Research and Development

Annual Report
2013/14

Correspondence to: Professor David M Reid
Director of Research and Development
Foresterhill House Annexe
Foresterhill,
AB25 2ZB

Telephone No: 01224 (5)51118
email: d.m.reid@abdn.ac.uk
## Contents

<table>
<thead>
<tr>
<th>Section 1:</th>
<th>Introduction</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2: Structure and Function of Research and Development Office</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Section 3: Achievements</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Section 4: Next Steps</td>
<td></td>
<td>12</td>
</tr>
</tbody>
</table>
Section 1
Introduction

This is the fourth annual report from the Research and Development (R&D) Office and as such aims to set out the structure and function of the department and inform the reader of our position in relation to this.

Once again the R&D Office has had a busy year with some increase in staffing to cope with the requirements for good governance as laid down primarily by the MHRA, but also some challenging staffing issues especially delay in being able to appoint to the Quality Assurance Manager post. The objectives laid down by the Chief Scientist Office (CSO), who provide NHS R&D funding and rigorously monitor its spend, require continuing improvement in processes to ensure maximum return on activity driven funding streams. With Professor David Reid having the joint role of NHS R&D Director and Head of the School of Medicine & Dentistry at the University of Aberdeen there is an ever-closer collaboration with the University of Aberdeen.

The R&D function will see significant challenges, not least financial, in the next few years but the R&D office and team are well placed to meet these challenges to safeguard and expand clinical research in NHS Grampian.
Section 2
Structure and Function of the Research and Development Office

2.1 The R&D Office offers specialist support, education and advice on all matters concerning research across Grampian.

The responsibilities of the R&D Office include:

- Administration of the management permission process for non-commercial and commercial activity
- Collation of data on R&D activity, including total number of projects and recruitment of patients to active projects
- Managing processes in relation to research sponsorship
- Developing and delivering training programmes
- Supporting researchers in relation to research proposals, grant applications, ethics applications, regulatory approvals and R&D management permission
- Monitoring a proportion of active studies to ensure and promote high quality research
- Formally reporting to the Chief Scientist Office, part of the Scottish Government
- Management of ring-fenced infrastructure funding for research activity from the Chief Scientist Office, part of the Scottish Executive
- Contributing to national initiatives to increase research activity and promote best practice
- Overseeing research nurses across Grampian

2.2 Roles of Individual Staff Members

R & D Director – Professor David M Reid
Overall responsibility for R&D in NHS Grampian in both the acute and primary care sectors.

Deputy R&D Director – Professor Julie Brittenden
Professor Brittenden has been seconded from the University of Aberdeen for a half day a week to provide Medical leadership support, where required, for the R&D Director.

Senior R&D Manager – Dr Joanne Rodger
Key role in R&D encompassing strategy, management, governance and business planning.

Commercial Research Manager – Dr Alison Stewart
Responsible for liaison with commercial companies and management of commercial research including feasibility, contracts, budgets, R&D permission, amendments and financial transaction throughout the duration of the study.

Non-Commercial Research Manager – Dr Susan Ridge
Responsible for the management of R&D permission of non-commercial research including contracts, Intellectual Property and costing of research studies.

Lead Research Nurse – Ms Carole Edwards
Support career development of research nurses, coordinate linking of established
Clinical Research Facilities (CRFs) and develop education/training sessions - including Good Clinical Practice (GCP) for nurses and other research staff.

Training Facilitators – Ms Laura Elliott and Ms Anna Strachan
Post to assist in the development and delivery of training to researchers of all levels and experience.

Research Governance Manager – Dr Gail Holland
A University of Aberdeen appointee responsible for sponsorship arrangements and final research governance check prior to R&D permission.

Research Governance Assistant – Mrs Stacey Dawson
A University of Aberdeen appointee responsible for giving administrative support to the Research Governance Service.

Quality Assurance Manager – position vacant
Responsible for improving the overall quality of research in Grampian.

Research Monitors – Mrs Caroline Campbell and Mrs Diane Stuchbury
Responsible for monitoring of ongoing research in Grampian as required under the Research Governance Framework.

Document Controller – Ms Anne Brebner
Responsible for the maintenance of quality system documentation.

Senior Project Administrator (Scientific) – Dr Rituka Sharma
Responsible for ensuring the accurate and timely processing of research projects taking place in Grampian prior to issuing R&D permission.

Finance and Business Support Assistant – Mr Graeme Paterson
Assists the commercial and non-commercial teams to ensure all income is invoiced and projects are correctly costed.

Commercial Trial Facilitator – Dr Maria R Amezaga
Appointed in the spring of 2012 she is responsible for supporting the process of feasibility assessment for commercial trials being offered by sponsors to NHS Grampian.

Commercial Clinical Trial Coordinator – Mrs Audrey Imray
Responsible for administration for commercial clinical trials.

Administrator / PA – Ms Rebecca Whiting
Personal Assistant to the R&D Director and provision of administrative support to senior members of the R&D Office.

Data Coordinators – Mrs Louise Milne and Mrs Lynn Massie
Responsible for gathering required documentation for proposed research in NHS Grampian including liaison with ethics and researchers. Addition of information to the R&D Database.
Section 3
Achievements

3.1 Supporting Research
Last financial year, NHS Grampian received an allocation circa £7.3M to support non-commercial research. The money helps fund staff and resources within Grampian to support research, such as Radiology; Pharmacy; Laboratories; Consultants time; Statisticians; R&D staff; and research nurses. Further income for non-commercial research is received via grants awarded by a variety of funding bodies.

The way non-commercial research is funded by the Chief Scientist Office (CSO), Scottish Executive, is changing and is increasingly based on activity as well as meeting a series of objectives and targets. NHS Grampian needs to increase its research base relative to other Boards to reduce the risk of further loss of research funding in future years which would potentially impact clinical budgets.

Work is ongoing to encourage further participation in research and to ensure successful delivery and completion of research to try to prevent further reductions. However, as the baseline funding allocation to Boards was based on historical data, the CSO is revisiting the allocations to Boards across Scotland. Unfortunately Grampian has previously received a disproportionately high budget relative to our activity and subsequently our budget will be cut over the coming years as the CSO seek to resolve this discrepancy across Scotland.

Within the financial year 2013/14 the R&D Office helped manage and oversee 521 individual non-commercial research projects.

3.2 Endowment Funds
Money is often bequeathed or given through charitable donation to NHS Grampian Endowment Funds to help support research in a given area. The NHS Grampian Endowment Committee allocates funding to be administered by the R&D Office. The research areas to which money was allocated to last year were:

- Breast Cancer
- Cancer
- Cancer in Gynaecology
- Deafness, Lack of Speech
- Dupuytrens Contracture
- General Research
- General – ARI
- General – Woodend Hospital
- Heart Research
- Kidney
- Neurology
- Ophthalmology
- Parkinsons Disease
- Rheumatoid Arthritis and related conditions
- Stroke
- Thoracic Disease

Endowment funds are allocated to researchers generally for no more than a one year project following peer review of their research proposals. The
proposals are typically for small sums of money (up to £12,000) and are considered to be pump-priming for larger studies to be supported by the major national international research funders. Out of 59 prospective researchers who applied for financial support for the year 2013/4, there were 20 successful applicants; each receiving direct funding from the R&D endowments fund at a total cost of £169,249.

3.3 Commercial Research
In the last year we had the first increase in number of new commercial studies for some years with 29 studies approved (43 in 2009–2010; 28 in 2010-2011; 23 in 2011-2012; 23 in 2012-2013; 29 in 2013-2014).

At the end of 2013-2014 there are currently 85 active commercial studies ongoing within Grampian – 29 actively recruiting, 56 in follow up.

The income from Commercial Research continues to increase, despite the slight fall in new projects because of the more complex types of studies that we are conducting. These are frequently in niche areas and involve more complex work than the previous types of studies conducted.

3.4 Recruitment of Commercial Trials Facilitator
There has been a considerable increase in the number of feasibilities sent to us over the past year, due to alliances with 2 Clinical Research Organisations (CRO). This meant that we had the chance to recruit a second Facilitator to help deal with the demand and to enhance the process. But despite 2 rounds of advertisements no suitable candidate was found. With changes planned by the CSO we are now awaiting a re-definition of roles/responsibilities to determine whether a 2nd Commercial Trials Facilitator is necessary.

3.5 Inspection by the Medicines and Healthcare products Regulatory Agency (MHRA)
The Medicines and Healthcare products Regulatory Agency (MHRA) ‘is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA also looks after blood and blood products, working with UK blood services, healthcare providers and other relevant organisations to improve blood quality and safety’.

To ensure compliance with regulations set out for Good Clinical Practice (GCP); The Medicines for Human Use (Clinical Trials) Regulations (SI No.1031), 2004 and The Medicines for Human Use (Clinical Trials) Amendment Regulations (SI No.1928), 2006; the MHRA regularly conduct inspections of both commercial and non commercial organisations.

Following separate inspections of NHS Grampian and the University of Aberdeen in 2011, the joint Research Governance team is continuing to work on corrective actions and continuous process improvements to the quality management systems for conduct of clinical trials within Grampian. The MHRA indicated that for a return inspection the institutions would be inspected together as processes are so intertwined. It is anticipated that the next inspection will be scheduled in 2014/15 as inspections at other Boards in Scotland have followed a 3 year cycle.
3.6 Joint Working with University of Aberdeen
The joint research governance team is located within the R&D office with both NHS Grampian and University staff members. This has promoted a high level of collaborative working. The Joint Working Protocol for all clinical research and the Co-Sponsorship Agreement have successfully engendered a more streamlined way of managing clinical trials within Grampian.

A number of joint generic Standard Operating Procedures (SOPs) for studies sponsored or co-sponsored by NHS Grampian and / or the University of Aberdeen have been published. These SOPs instruct researchers within NHS Grampian, to enable them to work consistently, efficiently and to comply with applicable legislation and local institutional policies. The SOPs are currently undergoing routine review with a number being considerably updated and reissued following improvements in the processes.

A joint NHS Grampian / University of Aberdeen Clinical Studies Oversight Group (CSOG) meets regularly to review and provide risk assessment of new higher risk studies being presented for sponsorship and / or co-sponsorship by NHS Grampian and / or University of Aberdeen and to deal with governance and safety issues escalated to them through monitoring and audit reports. The group also oversee reports of Serious Adverse Events.

Through R&D funding, a temporary Archiving Administrator has been brought in to assist with managing the backlog of hard copy research records on site within Grampian, which require archiving. This has been a successful project and well received by researchers from both NHS Grampian and University of Aberdeen.

3.7 Research Governance
The Research Governance Manager undertakes an initial risk assessment of all studies applying for sponsorship or co-sponsorship from either NHS Grampian and / or University of Aberdeen. Prior to receiving sponsorship approval and R&D permission, all research related documents and approvals are checked to ensure that these comply with standards set out within the Research Governance Framework (2006) and The Medicines for Human Use (Clinical Trials) Regulations (2004) (where appropriate), and that steps have been taken to assure the safety and wellbeing of any research participants.

Those studies considered to be high risk are reviewed by the Clinical Studies Oversight Group prior to sponsorship being agreed.

3.8 Adverse Events
The Medicines for Human Use (Clinical Trials) Regulations (2004) and Research Governance Framework (2006), designate the task of reporting and overseeing adverse events to the Sponsors of Clinical Trials of Investigational Medicinal Products (CTIMPs).

During the reporting period there were 18 serious adverse events reported within NHS Grampian / University of Aberdeen sponsored trials.
3.9 Research and Development Clinical Research Monitors
The R&D Office employs two clinical research monitors. All CTIMPs and interventional trials sponsored or co-sponsored by NHS Grampian or University of Aberdeen undergo an initiation visit prior to starting, at least one monitoring visit during the active phase of the project and a closeout visit. This helps to support researchers in delivering high quality research.

A percentage of non-commercial trials managed by external sponsors and hosted within NHS Grampian or University of Aberdeen are also monitored during the active phase of the study, unless they have recently been monitored by an external sponsor. Studies are selected randomly, unless concerns have been raised with regards to an individual study. Concerns may be highlighted when, for example:

- Monitoring other projects being undertaken by the same researcher or PI highlights concerns
- Information provided to R&D is concerning or inconsistent
- The trial is selected for inspection by the MHRA
- A Serious Breach or an Urgent Safety Measure (regulatory terms) are experienced on the trial

Studies are monitored to the standards set out within the Research Governance Framework (2006) and Good Clinical Practice (ICH GCP). Monitoring processes undergo continual review to improve the process and meet the needs of the researchers, R&D management and the sponsors.

Should issues be identified during the monitoring process, the monitors will work with the researchers, R&D management and the study sponsor(s) in order to rectify any problems and agree actions to prevent further issues.

During the financial year 2013/14 the research monitors reviewed 58 studies, including 5 initiation visits and 4 study close-out visits. Findings are graded, red, amber and green and all red findings are discussed at the Clinical Studies Oversight Group and any trends reviewed. Therefore, any gaps in training can be identified and further advice and support can be given to researchers if required.

3.10 Reporting Structures
R&D have been preparing quarterly sector reports to the Clinical Governance Committee, with the aim of highlighting any research issues that may impact directly on the NHS, or the care and safety of patient and / or staff. Research Governance reporting structures across NHS Grampian and the University of Aberdeen are undergoing review to ensure any issues are escalated as appropriate.

3.11 Education
In order to ensure that all studies involving NHS facilities, staff, patients and data are carried out to the highest standard, the R&D Office insists that Principal Investigators undertaking CTIMP and surgical intervention studies within NHS Grampian attend a one day GCP course (or complete an online course) prior to being given R&D permission to undertake the study. GCP courses are highly recommended to all others undertaking research within NHS Grampian. A database is maintained of all those attending the courses and Principal Investigators are expected to update their training at least every two years.
R&D in conjunction with the University of Aberdeen continue to run internal half day GCP courses for those involved in non drug studies. The course is based upon the current regulations governing research as documented within the Research Governance Framework (2006). From April 2013 there have been 23 courses with 291 attendees.

Other training organised by the department include sessions on Informed Consent, Ethics & the Integrated Research Application System (IRAS) Form and SOP training.

3.12 Research and Development Website Group

The R&D website www.nhsgrampian.org/randd is updated on a regular basis to provide guidance to researchers undertaking non-commercial and commercial research involved in NHS Grampian. The website steers researchers through all the processes involved in research and directs them to sources of further information. The site is now linked to the NHS Research Scotland (NRS) website www.nhsresearchscotland.org which directs “clients” to the Grampian website as required.

All research nurses are employed via the Lead Research Nurse to ensure that current research nurses are kept in employment and new nurses are properly inducted into the system.

3.13 Grampian Data Safe Haven – DaSH

(http://www.abdn.ac.uk/iahs/facilities/grampian-data-safe-haven)

Using electronic health data for research is an important means of understanding the factors that influence health and disease over the life-course. DaSH facilitates safe access to Scottish population data for linkage studies while ensuring adherence to the highest standards of security and governance, thus ensuring patient confidentiality is protected. DaSH is a member of the Scottish Safe Haven network and is supporting Farr Scotland, SHARE and the Scottish Informatics Linkage Centre.

Since opening in May 2012, DaSH has supported more than 70 data linkage projects.

3.14 Quality Assurance

The quality management system for clinical research covers standard operating procedures and templates, researcher training, information resources, monitoring and audit, corrective action tracking, handling of compliance issues, data handling and archiving of research data.

Due to the vacancy in the Quality Assurance Manager post an audit of an external laboratory involved in a locally sponsored drug study was outsourced. Outsourcing of site audits for a number of other current studies has been arranged and will take place in the next reporting period.

3.15 NRS Research Fellows

The NRS Research Fellowship scheme is to support NHS-funded clinical staff (qualified doctors, nurses, AHPs, pharmacists, biomedical/clinical scientists,
public health specialists) in developing a research career within their NHS post. The award provides funding for protected time to contribute to, conduct and lead clinical research. This will lead to strengthening the research culture in the NHS and to increasing capacity in areas that are either aligned to research excellence either locally or nationally or areas where the potential exists to develop research excellence.

NHS Grampian appointed 4 NRS research fellows for a period of 3 years, starting in April 2012. The appointees have all had 0.4 WTE of their time protected for research and are based in the following areas: Emergency Medicine, Pharmacy, Psychology and Medicine for the Elderly.

A further 4 NRS research fellows were appointed and commenced in April 2013, again for a period of 3 years. This year’s appointees are based in the following areas: Health Psychology, Gastroenterology, General Surgery and Intensive Care Medicine and Diabetes/ Endocrinology.

A further NRS Fellow has been appointed and will start in April 2014 with a specialty interest in Obstetrics & Gynaecology.

3.16 The Scottish Health Research Register – SHARE
SHARE (http://www.registerforshare.org) is a list of people living in Scotland willing to provide secure access to their NHS computer records, and giving permission for SHARE to contact them to see if they might be willing to take part in research studies. The register will be held in the local Safe Haven node and a steering committee has been set-up to determine recruitment methods to aid recruitment to the register in Grampian and to advise on governance and use of the register to help with recruitment for clinical trials. NHS Grampian is represented on the national steering group by Dr Sam Philip, Consultant Diabetologist. A very successful high-profile launch of SHARE in Grampian was held on the 10 October 2013. As at the beginning of April 2014, 2301 participants from Grampian are registered with SHARE.

3.17 Biorepository
The Grampian Human Tissue Bank (Biorepository) was committed to achieving accreditation by Health Improvement Scotland and invested heavily to achieve this during the reporting period. Accreditation was achieved just after the end of the reporting period (9th April 2014).
Section 4
Next Steps for 2014

4.1 North Node Privacy Advisory Committee
R&D along with ethics and the DaSH team are developing a North Node Privacy Advisory Committee to ease the bureaucracy surrounding research approvals for data linkage studies.

4.2 The Farr Institute of Health Informatics and Research
The Farr Institute is a pan-UK collaboration to harness health data for patient and public benefit by setting the international standard for the safe and secure use of electronic patient records and other population-based datasets for research purposes.

Clinical, population and computer scientists will combine their expertise to interpret large and complex health datasets in research environments that safeguard patient confidentiality. Researchers will develop methods for safely sharing, combining and analysing diverse datasets across boundaries, enabling new discoveries and validating research findings with a speed and scale not previously possible.

The Farr Institute @ Scotland is a collaboration between six Scottish Universities and NHS National Services Scotland. The aim is to both improve the health of the Scottish population and place Scotland as a global leader in health informatics research.

By summer 2014, researchers and analysts from many disciplines will be brought together initially into two sites at Dundee Medical School and in Edinburgh’s Bio-Quarter. These two hubs will be backed by a network of spokes across Scotland including the Grampian Safe Haven.

The Institute’s independent research will support innovation in the public sector and industry leading to advances in preventative medicine, improvements in NHS care and better development of commercial drugs and diagnostics.

4.3 Increase in Commercial Studies
We continue to encourage NHS consultants to take part in commercially sponsored clinical trials by ensuring that they can be provided with appropriately funded research nurses and research doctors when required. Funds are being sought to enable NHS consultants who are on a 10 or 11 PA contract to be allocated additional PA time specifically to allow them to act as local Principal Investigators (PI) for commercial clinical trials.

4.4 Clinical Research Facilities
There are a number of “clinical research facilities” (CRFs), mainly in side wards or single rooms in clinical areas, throughout NHS Grampian, especially on the Foresterhill Campus but relatively few are specifically designed for undertaking clinical trials. In 2007 the University of Aberdeen with support funding from NHS R&D opened a dedicated CRF in the University Health Sciences Building (HSB) Designed for ambulatory out-patients participating in clinical trials, this facility has a high spec digital X-ray facility in the basement
and hence is an ideal base for many commercial and non-commercial studies. The opportunity for NHS and University consultants to participate in commercial trials is increasing with the agreements now in place with two Clinical Research Organisations (PPD and Quintiles) to offer Scottish centres increasing numbers of studies. Further agreements with Roche and Pfizer are nearing completion. These agreements will bring increasing offers of clinical research to NHS Grampian and the R&D office plans to gear up to meet this challenge by appointing a CRF manager to co-ordinate activity in the main and satellite CRFs.

4.5 Translational Research Unit
In 2012 external funds were sought from a charitable Foundation to support the development of a more translational CRF where invasive procedures and injectable therapies could be trialled. While the application was favourably received funding was not awarded but NHS Grampian did commit to identifying space on the main hospital site. A Cardiac CRF within a new Cardiac Centre is in the planning stage to be backed by a fundraising campaign and this facility should be able to be used to meet the immediate objective.

4.6 NRS Permissions
The NHS Research Scotland Permissions Centre which has been in existence for 6 years is based in Grampian although it is responsible for processing multi-centre studies for R&D approval in all Scottish Health Boards as well as supporting the feasibility. It is directed by Professor Reid as NHS R&D Director and has a National Coordinator and with 5 additional staff when at full establishment. Although it has been recognised as having been a great success in ensuring permission times are highly competitive in Scotland current challenges in achieving full staffing are threatening its reputation for speed and excellence.