there is more that can be done in developing best practice in these areas and we will explore bringing these groups together to build a greater sense of common enterprise. CSO will continue to encourage the component parts of NRS to engage directly with patients and patient groups, and further develop ways in which members of the public can be empowered to become actively involved in clinical research.



"The CSO has fully embraced public involvement in its work streams and, since I joined the Public Engagement Group (PEG) 4 years ago, our role has expanded and now the Office is actively encouraging researchers to include lay or patient participation in their work. This is not just a paper exercise, our opinions have helped to shape the new strategy. Fascinating and absorbing work."

Barbara Lamb –
Chair of CSO's
Public Engagement
Group

Action

13. CSO will require the NRS Research Networks to show evidence of public involvement in their work.



"As a clinical researcher, I know that having a strong and flexible recruitment strategy is key to study success. I have used SHARE to recruit to 2 studies involving older people, and have found it to be a user-friendly and efficient means of recruiting interested participants with a high probability of participation. My Ageing and Health team has a strong track record in recruiting the right number of participants within the planned timescale and working with SHARE is helping us to deliver this."

Professor Marian McMurdo –
University of Dundee

Scottish Health Research Register

CSO is also funding an initiative for members of the public who wish to express an interest in being contacted about participating in health research. Following registration on the Scottish Health Research Register (SHARE), details will be maintained on a database of those who are willing to be approached about taking part in research studies. Through electronic linkage of health information, SHARE will be able to identify potential recruits for studies far more efficiently than at present. Initially funded through a CSO small grant, SHARE has now been brought within the NRS Infrastructure budget to ensure sustainability and facilitate larger scale recruitment. In October 2015 there were over 80,000 people on SHARE but the long-term goal is to create a far larger register for use in relevant studies.

Such a register is only of use if it facilitates recruitment into clinical studies. Although SHARE provides an opportunity for many to indicate a general willingness to be approached to take part in research, routes for facilitating involvement for patients who want to take part in specific studies are relatively underdeveloped. While medical researchers often find it difficult to identify suitable patients for clinical trials, it is often equally hard for patients interested in taking part in studies to find clear, accessible information. Current lists of active studies do not generally provide lay summaries of what projects involve, and current mechanisms to enable patients to express an interest in taking part are not always sufficiently targeted.

Action

14. CSO will review the effectiveness of SHARE in the first half of 2016.
15. The SHARE website will be developed to allow NHS patients across Scotland to identify clinical studies which are actively seeking participants. Patients will be able to review a list of available studies, and express their interest online.

Aggregate data derived from NHS health records allows planning and feasibility assessments of the potential success of research projects to be made. However, individual patient data are not currently used to inform patients about research projects that would be of personal relevance to them.

Projects such as SHARE therefore require potential participants to register their general agreement for their electronic records to be checked. This, however, limits the identification of patients who may benefit from new treatments available through clinical trials to those who have previously registered an interest. As a consequence, patients undergoing treatment in the NHS are not routinely informed of research taking place that could be relevant to them.





"The SHARE register has been invaluable in helping us recruit healthy volunteers into our study. In previous years it has been extremely difficult to find asymptomatic volunteers who are willing to undergo an invasive procedure like endoscopy. SHARE has made recruitment a much easier process and as a result we are close to achieving our target number well within our time frame."

Dr David R. Mitchell
– Senior Clinical Research Fellow,
Gartnavel General Hospital

We believe offering patients participation in clinical studies should be a key aim of the NHS as an integrated part of patient care. Assisting GPs and hospital consultants in identifying patients who might be invited to participate in a research study relevant to their condition is therefore a service we believe worthy of consideration. NHS staff using NHS patient records solely to advise GPs and hospital consultants of studies that may be of interest to their patients strikes an acceptable balance of security and service to patients. The appropriateness of such a service was supported by those who responded to our general consultation exercise however we intend to consult specifically with members of the public on this issue.

In doing so we are aware of proposed amendments to the EU Data Protection Regulations that, if accepted, would prevent such service being provided. Our aim therefore is to conclude the further consultation and await the outcome of the EU consideration of these amendments.

Action

16. CSO will conduct a more focused consultation with members of the public, including its own Public Engagement Group, before progressing this initiative.

Supporting Quality Improvement

While it is essential for CSO to continue to be outward looking in delivering success, we must also ensure that we use our research expertise to support key initiatives of importance to the Scottish Government. Underpinned by the Quality Strategy, the NHS in Scotland has made significant strides in improving patient safety and the quality of care in recent years. Quality Improvement is now a unifying theme of NHSScotland and increasingly across public service. While to date NHSScotland has used its expertise to drive changes forward and there has been limited research to develop new knowledge, or publication of our work in respected peer reviewed journals. As a consequence there is considerable scope to expand the volume of research related to quality improvement science in the context of the Scottish healthcare system.

For this reason CSO is a partner in the creation of the Scottish Improvement Science Collaborating Centre (SISCC). Co-funded in collaboration with NHS Education Scotland, the Scottish Funding Council and the Health Foundation, it is a national resource and centre of expertise in improvement science research, development and knowledge translation.

With the integration of Health and Social Care, it is important to recognise the benefits that will flow from research in this area. CSO already funds health research project grants with a social care component, and initiatives such as the SISCC have a social care dimension.

Action

17. CSO will continue to support research in pursuit of health and social care integration and will work with colleagues within the Scottish Government to ensure this important agenda has a properly constituted research dimension.



CHAPTER 3 – TARGETED DEPLOYMENT OF RESOURCES



CSO invests a total of £67m per annum in Scottish research, representing a significant investment from the taxpayer and the Health Directorates. It is therefore important that all CSO investments are reviewed regularly against competing demands for funding and are not considered ring-fenced for any particular discipline or geographical area.

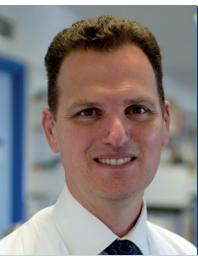
The need for regular review has been heightened by the need to invest in new or emerging technologies to allow Scotland to remain at the forefront of health research. In recent years the importance of Precision Medicine as a means of transforming the way the NHS diagnoses disease and provides care has been recognised as an important area in which research is essential, while the capacity of informatics is only now beginning to be realised. For this reason CSO needs to ensure that it has an acceptable balance of longer-term commitments and flexible funds to deploy as new priorities and initiatives emerge. At present there is an imbalance towards the former.

Action

18. CSO will aim to free up a minimum of 1% of its budget in 2016-17, rising to 5% by 2019-20, to be deployed in support of new initiatives.

Such a change will allow CSO to invest strategically in the future, but will require compensating savings to be made elsewhere. To ensure existing investments remain a priority and have a suitable focus, a number of reviews of long standing areas of investment commenced in 2014-15 and will continue over the next three years. CSO's intentions for those investments are set out in the remainder of this chapter.





“The CSO response mode grant schemes are an invaluable resource for the Scottish clinical research community. They furnish studies that have, over the years, delivered high-quality data, increased understanding of disease processes and in turn have thereby led to meaningful change in clinical practice. CSO grants offer an admirable degree of flexibility that allows for example leverage of additional funding to mutual benefit with partner agencies. Moreover they have not infrequently provided Scottish-based researchers with the critical early data to facilitate further large scale funding opportunities from UK and international organisations.”

Professor Iain McInnes –
Institute of Infection and
Immunity and Inflammation,
University of Glasgow

Response Mode Grants

CSO currently funds research projects through its two response mode funding committees:

- The Experimental and Translational Medicine Research Committee (ETM)
- The Health Services and Population Health Research Committee (HSP)

At any one time around 100 CSO funded studies are active with a value of around £15m. Early findings from the ResearchFish evaluation database suggest that CSO grants generate a considerable volume of additional activity, and in the most recent university Research Excellence Framework exercise 21% of the case studies submitted cited CSO support. CSO grants are highly valued by the research community and demand remains high at over 150 applications per year. However only 20% of applications are funded.

CSO also operates within the wider landscape of UK health research funding and contributes to a National Institute for Health Research (NIHR) funding pool in excess of £100m annually, allowing Scottish-based researchers to apply for the majority of the research programmes administered by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). Notwithstanding the scale of funding available through these programmes, applications to NETSCC are just a third of those made to the CSO response mode schemes and also proportionately lower compared with the total number of applications made to NETSCC programmes from across the UK. There is therefore a need to address this imbalance.

CSO has re-examined the remits of its response mode committees and was unable to identify any major thematic gaps in the NETSCC programmes that were being filled by the CSO funding stream.

We therefore believe that CSO response mode schemes need to have a clearer definition of how they play into this wider funding environment. Going forward:

Action

19. CSO will create a budget to support pilot work designed to provide underpinning evidence for applications to larger funding schemes. At up to £35k, such awards will be determined within CSO in response to applications.
20. The CSO ETM and HSP Committees will be replaced with researcher initiated grant schemes with a closer focus on proposals of direct patient, or health services or public health, benefit. This emphasis will mean that early stage studies are unlikely to progress for consideration. The upper threshold of this scheme will increase to £300k.
21. To increase the policy relevance of the research funded, CSO will create a new scheme for research proposals that address specific Scottish Government policy priorities.
22. A greater emphasis will be placed on the analysis of project outcomes and impact on health and public health systems nationally and/or internationally. To that end CSO will introduce end of project interviews with the project principal investigator.

These changes should be sufficient to refocus applications to the appropriate funding source and ensure the relevance to the Scottish Government Health Directorates of the research it funds. CSO will review these new arrangements in 2018-19 to ensure they are delivering as expected.



"CSO support for developmental research studies to underpin much larger applications to other funders is really valuable. Following on from our CSO grant for an exploratory study of a specialist mental health service for maltreated children, we were awarded £3.4m by NIHR for a definitive trial. The knowledge we gained from our CSO funded study was crucial, allowing us to establish the acceptability, feasibility and size of a definitive trial and support our application to NIHR."

Professor Helen
Minnis – Institute of
Health & Wellbeing,
University of
Glasgow



"CSO funding has provided us with the stability necessary to construct a solid foundation not only to deliver high-quality research that makes a difference to the health of the people of Scotland, but also to generate enhanced research opportunities for the NMAHP community. This stable support, coupled with detailed oversight and monitoring, has enabled us to maintain a focus on important long term outcomes, and the freedom to work strategically with other HEIs, policy makers and Health Boards to achieve those outcomes on a non-partisan basis."

Professor Brian Williams
– Director, The Nursing,
Midwifery and Allied
Health Professions
Research Unit



CSO Core Funded Research Units

Each CSO unit is funded as a centre of excellence to help inform the development of effective health service or public health practices and policies. They provide different functions such as undertaking research in areas of strategic need, providing policy advice and capacity building, and working in even closer collaboration with CSO and Scottish Government colleagues. In addition to CSO core-funding, units attract significant funding from other sources.

Total investment in units represents £3.9m which is just under 6% of CSO's annual expenditure. Each unit enjoys an effective working partnership between the CSO and the unit's host institution.

Action

23. CSO will conduct a strategic review of unit purpose and funding in the course of 2015-16.

As a priority CSO will:

- review the scope for closer relationships between CSO units and Scottish Government policy interests; and
- consider the funding consequences of posts funded by CSO yet attracting significant grant funding from external funders.

NRS Strategic Investments

Since April 2008 CSO has been investing an additional £10m per annum in NRS Infrastructure. This budget was allocated to the Health Boards in Grampian, Greater Glasgow and Clyde, Lothian and Tayside to ensure that new staff were in place both to support current NHS research needs and deliver our requirements for the future. Critically, CSO allowed the Health Boards to determine the specific areas in which to deploy the new staff to best meet CSO's strategic aims. Now that these investments have been in place for some time, it is appropriate to review their effectiveness and the extent to which they are contributing to our national ambition.

With clinicians indicating that there are still unmet needs to support ongoing studies there may also be a need to assess the prioritisation of the resources to meet key NHS needs.

Action

24. The paramount priority for deployment of CSO resources is meeting the NHS service support costs for eligible funded studies. CSO will ensure this principle is clearly applied across all of our investments, with funding being redeployed where necessary.

The aforementioned £10m infrastructure allocation was delivered as a redeployment of resources already with the Health Boards; as a consequence the level of funding had little relationship to the scale of the wider research activity. This is rightly seen as inequitable by those Health Boards who were relatively underfunded.

Managing the infrastructure as a single investment has also been challenging, both from a local and national perspective. Additionally the various streams of investment require different methods of assessment to determine their success.

Some investments have been made to pump-prime posts that would otherwise be funded through research grants on a study by study basis. CSO fully funds such posts and has not assumed a level of cost recovery of these services through grants. While CSO is advised that these investments are being fully utilised, that has not been evidenced to date from the costs declared as recovered from grants.

Action

25. From 2016-17 CSO will revise the allocation of NRS infrastructure funds to ensure a more equitable deployment of resource based on activity.
26. From April 2016, NRS Biorepository and NRS Safe Haven funding will be separately contracted. Where costs for these and other activities should be included in research grant applications, this will be reflected in the NRS funding offered for subsequent years. This will allow Health Boards and universities to consider whether they wish to continue to have all such posts funded.

More generally, CSO is keen to ensure that a greater emphasis is placed on the creation of a biorepository network for the supply of tissue for eligible funded non-commercial and industry research, with the biorepository resources working to the NRS principle of common costs and processes. It is recognised that there is greater co-ordination of activity than was previously the case but, eight years on, a fully co-ordinated and efficient national service is still not fully in place.

With Precision Medicine assuming greater prominence we anticipate an upturn in demand, but whether that will focus on the provision of fresh tissue or utilise the investment in stored tissue, and on what scale, is yet to be determined. It is important that this demand is properly assessed and matched with investment.

Likewise, the rapid development of health and bio-informatics research infrastructure in Scotland, following the launch of the Farr Institute, requires us to ensure that the NRS safe havens investment is suitably targeted towards supporting a national network and adding value. We anticipate that a fully functioning network of NRS safe havens will be a valuable resource, both in its own right as a vehicle through which research quality data can be accessed and as a resource that will support Farr research activity.

Action

27. A review of NRS biorepository activity and funding that will be completed during 2015-16 to inform future investment in the network. A review of the NRS Safe Haven opportunities and investments will be conducted in the course of 2016-17.

The remainder of the functions funded under the NRS Infrastructure budget will be reviewed during the life of this Strategy. Some of those posts are clearly linked to the level and type of studies undertaken e.g. pharmacists to clinical trials and can therefore be linked to activity.

It is a long-standing matter of concern of some Health Boards that while the four most active Health Boards have been the main recipients of the additional investment in infrastructure, the remaining Health Boards have not had the opportunity to have similar support. CSO believes that there are good reasons why strategic investments should be restricted to those Health Boards that lead on the majority of externally funded studies with their university partners. However the same case cannot be made for service support costs, which apply equally to all participating Health Boards. With the recent introduction of a single service support cost across Scotland, there is no reason why the opportunity to have such posts funded through NRS Infrastructure funding should not be extended to all Health Boards.

Action

28. CSO will extend to all Health Boards the opportunity to have service support posts funded as NRS infrastructure.



"CSO support for the network of NRS safe havens facilitates safe and secure access to routinely collected health data for research. Through the NRS Safe Havens, we used data from a number of Health Boards to develop a risk calculator identifying diabetes among people admitted to hospital in Scotland to help early diagnosis."

Dr David McAllister
– University of Edinburgh



CHAPTER 4 – INVESTING IN THE FUTURE



This chapter sets out proposals to ensure Scotland is well placed to realise the benefits of the changing research environment and have an NHS workforce supportive of that ambition.

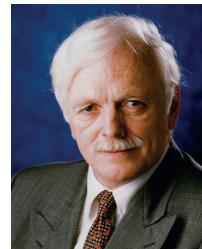
NHS Research Capacity

The capacity of NHS clinicians to undertake research is an important area if we are to see the planned increase in research activity. The combination of many research active clinicians approaching retirement age, and new appointees finding it difficult to have time allocated for research, is a specific concern. To address the latter, CSO introduced a programme of NRS Career Research Fellowships in 2011, designed to support early stage clinicians participate in research.

The Fellowship scheme has been well received, however its success has had an unforeseen consequence in that, due to a high level of interest and therefore competition, the threshold is higher than anticipated with most appointed fellows being research active doctors. As a consequence staff in other professions with an interest in developing a career in research, but without previous experience, are unsuccessful or being put off applying.

Action

29. CSO intends to develop the NRS Fellowship scheme for candidates with little or no research experience but who demonstrate a clear wish to develop research as part of their career.



“CSO continues to play a vital role in the generation of high-quality research relevant to the work of the NHS in Scotland. The clinical academic constituency has been greatly heartened by the central role of NHS Research Scotland (NRS) in establishing a new programme of Scottish Senior Clinical fellowships in partnership with the Scottish universities with medical schools. These fellowships will strengthen Scotland’s capacity to conduct internationally competitive biomedical research by supporting an emerging generation of talented clinical academics to become the clinical research leaders of the future.”

Sir David Carter – Chair of the Board of Academic Medicine



"The Stroke Association is delighted to be working in partnership with the Chief Scientist Office. We share a commitment to maintain and build research excellence and capacity in Scotland. We took that shared value and worked together to create a jointly funded Clinical Senior Lecturer post in stroke and a jointly funded programme of research to help stroke survivors deal with the psychological consequences of stroke. CSO is a fully engaged, committed partner, and one that is passionate about its mission to develop research excellence in Scotland."

Dr Dale Webb – Director of Research and Information,
The Stroke Association

Clinical Academic Capacity Building

Clinical academics are a valuable resource for Scotland, and complement the capacity building activity within the NHS. As University employees who spend at least half of their working week delivering and developing clinical services for the NHS, clinical academics undertake research that not only improves Scotland's health and healthcare but also drives economic growth. There is currently a risk that carefully nurtured early-career clinical academics may be attracted to long-term career posts outside Scotland.

For this reason CSO, the Scottish Government Health Directorates and Scottish Universities have agreed to jointly fund a successor to the Scottish Senior Clinical Fellowship (SSCF) scheme. At a total cost of £12m over 10 years, the new NRS/University Senior Clinical Academic Fellowships will recruit 15 senior fellows over a five year period. Taken together with the CSO Clinical Academic Fellowships for pre-doctoral medics and dentists, we have effective early and late stage schemes for the key researchers of the future.

However there remains an important mid-career gap for registrars with the risk that they will cease to undertake sufficient research while working towards their Certificate of Completion of Training. NHS Education Scotland currently supports this cadre, allowing 20% of their time for non-training activities such as research. However this threshold of time is less attractive to developing a research career in academia.

Action

30. CSO will work with NES to produce a new jointly funded scheme where a limited number of pre-CCT candidates would receive 50% of their funding to undertake research.

Ensuring the development of a strong cohort of researchers who can contribute to the evidence in the areas of health services and public health has been a key focus for CSO. As a consequence CSO has funded fellowships in health services and population health since 2007 to build capacity in this area. The scheme has been successful and many of our Fellows have gone on to secure research posts in Scotland. As such the desired increase in capacity in this specific area has been achieved and there is no strong case for CSO continuing to run a dedicated personal awards scheme to this specific area of research, particularly when CSO already funds units with a capacity building role.

Action

31. CSO will discuss with its health services and public health research units how capacity building in these areas could be sustained by other means.

Emerging Areas of Importance

Informatics

Scotland has long been a pioneer in the use of linked health service data for research. Data linkage is a highly efficient way to evaluate the capacity of interventions to deliver patient and population health benefit. It allows us to measure long-term outcomes in clinical trials, assess the safety of new and existing medicines and healthcare interventions, and to evaluate the impact of interventions across the whole population.

Much has been done already by way of strategic investments to improve the quality of the NHS datasets and develop the infrastructure for their utilisation. Key developments to date include:

- The Scottish Health Informatics Programme (SHIP)
- e-Health Informatics Research Centre (e-HIRC)
- The Farr Institute
- Health Informatics Research Advisory Group (HIRAG)

However there is an overarching need to ensure that investments are appropriately co-ordinated and focused on providing a coherent and structured informatics policy to direct activity and future investment across Scotland. Scotland cannot rely only on past success, and must consider how to maximise the economic return on this internationally competitive research



“CSO’s proportionate approach to tissue governance, and its investment in a national network of biorepositories through NHS Research Scotland, makes Scotland an attractive place to undertake research. Combined with Scotland’s recognised expertise in informatics and recent investments in genome sequencing, it is well placed to realise its ambition of being a global centre of excellence in precision medicine.”

Professor Sir John Saville – University of Edinburgh



strength. In doing so we should aim to consolidate and expand the role of the biomedical informatics industry as a dynamic contributor to Scotland's economic growth and social wellbeing.

The Scottish Government has now published *A Health and Biomedical Informatics Research Strategy for Scotland*, setting out a number of recommendations for action including:

- establishing a charter of principles for a federated network of safe havens in Scotland that will provide a basis for a safe haven accreditation scheme;
- improving the speed and consistency of health informatics research governance decisions;
- improving the provision of national health datasets for research, and
- developing a programme of public engagement;
- investing in health informatics research training and expertise.

Action

32. CSO will work with key stakeholders so that the recommendations of the Health and Biomedical Informatics Research Strategy for Scotland are taken forward. The charter for safe havens will be published in the course of 2015-16.

Precision Medicine and Digital Health

Many of the investments through the NRS Infrastructure funding are designed to support new areas of research. One such area is Precision Medicine (Stratified Medicine), where using NHS data, tissue and imaging analysis has the capacity to support research that can radically transform the way treatments are provided to patients. If the ambition of providing a patient with the right treatment the first time is to be realised, then there is a need to evidence the economic benefit to the NHS of such an approach in addition to the obvious benefit to the patient.

Investments by the Scottish Funding Council (SFC) in the Stratified Medicine Scotland Innovation Centre (SMS-IC) have created a valuable resource that is ready to be used by public sector and industry researchers. The recent £1.2m CSO Stratified Medicine Applied Research Programme was designed to evidence the value to the NHS of adopting a stratified approach. While it was focused on evidencing the value of existing yet unadopted innovations it is anticipated that any subsequent Precision

Medicine Applied Research Programme funding might link in more closely to the innovations emerging from the SMS-IC. Similarly for innovations coming from the Digital Health Institute.

Action

33. CSO will work with the SFC, Industry and the Innovation Centres – particularly the SMS IC and Digital Health Institute – with a view to ensuring that relevant outputs from these initiatives are suitably evaluated through research to warrant their adoption in the NHS.

International Partnership

Working collaboratively in Scotland is relatively easy because of our culture and scale. However if we are to realise our ambition of being world class in our research we must look outwith our geographical boundaries for independent advice on strategic issues. It is some years now since CSO convened its Chief Scientist Committee, where membership was drawn largely from within Scotland and its remit focused on specific Scottish issues. If Scotland is to deliver on its global ambitions then it must have access to advice on a similar scale.

Action

34. CSO will explore the creation of a new CSO International Advisory Board to provide expert advice on strategic research issues. Meeting once a year, with membership comprising key global leaders in their field, it would provide high level advice on the steps Scotland should be taking to deliver on its aspirations.



SUMMARY OF ACTIONS

Chapter 1 – Efficient R&D Support for Research

1. CSO will define the job description of a nodal NRS R&D Director and become formally involved in the recruitment of new appointments to these posts.
2. CSO will define the functions of key NRS posts, particularly where they provide a nodal or national function. CSO will also more closely define the NRS services to be delivered locally and the associated delivery targets, but will not normally determine the grading or detailed functions of posts delivering those services.
3. CSO will undertake a formal review of the NRS Central Management Team in April 2016 in order to ensure it is optimally delivering on its functions.
4. CSO will require that all Health Boards take adequate steps to promote the availability of resources to support research.
5. CSO will require formal consultation and joint planning of NRS Infrastructure investments with partner universities and NRS Network and Specialty Group leads as a condition of funding.
6. By the end of 2015 CSO will require the submission of proposals from Health Boards on how the NRS Researcher Support funds will be pro-actively managed and allocated for researcher time and associated activities by their NRS R&D Directors, from April 2016. Access to NRS funding schemes will be conditional on CSO agreement to the Health Board proposals.
7. To ensure that the Networks and Specialty Groups remain the most efficient way of supporting our research activity, CSO will review the success of these revised arrangements in the second half of 2016.
8. CSO will seek to combine the Scottish Research Ethics Service and NRS R&D Offices into a single integrated service for researchers while retaining the independence of the REC decision making function.
9. CSO will arrange for shared access to study data for ethics and R&D staff through the Health Research Authority HARP database, streamlining access to electronic documents for R&D staff throughout Scotland.
10. CSO will refocus the early contact of ethics and NHS R&D staff with researchers on facilitating study approvals, with named R&D contacts being given to support the researcher in obtaining those approvals.
11. CSO will work with the HRA to revise the Research Governance Framework and implement an efficient ethics and R&D permission system across the UK that both builds on the efficiencies already delivered through NRS and operates seamlessly for sponsors and researchers across the UK.
12. It is proposed that the NRS website will be the portal through which researchers access relevant information on NRS resources and services, with local sites being linked through that portal. This will greatly improve understanding of the national NRS systems, infrastructure and service standards that NHS R&D Offices deliver through NRS funding.

Chapter 2 – Partnership with Scottish Patient and Public

13. CSO will require NRS Research Networks to show evidence of public involvement in their work.
14. CSO will review the effectiveness of SHARE in the first half of 2016.
15. The SHARE website will be developed to allow NHS patients across Scotland to identify clinical studies which are actively seeking participants. Patients will be able to review a list of available studies, and express their interest online.
16. CSO will conduct a more focused consultation with members of the public, including its own Public Engagement Group, before progressing this initiative.
17. CSO will continue to support research in pursuit of health and social care integration and will work with colleagues within the Scottish Government to ensure this important agenda has a properly constituted research dimension.

Chapter 3 – Targeted Deployment of Resources

18. CSO will aim to free up a minimum of 1% of its budget in 2016-17, rising to 5% by 2019-20, to be deployed in support of new initiatives.
19. CSO will create a budget to support pilot work designed to provide underpinning evidence for applications to larger funding schemes. At up to £35k, such awards will be determined within CSO in response to applications.
20. The CSO ETM and HSP Committees will be replaced with researcher initiated grant schemes with a closer focus on proposals of direct patient, or health services or public health, benefit. This emphasis will mean that early stage studies are unlikely to progress for consideration. The upper threshold of this scheme will increase to £300k.
21. To increase the policy relevance of the research funded, CSO will create a new scheme for research proposals that address specific Scottish Government policy priorities.
22. A greater emphasis will be placed on the analysis of project outcomes and impact on health and public health systems nationally and/or internationally. To that end CSO will introduce end of project interviews with the project principal investigator.
23. CSO will conduct a strategic review of unit purpose and funding in the course of 2015-16.
24. The paramount priority for deployment of CSO resources is meeting the NHS Service Support Costs for eligible funded studies. CSO will ensure this principle is clearly applied across all of our investments, with funding being redeployed where necessary.
25. From 2016-17 CSO will revise the allocation of NRS infrastructure funds to ensure a more equitable deployment of resource based on activity.
26. From April 2016, NRS Biorepository and NRS Safe Haven funding will be separately contracted. Where costs for these and other activities should be included in research grant applications, this will be reflected in the NRS funding offered for subsequent years. This will allow Health Boards and universities to consider whether they wish to continue to have such posts funded.
27. A review of NRS biorepository activity and funding will be completed during 2015-16 to inform future investment in the network. A review of the NRS Safe Haven opportunities and investments will be conducted in the course of 2016-17.
28. CSO extend to all Health Boards the opportunity to have service support posts funded as NRS infrastructure.

Chapter 4 – Investing in the Future

29. CSO intends to develop the NRS Fellowship scheme for candidates with little or no research experience but who demonstrate a clear wish to develop research as part of their career.
30. CSO will work with NES to produce a new jointly funded scheme where a limited number of pre-CCT candidates would receive 50% of their funding to undertake research.
31. CSO will discuss with its health services and public health research units how capacity building in these areas could be sustained by other means.
32. CSO will work with key stakeholders so that the recommendations of the Health and Biomedical Informatics Research Strategy for Scotland are taken forward. The charter for safe havens will be published in the course of 2015-16.
33. CSO will work with the SFC, Industry and the Innovation Centres – particularly the SMS IC and Digital Health Institute – with a view to ensuring that relevant outputs from these initiatives are suitably evaluated to warrant their adoption in the NHS.
34. CSO will explore the creation of a new CSO International Advisory Board to provide expert advice on strategic research issues. Meeting once a year, with membership comprising key global leaders in their field, it would provide high level advice on the steps Scotland should be taking to deliver on its aspirations.



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