

UK CLINICAL RESEARCH COLLABORATION

igniting our potential

UK Clinical Research Collaboration

Progress Report 2006 - 2008

UKCRC PARTNER ORGANISATIONS

abhi

abpi

amrc
ASSOCIATION OF MEDICAL RESEARCH CHARITIES

ACADEMY OF MEDICAL ROYAL COLLEGES

The Academy of Medical Sciences

BIA

CANCER RESEARCH UK

Department for Employment and Learning
www.delni.gov.uk

DH Department of Health

Department for Innovation, Universities & Skills

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

HIGHER EDUCATION hefce FUNDING COUNCIL FOR ENGLAND

Cyngor Cyllido Addysg Uwch Cymru
hefcw
Higher Education Funding Council for Wales

INVOLVE
Promoting public involvement in NHS, public health and social care research

MHRA

MRC Medical Research Council

THE NHS CONFEDERATION

NHS

CHIEF SCIENTIST OFFICE

NHS National Institute for Health and Clinical Excellence

NHS National Institute for Health Research

r&d office

Scottish Funding Council

Llywodraeth Cynulliad Cymru
Welsh Assembly Government

wellcome trust

Commentary

One of the strengths of the health research environment in the UK is the broad range of public, charity and commercial organisations which have a stake in making sure that it delivers high quality research for the benefit of patients and the public.

But this diverse environment can be a double edged sword; some issues, particularly those outside the influence of any one organisation, can become long standing problems with no clear route to find solutions. By 2004, there was an appetite for change from both academia and industry to prevent these problems from damaging the reputation of UK health research.

The recommendations from the Research for Patient Benefit Working Party set the Collaboration some ambitious goals. Many of the problems to be tackled were complex and had been an issue for a number of years. There was a clear need for all the organisations with a stake in the UK research environment to work together in a way that had not been seen before.

We were all under no illusion that this would be a challenging task. We represent very different communities with different issues and needs. From our perspective on the UKCRC Board, it has impressed us how quickly the broad range of organisations involved found constructive ways to work together.

We have achieved a great deal by working together, but we cannot be complacent. One of the biggest challenges we face will be to ensure that the positive changes to the research environment in the UK continue and remain fit for purpose, and we will need to think innovatively about how best to do this. However we are confident that the UKCRC way of joint working is now becoming firmly embedded in the Partners' organisations and has already begun to shape the future UK health research environment for the better.



Nick Partridge
UKCRC Deputy Chair and
Board member for INVOLVE



Dr Richard Barker
UKCRC Deputy Chair and Board member for
Association of the British Pharmaceutical Industry

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Chair's Introduction



It is now four years since we came together as stakeholders in, and the leaders of, the major organisations that shape clinical research in the UK. By working together to tackle the challenges facing UK clinical researchers we have achieved much more than I think we would have done if we had continued to address these problems in isolation.

What has impressed me as the Chair of the Collaboration is the degree to which the Partner organisations have been prepared to commit time, expertise and resources to work together to develop innovative solutions to complex and often long-standing problems. It was clear from the beginning that the Collaboration was not going to become just another 'talking shop' and the last two years have clearly demonstrated the long-term commitment of the Partners to deliver on the challenges we were given. A particular characteristic of this is the degree to which industry has been active in helping to shape the agenda rather than merely responding to it.

I suspect many of us around the table are pleasantly surprised at how much we have achieved in such a short space of time; however, there is still a lot to do. Much of our work is ongoing and the combined benefits of our bureaucracy-busting and infrastructure building will only be truly felt when everything is in place. If the UK is to do its part in the global health research effort we will need to continue to work in partnership in order to benefit patients.

Professor Sally C. Davies
Chair, UK Clinical Research Collaboration

Chief Executive's Report



A great deal has changed in the four years since the UKCRC Partners came together. Individual researchers at the 'coal face' are beginning to see the benefit of the improvements that the UKCRC Partners have worked so hard to bring about. However, perhaps more significant is the cultural change that the UKCRC represents.

When the UKCRC Board first came together four years ago it wasn't obvious how the collaboration was going to work. With 23 organisations around the table, each with a slightly different take on an issue, it would have been easy for us to have filled four years with talk. However, at the start of the collaboration, the UKCRC Partners began establishing a way of joint working that would allow them to tackle some of the complex and long-standing issues that have affected the environment for clinical research in the UK.

Key to this UKCRC way of working has been leadership and engagement. The appropriate leadership to tackle an issue has been agreed and then the UKCRC has provided an independent forum for engaging with the range of stakeholders needed to create the reforms required. Momentum for many of the changes has come through implementation of the R&D strategies of the UK Health Departments.

On many occasions the Health Departments have chosen to work through the UKCRC Partnership to develop their own strategies and implement their changes.

One of the best examples of this new way of working has been the development of the Integrated Research Application System (IRAS). It is a great example of partnership working between many stakeholders throughout the UK. Its development required input from a wide range of different organisations, whilst its long-term future will be guaranteed through oversight by a joint management structure.

This 'UKCRC way of working' is now widely accepted by the UKCRC Partners and this will be important if we are to sustain momentum into the future. With the planned reduction in the role of the UKCRC Secretariat, Partner organisations will increasingly take the lead on issues on behalf the wider partnership. This should ensure that the work needed to develop and support a world class health research environment in the UK will continue long into the future.

Liam O'Toole
Chief Executive, UK Clinical Research Collaboration

Executive Summary

The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working together to establish the UK as a world class environment for clinical research. The Partnership's ultimate aim is to harness the research potential of the Health Service and to benefit patients and the public by improving national health and increasing national wealth.

The partnership was established by the Chancellor in the 2004 Budget speech. Over the last four years, the UKCRC Partners have adopted a coordinated approach to:

- Building up the infrastructure for research in the NHS
- Building up the research workforce
- Developing incentives for research in the NHS
- Streamlining the regulatory and governance environment
- Coordinating research funding.

The UKCRC Partners have promoted cultural change by working to:

- Promote patient and public involvement in research
- Raise public awareness of the importance and value of clinical research
- Establish a new model for working with industry.

Through both independent and collaborative work, the Partners are transforming the UK clinical research environment by implementing key changes within these areas. *Best Research for Best Health* in England and the R&D strategies in Northern Ireland, Scotland and Wales will continue to be key drivers for change in the Health Service.

Over four years the UKCRC Partners have developed effective ways of working together and have undertaken an ambitious programme of work. Many key changes have been implemented through working both individually and collaboratively to achieve shared goals. More is planned for delivery in 2009 and beyond, and the UKCRC way of working in partnership is now becoming a permanent feature of the UK clinical research landscape.

ACTIVITIES

Building up Research Infrastructure in the UK
A world-class infrastructure is being established by the UKCRC Partners to support all aspects of clinical research in the UK. This includes staff, facilities and enabling technology. Rapid progress has been made in:

Clinical Research Networks
The UK Clinical Research Network (UKCRN) has been established, developed and funded by the Health Departments of the four UK nations. This is providing world-class infrastructure across the UK to underpin clinical research, based on a network of professional and dedicated research staff working in the Health Service.

Development of the UK Clinical Research Network has continued over the past two years with patients being recruited into a growing portfolio of commercial and non-commercial studies across the UK. By September 2008 1397 studies had been adopted into the UKCRN portfolio.

The UKCRN comprises a family of four national sets of clinical research networks: the NIHR Clinical Research Network in England, the Northern Ireland Clinical Research Network, the Scottish Clinical Research Networks and Clinical Research Collaboration Cymru. UK-wide coordination is provided by the NIHR Clinical

Research Network Coordinating Centre, based in Leeds and London.

Experimental Medicine

The UKCRC Partners agreed that more investment in experimental medicine infrastructure and research was needed in the UK. By 2006, a collective investment of £134m had been made in experimental medicine research facilities by UKCRC Partners including the Wellcome Trust, the Medical Research Council (MRC), Wolfson Foundation, UK Health Departments, Cancer Research UK, the British Heart Foundation and the Health Research Board of Ireland.

The last four years have seen continuous investment and development in this area. Recent key elements of this initiative have included:

- Establishment of 12 Biomedical Research Centres and 15 Biomedical Research Units by the NIHR, six Translational Medicine Centres by the MRC and 19 Experimental Cancer Medicine Centres by Cancer Research UK and the UK Health Departments
- Launch of the Experimental Medicine Resources website to provide the first centralised information on the UK's capability and expertise in this field.

Streamlining the Regulatory and Governance Environment

The UKCRC Partners have continued to implement several major changes aimed at delivering a new streamlined regulatory and governance environment. Achievements have included:

- Development of IRAS (Integrated Research Application System)
- Development of model agreements for commercial and Clinical Research Organisation-managed clinical trials and for commercial medical device clinical investigations
- Development and roll-out of the Research Passport system for Honorary Contracts
- Establishment of a UK-wide Advice Network for consistent, authoritative advice.

Building up the Research Workforce

Working with a wide range of stakeholders, the UKCRC Partners have developed and implemented an integrated career pathway for training clinical academics. This pathway is now well established, with three rounds of awards launched for NIHR Academic Clinical Fellows, NIHR Clinical Lecturers and Clinical Senior Lecturers in England and Wales. In Scotland, the Scottish Clinical Research Excellence Development Scheme is in place, and in Northern Ireland there are plans to create similar awards at Foundation Year, Academic Clinical Fellowship and Clinical Lecturer levels.

Building on this success, the UKCRC Partners made recommendations on a similar scheme for clinical academic nurses, midwives and allied health professionals.

Coordinating Research Funding

Building on the success of the first ever analysis of health research funding in the UK, published in 2006, the UKCRC Partners have conducted a further analysis of smaller and medium-sized charity funding. Health research funders have begun to adopt the UKCRC's Health Research Classification System, developed as part of the 2006 Health Research Analysis, for ongoing research management.

Collaborative funding from the UKCRC Partners has enabled the establishment of five UKCRC Public Health Research Centres of Excellence

through a £20m joint initiative, and the launch of a £16.5m jointly-funded UKCRC Translational Infection Research Initiative, which has included the creation of two Infection Research Consortia.

NHS IT Systems and Research
The UKCRC Partners agree that new developments in managing patient data open up enormous opportunities for research which can improve patient safety and enhance the effectiveness of clinical treatments in the UK. The UKCRC has worked with NHS Connecting for Health in England to ensure research will be a key component of their developing programme of work. The UKCRC Partners conducted a series of research simulations to test the feasibility of using the NHS Care Record System for a range of different research applications. Recommendations from these simulations have been endorsed by the Government and the NHS Connecting for Health Research Capability Programme has been established with NIHR funding to take this forward.

Patient and Public Involvement in Research
The UKCRC partners are working to promote active involvement of patients and the public in developing a world-class clinical research environment in the UK. The UKCRC and INVOLVE, an NIHR programme, have launched People in Research, a web-based resource for involving patients and the public in clinical research. A pilot scheme is underway which involves patients and the public as members of UKCRC advisory groups, Board Subgroups and the UKCRC Board. A UKCRC Strategic Plan for patient and public involvement 2008 – 2011 has been developed to ensure that active involvement of patients and the public in clinical research remains a central tenet of the UKCRC's work.

Raising Public Awareness of Clinical Research
Increasing public understanding of the importance and value of clinical research has always been a goal of the UKCRC Partners. Providing clear information for patients and the public about clinical trials has been a key part of this work and the UKCRC has therefore developed generic information resources aimed at people who may be considering becoming involved. The resources are being used throughout the UK Clinical Research Network, the wider NHS and by commercial organisations. To date over 25,000 copies of *Understanding Clinical Trials* have been distributed.

In addition, the UKCRC has developed information materials and classroom resources on clinical research for teachers and students designed to support the national curricula for science across the UK.

Working with industry
Continued industry involvement in the broad range of UKCRC activities has ensured that the solutions being implemented by the UKCRC Partners not only improve the environment for non-commercial research but also meet the specific needs of the different industry sectors. Delivery of key pieces of the UKCRC's agenda has only been possible because of direct involvement by individuals from commercial organisations and their trade bodies.

TAKING THE AGENDA FORWARD

By joining forces, the UKCRC Partners have achieved an impressive amount in just four years. These achievements provide increased incentives for research in the NHS. But there is still work to be done. The UKCRC way of working is fast becoming a permanent feature of the clinical research landscape, and will have impact long into the future as the UK realises its potential as a world leader in health research.

Further information can be found on the UKCRC website ***www.ukcrc.org***

Introduction

The UKCRC Partners have worked together over the past four years to realise their shared ambition of establishing the UK as a world leader in clinical research. Their ultimate aim is to benefit patients by increasing the health and wealth of the UK, through harnessing the research potential of the NHS.

The UKCRC was established in 2004 by the then Chancellor of the Exchequer, Gordon Brown. A progress report on the UKCRC's first two years of operation was published towards the end of 2006.

This subsequent report provides an update on these activities and details the work and achievements of the third and fourth years of the Partnership.

The UKCRC way of working

The UKCRC is a broad-based partnership of organisations working together towards a shared vision for health-related research in the UK. It includes the main public and charity sector funders of health-related research; the academic and university sectors; the NHS; regulatory bodies; the bioscience, healthcare and pharmaceutical industries; and patients. The UKCRC Board oversees the work of the Collaboration and jointly funds a secretariat to help facilitate and coordinate this work.

Together, the UKCRC Partners are tackling a broad agenda of issues affecting clinical research through several interconnected areas of activity:

- Developing the infrastructure to underpin clinical research in the NHS
- Building up an expert workforce to support clinical research
- Streamlining the regulatory and governance environment
- Developing incentives for research in the NHS
- Coordinating research funding.

The Partners are also working to raise public awareness of the value of clinical research and encouraging appropriate patient and public involvement in the clinical research process.

From an early stage, the UKCRC Partners developed a way of working that would allow them to tackle complex, long-standing issues through engaging with the necessary stakeholders, without creating a bureaucratic representational structure. The UKCRC has always been intended as a forum for leadership where individual organisations can lead specific pieces work in a supportive environment under an independent umbrella. A mixed model of working supports this approach, under which the UKCRC partners have taken forward joint activities in three main ways:

- Led and administered by individual Partner organisations on behalf of the UKCRC Partners
- Led by individual Partners but administered and supported by the UKCRC Secretariat
- Led and administered by the UKCRC Secretariat.

The last two years of the Partnership have clearly demonstrated the benefit of this approach, particularly in complex areas such as the work to streamline the regulatory and governance environment in the UK.

The Research for Patient Benefit Working Party identified the changes required to make the UK a world class environment for health research and it was clear that putting research back as a core business of the NHS would be vital to achieve this goal. The UK Health Departments have been key

drivers of the cultural and organisational changes required to support and raise the profile of research within the health service. Their R&D strategies – *Best Research for Best Health* in England, *Research for Health and Wellbeing 2007-2012* in Northern Ireland, *Research Strategy for Health and Healthcare* in Scotland and *A Health and Social Care Research and Development Strategic Framework for Wales* in Wales – have set out a clear vision for health research and all are using the UKCRC as the forum for joint working and broad stakeholder engagement. The health service in the UK is devolved and has different structures and organisational cultures in each of the four nations. Therefore, the UKCRC also provides an important forum to ensure that any solutions developed have compatibility and connectivity across the UK.

The UKCRC's evolving remit

The first two years of the UKCRC Partnership focused on ***planning*** and ***implementation*** of the changes necessary to create a world class health environment. Much of this involved setting up the structures and processes necessary to implement the agreed changes in each area of activity. Years three and four have seen a clear shift of focus onto ***delivery*** and ***communication***, and the majority of the Partnership's key pieces of work are now coming to fruition. The UKCRC's communication strategy has also evolved to focus on explaining how all the different elements of the new research environment fit together and what it means for the different stakeholder groups.

Working with Industry

The bioscience, healthcare and pharmaceutical industries have always had a central role in the UKCRC agenda and their engagement in the process of change within the health service has been vital to ensure success. The last two years of the Collaboration have seen increased engagement with industry and all sectors have been involved in negotiating and delivering many of the solutions required. Their involvement has been particularly important in the changing regulatory and governance environment in the UK, helping to ensure that solutions put in place meet the needs of all involved in clinical research in the UK, ultimately leading to benefit for patients.

Bioscience, healthcare and pharmaceutical companies have also been important advocates of the improving environment for research in the UK, helping to promote the UK research environment on the world stage. An important part of this process is having the appropriate metrics to demonstrate that the UK can deliver a world class research infrastructure and industry has been a key driver of this within the UKCRC Partnership.



Building up Research Infrastructure in the UK

The UKCRC Partners are helping to establish UK-wide infrastructure to support all aspects of clinical research, including staff, facilities and enabling technology.

BACKGROUND

In the past, the necessary infrastructure to support research in the NHS was not always available, and there was a decline in the number of NHS staff spending dedicated time on research. Principal investigators were experiencing difficulties in getting the research up and running, and 'state of the art' experimental medicine facilities were in short supply.

During the UKCRC's first two years the four UK Health Departments invested in UK-wide clinical research networks to provide the infrastructure to support high quality clinical research studies. In addition, joint initiatives between several UKCRC Partners provided up to £134m of new investment in experimental medicine. This included:

- a major programme to invest in clinical research facilities, led by the Wellcome Trust
- establishment of a network of experimental cancer medicine centres led by Cancer Research UK
- funding for a major programme of experimental medicine research led by the Medical Research Council.

ACTIVITIES AND ACHIEVEMENTS

Clinical Research Networks

A world-class infrastructure based on a network of dedicated research support staff working in the NHS was a key recommendation of the Research for Patient Benefit Working Party. February 2005 saw the establishment of clinical research networks, funded and developed by the Health Departments of the four UK nations.

Establishing the NHS infrastructure for research has been a major achievement for the four UK Health Departments and remains a central part of their R&D strategies.

The emerging UK-wide infrastructure

The aim of establishing clinical research networks is to ensure that patients and healthcare professionals from across the UK are able to participate in, and benefit from, clinical research. The networks are intended to improve the quality, speed and coordination of clinical research. They also aim to increase collaboration with industry partners and ensure that the NHS can meet the health research needs of industry.

The UK Clinical Research Network (UKCRN) consists of a series of national networks. The approach in England and Scotland has been to develop networks for certain areas of health and disease. These are complemented by funding for studies outside the topic-specific networks in Scotland and via a comprehensive network in England to underpin other areas of clinical research. Wales and Northern Ireland have funded comprehensive networks to support all research in these nations, which are subdivided into themed research areas. The NIHR Clinical Research Network Coordinating Centre, funded by the Department of Health in England and based in Leeds and London, plays a key role in ensuring that all the different networks across the UK can work together effectively to host large multi-centre commercial and non-commercial studies.

The last two years have seen significant progress in the development of the networks across the UK. The NIHR Topic Specific and Primary Care Research Networks in England are fully operational and recruiting patients to trials. The appointment of staff in the NIHR Comprehensive Clinical Research Network is being completed. The Clinical Research Collaboration Cymru is now fully operational. The networks in Scotland are also now close to being fully operational and it is expected that the Northern Ireland Clinical Research Network will be fully operational by 2009. These networks will provide a world-class platform in the UK to underpin clinical trials and other well designed studies funded by government, the charity sector or Industry.

Key Achievements

Clinical Research Networks

- Continued development of the UK Clinical Research Network to support clinical research in the Health Service, funded by the four UK Health Departments:
  - National Institute for Health Research (NIHR) Clinical Research Network
  - Northern Ireland Clinical Research Network
  - Scottish Research Networks
  - Clinical Research Collaboration Cymru.
- All of the networks are now recruiting patients into a growing portfolio of commercial and non-commercial studies.

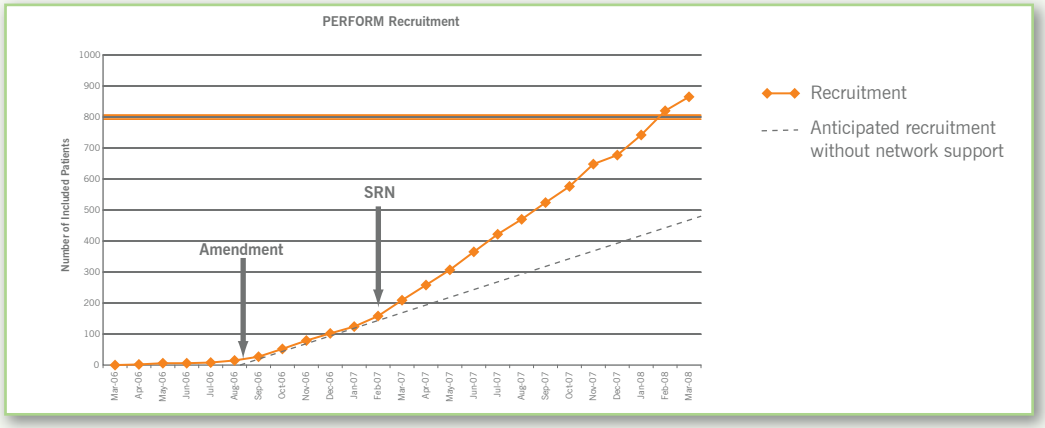
How the research networks can aid commercial trials

In January 2006, pharmaceutical company Servier began the PERFORM study. This was a major clinical trial in 42 countries to compare a new anti-platelet treatment with aspirin for reducing cerebrovascular and cardiovascular events in patients with cerebrovascular disease.

Recruitment in the UK during the early stages of the study was slower than predicted and was falling behind other comparable countries. By July 2006, just 30 sites were open in the UK and only 16 patients had been recruited. Servier contacted the newly-created Stroke Research Network and it adopted the trial.

Following adoption of PERFORM, several measures were implemented:

- Ten new sites affiliated to Stroke Local Research Networks were identified and opened
- Seven original inactive sites were closed
- Dedicated SRN-funded research staff were placed in most PERFORM sites
- Regional motivational meetings were organised with the Local Research Networks
- Performance management and motivation was undertaken by the Local Research Networks
- Incentives were established for Local Research Networks to reach recruitment milestones.



By the end of 2006, just over 100 patients had been recruited to the trial in the UK, which was projected to include an estimated 500 patients by the end of the recruitment period. With the active involvement of the CRN, the recruitment curve significantly shifted and the agreed recruitment target of 800 patients was reached within the agreed timelines (28 February 2007). Most of the trial participants were recruited to the Stroke Research Network sites, and on average, these sites were 42% better recruiters than their non-Stroke Research Network counterparts. The ranking of UK recruitment, amongst the 42 countries involved, progressed from 8th in early 2006 to 6th by the end of trial in March 2008.

PERFORM has been a good test case for the Stroke Research Network because the study opened before it was fully established. The Stroke Research Network and Servier believe that without Network support the study would not have achieved the recruitment target on time.

Strategic oversight for the development of the UKCRN is provided by a subgroup of the UKCRC Board which includes representation from industry and the major government and charity funders of health research. The different approaches being developed across the UK are detailed below.

England

The NIHR Clinical Research Network in England is funded by the Department of Health and forms a key component of the Government's R&D strategy, *Best Research for Best Health*. The networks comprise six Topic Specific Clinical Research Networks, a Primary Care Research Network and the NIHR Comprehensive Clinical Research Network.

NIHR Topic Specific Clinical Research Networks provide infrastructure support for disease-focused research in cancer, diabetes, dementia and neurodegenerative diseases, mental health, medicines for children and stroke. Each network has a coordinating centre with directors and staff to oversee its development and comprises several local research networks made up of network managers, research nurses and other research support staff.

The NIHR Primary Care Research Network brings together a wide variety of primary care practitioners - including GPs, dentists, pharmacists and health visitors - to facilitate the involvement of staff and patients in clinical studies. As the network develops it will offer patients in primary care settings increased opportunities for involvement in high quality clinical studies. These will include innovations in prevention, diagnosis, treatment and health care delivery in the community.

The NIHR Comprehensive Clinical Research Network is rapidly being implemented across England, overseen by the NIHR Clinical Research Network Coordinating Centre. This process is expected to be completed in April 2009. It consists of 25 Comprehensive Local Research Networks covering the whole of England, which are the primary route for providing infrastructure to support study involvement. They will encourage participation in the NIHR Clinical Research Network's portfolio of high quality clinical studies and provide a coordinated and efficient infrastructure of research support personnel and facilities to support recruitment. The structure and organisation of each of these networks will vary according to the demographic make-up of the local population and the nature of the service providers within it.

The NIHR Comprehensive Clinical Research Network, Topic Specific Clinical Research Networks and Primary Care Research Network are working together to support a high quality national portfolio of clinical trials and other well-designed studies funded by government, medical research charities and industry.

Northern Ireland

In Northern Ireland, the Health & Social Care (HSC) R&D Office has established the Northern Ireland Clinical Research Network (NICRN). As part of the wider UKCRN the NICRN aims to increase access to, and participation in, high quality clinical research studies throughout Northern Ireland. A single NICRN Coordinating Centre supports nine interest groups in the following areas:

- Cardiovascular
- Children
- Critical Care
- Dementia
- Diabetes
- Primary Care
- Respiratory
- Stroke
- Vision

Other clinical groupings are expected to emerge as the NICRN proves its value. The NICRN is fully involved with the wider UK Clinical Research Network and is liaising with the Topic Specific and Comprehensive Research Networks in England and its counterparts in Wales and Scotland.

Although the NICRN will not be fully operational until later in 2009 it is already recruiting study participants, network staff and research support staff. The NICRN Coordinating Centre will continue to consolidate working arrangements and the processes required to deliver a robust NICRN portfolio and a supportive and conducive clinical research environment. An important part of that environment is the Clinical Research Support Centre which provides a vital Clinical Trials Unit function for the NICRN. The Health and Social Care (HSC) Trust Research Offices provide another important element and they are working with the NICRN Coordinating Centre to integrate functions and optimise support.
Web: www.nicrn.hscni.net

Scotland
As part of the UKCRN, the Chief Scientist Office of the Scottish Government (CSO) has established four topic-specific clinical research networks in Scotland to complement the existing Primary Care and Cancer Networks. A further network in Dementia has been approved and implementation began in August 2008. These networks provide the infrastructure to support a range of high quality studies across the full spectrum of disease and clinical need in Scotland.

The CSO has encouraged NHS Scotland and the clinical academic research community to plan the expansion of its clinical research activity in a collaborative way and to also work with partner networks across the UK. The Research Networks are:

- Scottish Cancer Research Network
- Scottish Dementia Research Network
- Scottish Diabetes Research Network
- Scottish Medicines for Children Network
- Scottish Stroke Research Network
- Scottish Mental Health Research Network
- Scottish Primary Care Research Network.

Generic support has also been allocated to NHS Scotland to allow participation in research areas outside these specific topics. This support typically helps to provide additional key skills in areas such as imaging, statistics and nursing. Further support is currently being discussed to strengthen areas of under-supply and encourage greater operation and managerial efficiency.
Web: www.sehd.scot.nhs.uk/cso

Wales
In Wales, the provision of internationally competitive research infrastructure for health and social care is being coordinated by the Clinical Research Collaboration Cymru (CRC Cymru), which was launched in July 2006. The Collaboration is part of the strategic work programme of the Wales Office of Research and Development (WORD) and is backed by annual funding of £4.5m for a period of three to five years. CRC Cymru aims to increase research activity in Wales, particularly large-scale, multi-centre trials, and to improve the research community's capability to generate income from both commercial and non-commercial sources. It works closely with UKCRN and key partners across the UK.

CRC Cymru comprises ten Thematic Research Networks, six research infrastructure and technical support groups, three trials units and a Cardiff-based coordinating centre.

The CRC Cymru Thematic Research Networks are:

- Children and Young People's Research Network
- Dementias and Neurodegenerative Diseases Research Network (NEURODEM)

- Diabetes Research Network Wales (DRN)
- Thematic Research Network for emergency and UnScheduled Treatment (TRUST)
- Learning Disabilities and Autism Research Network (LDAN)
- Mental Health Research Network Cymru (MHRNC)
- Older People and Ageing Network (OPAN)
- Public Health Improvement Research Network (PHIRN)
- Wales Cancer Trials Network
- Wales Epilepsy Research Network (WERN).

The CRC Cymru Coordinating Centre coordinates and manages the generic support needs of the networks. It oversees operational matters needed to run the Welsh infrastructure effectively, in particular the recruitment and management of a research professional network. It also has groups for training, involving people, portfolio and industry.

CRC Cymru has three Clinical Trials Units: the South East Wales Trials Unit (SEWTU), the North Wales Organisation for Randomised Trials in Health (NWORTH) and the Wales Cancer Trials Unit (WCTU).

Within CRC Cymru, the Welsh infrastructure also includes four infrastructure support services, a Health Information Research Unit (HIRU), and an academic research network for specialist advice and support across CRC Cymru: the All-Wales Alliance for Research and Development (AWARD).
Web:www.wales.nhs.uk/sites3/home.cfm?orgId=580

Cross-cutting UKCRN activities

The past four years have seen the development of national systems to support network staff in areas such as training and education, patient and public involvement, collaboration with industry, and regulatory and governance advice. Most of these initiatives are UK-wide, but where there are initiatives in the various countries in place, links have been established to ensure that the approach across the UK is coordinated.

UK Clinical Research Network Clinical Research Portfolio

The UK Clinical Research Network is building a picture of the current clinical research which is taking place across the UK supported by the networks.

Details of studies which meet specific eligibility criteria are recorded in linked databases. This comprises the NIHR Portfolio in England, and the corresponding portfolios of Northern Ireland, Scotland and Wales. The database is available online and studies are listed by disease area/topic using the Health Categories developed for the UKCRC Health Research Analysis.
Web: http://public.ukcrn.org.uk/search

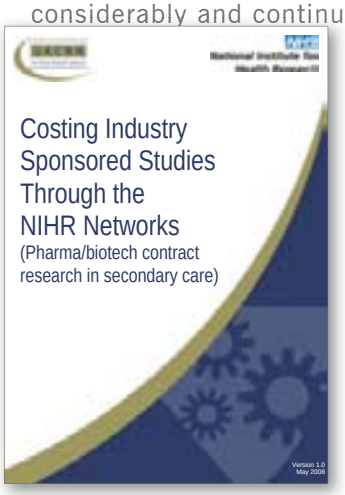
This Research Portfolio is a national data resource, which, in England is being used to manage the allocation of NHS infrastructure funding and which will support the performance management of the NIHR Clinical Research Network.

Collaboration with Industry

Each of the four UK Health Departments is committed to productive collaboration with industry to ensure that the UK retains its global position as a preferred

clinical research location. Whilst continuing to work with the UKCRC Industry Road Map Group, the NIHR Clinical Research Network Coordinating Centre has also established a dedicated Industry Team. This team seeks to address the specific challenges and pressures faced by the healthcare industry in successfully delivering their research and development projects through the NHS.

In the last two years, the number of commercial studies adopted into the networks has increased considerably and continues to expand.



In May 2008, a transparent and consistent national costing system for contract trials of pharmaceutical and biotechnology agents in secondary care being run in the NIHR Networks was published: the UKCRN Costing Template. This was developed and piloted in a collaborative process involving NHS and industry stakeholders and is designed to speed up the initiation of industry contract trials by reducing the time required for site-by-site negotiations. Templates suitable for use in primary care and in studies of medical devices are being developed. A version of this template for use in Wales is currently under development.

Building on the successful launch in Scotland of NHS Research Scotland (NRS) as a country-wide system of R&D approval for all non-commercial studies, the ambit of NRS is being extended to embrace commercial studies. Although still in an early pilot stage, the aim is to deliver a single point of contact in a Health Board for Scotland-wide trial negotiation. One of the perceived attractions of this system is that companies need not go through a central point which is separate from their established clinical contacts, but may progress Scotland-wide negotiations through any lead NHS Board with which they have a good working relationship. This arrangement also means that a single site study may be extended throughout Scotland without revisiting generic contractual and R&D issues.

Although the UKCRN Costing Template has not been adopted in Scotland, the designated Board will deal with all financial negotiations and will be able to confirm costs as acceptable on behalf of Scotland. In light of the experience of the pilot, it is hoped that NRS will extend its activity to all commercial studies from next year.

Education and training

It is vital that the new research infrastructure is supported by a well-trained clinical research workforce to deliver high quality research studies. The NIHR Clinical Research Network Coordinating Centre has therefore developed a comprehensive training programme for all staff, public and patient representatives involved with the NIHR Portfolio of studies. Since 2006, 58 courses have been developed and over 5000 researchers and patient representatives have participated in them. CRC Cymru Coordinating Centre has also developed a comprehensive training and education programme for research staff in Wales who are working with, or associated with, CRC Cymru research. In Scotland, a wide variety of training courses are offered by the Wellcome Trust Clinical Research Facility in Edinburgh, which has also developed a National Database of training opportunities across Scotland. All of these training programmes can be accessed by researchers across the UK who are working on the UKCRN portfolio of studies.

UKCRC Registered Clinical Trials Units

As the portfolio of studies taking place in the clinical research networks grows, it will be important to ensure that there are sufficient clinical trials units with the expertise to coordinate high quality, multi-centre studies. To help meet this need, the UKCRC has established a registration process for Clinical Trials Units (CTUs) that recognises those Units which have the appropriate expertise to deliver high quality clinical research. The overall aim of this process is to help improve the quality and quantity of available expertise for carrying out clinical trials in the UK.

To gain UKCRC Registration, CTUs are required to demonstrate a track record of experience in coordinating multi-centre trials, and must have expert staff to develop studies, robust quality assurance systems and evidence of long term viability of capacity for trials coordination. The registration process is coordinated by the NIHR Clinical Research Network Coordinating Centre on behalf of the UKCRC, and the first round took place in late 2007. An international review panel recommended the award of UKCRC Registration to 40 CTUs, of which 26 were awarded full registration and 14 were awarded provisional status. National Cancer Research Institute-accredited CTUs were automatically eligible for full UKCRC Registration. A second call for applications is planned for early 2009.

A new website has been developed by the NIHR Clinical Research Network Coordinating Centre to provide information on the UKCRC Registered CTUs. Users of the site are able to access contact details for each CTU and search for CTUs with expertise in a particular disease area or research methodology.
Web: www.ukcrc-ctu.org.uk

The Directors of the UKCRC Registered CTUs meet regularly to share best practice and address common issues faced by CTUs. Working groups have been established for information systems, quality assurance systems, trial management, and training and professional development.

In order to assess the current CTU core capacity and expertise available in the UK, the NIHR Clinical Research Network Coordinating Centre has undertaken a mapping project on behalf of the UKCRC. A model has been developed for the minimum core CTU resources and infrastructure required to support future research studies. Together the information from the mapping project and core CTU estimated resources model will inform where further investment may be needed.

Key Achievements

UKCRC Registered Clinical Trials Units

- 40 Clinical Trials Units (CTUs) awarded UKCRC Registration
- UKCRC Registered CTUs website developed to provide centralised information on the units' research interests and experience
- Assessment of current core capacity of CTUs and development of a model to determine minimum core CTU resources required to support UK clinical trials
- Development of a nationally agreed set of data and information system standards for CTUs

Experimental Medicine

During the early period of the UKCRC, the Partners agreed that more investment in experimental medicine infrastructure and research was needed, within the context of a national coordinating framework. The major outcome from this agreement was a coordinated initiative which resulted in a commitment of £134m to boost experimental medicine in the UK and Ireland.

The initiative consisted of four programmes of funding. The first of these was the Clinical Research Infrastructure Initiative: a joint call to fund new Clinical Research Facilities and strengthen existing ones. This call was led by the Wellcome Trust and supported by the Wolfson Foundation, UK and Irish Health Departments, Medical Research Council, British Heart Foundation and Cancer Research UK. The second programme of funding was an initiative to expand a network of Experimental Cancer Medicine Centres, supported by Cancer Research UK and the UK Health Departments. Thirdly, a Medical Research Council funding programme was launched which provided direct support in the form of grants for experimental medicine research. In addition NIHR has funded a number of Clinical Research Facilities, as has the Chief Scientist Office through its generic infrastructure funding.

These linked initiatives have given a considerable boost to the UK's capacity and capability to conduct experimental medicine research, which has been built upon with further investment from the UKCRC Partners. Work has focused on promoting networking and coordination between the new and existing facilities and spreading the word about the nature and availability of the new resources.

Key Achievements

Experimental Medicine

- Further major investment by UKCRC Partners in experimental medicine infrastructure and research, including:
  - Establishment of 12 Biomedical Research Centres and 15 Biomedical Research Units by the NIHR
  - Establishment of 19 Experimental Cancer Medicine Centres by Cancer Research UK and the UK Health Departments
  - Creation of 6 Translational Medicine Centres by the MRC
  - Second round of grants for experimental medicine research funded by the MRC and the British Heart Foundation.
- Launch of the UKCRC Experimental Medicine Resources website, funded by NIHR
- Establishment of effective networking between UK experimental medicine facilities

New investment in Experimental Medicine

The UKCRC Partners have been actively building on their initial investment by providing further support for research in experimental medicine and the underlying infrastructure.

The NIHR has created 12 Biomedical Research Centres with total funding of £450m over five years. These Centres are major NHS-University partnerships selected through open competition. They focus on

translational research to move advances in basic biomedical research from the laboratory to patient care settings.

Further NIHR funding has established 15 Biomedical Research Units to undertake translational research in priority areas of high disease burden and clinical need which have formerly received limited amounts of research funding. Each Unit will receive £3.75m over four years.

In addition, the Medical Research Council has announced £15.5m support for six Translational Medicine Centres aimed at translating discoveries into new drugs, therapies, diagnostic tools or methods of prevention; or using clinical knowledge to inform fundamental research priorities. A second round of grants for experimental medicine research provided a further £15m of funding during 2008 from the Medical Research Council and the British Heart Foundation.

UK Experimental Medicine Resources

To develop and coordinate the many new developments in experimental medicine the UKCRC has launched an online information resource on UK experimental medicine research: the **UKCRC Experimental Medicine Resources** website. This provides, for the first time, a central information repository on the UK's capability and expertise in experimental medicine and early phase clinical trials. It is an optimum entry point for those wanting to gain insight and find up-to-date information on available expertise, resources and techniques.

The website was developed and funded by the NIHR Clinical Research Network Coordinating Centre, on behalf of the UKCRC Partners, and was launched in January 2008. It contains up-to-date information on over 40 major UK experimental medicine facilities. Site users can search for facilities by location, health or disease research topic, or skills and equipment.

The website also provides pages describing the latest news and events in experimental medicine in the UK.
Web: www.ukcrcexpmed.org.uk

> *"Bringing together information on the UK's resources for early phase experimental medicine research in one place is a great step forward. It should have immediate benefit for the smaller pharmaceutical companies and investigators who have limited knowledge of what is available in the UK.*
>
> *Some of us are lucky enough to have the in-house knowledge and contacts to find the external expertise to meet our needs. But as large pharma companies downsize and outsource work and also as the nature of the tools, methods and technologies becomes more and more specialised, the need to rapidly locate the right sites and individuals to carry out our work will be increasingly important.*
>
> *I am sure this one-stop-shop will prove invaluable for those who have the job of finding places and sites with the skills and experience to get work done"*
>
> Richard Peck, Global Head Clinical Pharmacology, Roche

Effective Networking

Further work has taken place to establish effective networking of facilities and to ensure compatibility and coordination across the range of activities in experimental medicine.

On behalf of the UKCRC Partners, the NIHR Clinical Research Network Coordinating Centre is taking a lead on many issues in experimental medicine, and it has a dedicated team for this purpose. It has established a Directors' Forum which is open to the leaders of all the UK's major experimental medicine facilities. The Forum aims to facilitate the joint development of best research practice and coordinated research activities. In partnership with the Medical Research Council, the Coordinating Centre is also developing a series of investigators' guides which will include templates for grant applicants and a reviewer's guide to experimental medicine.

Another major initiative to promote effective networking is the Experimental Cancer Medicine Centre Network. This was launched in October 2006, and links together the 19 Experimental Cancer Medicine Centres, led by Cancer Research UK and supported by the UK Health Departments. Around 50% of studies running in the Experimental Cancer Medicine Centres have commercial involvement. Further information on this network can be found at **www.ecmcnetwork.org.uk.**

The UK Clinical Research Facility Network has also been established by the NIHR and the Chief Scientist Office of the Scottish Government Health Directorates. The Network will develop an integrated approach across the four UK nations to identify, conduct and share common themes and good operating practices across facilities. The planned outcome is the development of a comprehensive collection of standard operating procedures and management initiatives to guide standards in clinical and experimental medicine research processes.

LOOKING AHEAD

Establishment of the clinical research networks throughout the UK will continue and all are expected to be fully operational by 2009.

A second round of UKCRC CTU Registration is scheduled to take place in early 2009. The UKCRC CTU Registration Committee highlighted the need for a set of national standards and requirements for data management systems. The NIHR Information Systems Team is working closely with the UKCRN clinical trials team to address this issue. The project has been endorsed by the UKCRC Partners, and a project board has been established to review the current data and information systems standards across the UK. This work will inform the development of a nationally agreed set of data and systems standards. It will also establish options for a strategy and policy for CTU information and data management.

The UKCRC Partners will continue to work towards a coherent framework for experimental medicine. The NIHR Clinical Research Network Coordinating Centre will be central to this effort and will lead on:

- Continued encouragement of networking between new and existing experimental medicine facilities across the UK
- Expansion of the scope of **UK Experimental Medicine Resources** to include new clinical research facilities and early phase commercial clinical research units. A process has been established to solicit and judge applications for inclusion on the basis of them meeting specific minimum criteria to ensure that they are comparable and compatible with the peer reviewed facilities currently on the website
- Assessment of capacity and capability in specific areas of the UK's experimental medicine infrastructure. This strategic information should help to maximise the use of resources and focus future investment on areas in which it will have the greatest impact.



Streamlining the Regulatory and Governance Environment

The UKCRC Partners are working towards a streamlined regulatory and governance environment for research that protects the rights, safety and dignity of patients whilst minimising unnecessary bureaucracy and red tape.

Key Achievements

- **UKCRC Regulatory and Governance Advice Service**
  launched UK-wide in April 2007
- **Research Passport for Honorary Contracts**
  introduced across the UK from October 2007
- **Model Agreements** launched for:
  - **Commercial pharmaceutical clinical trials** (Revised mCTA)
    October 2006
  - **CRO managed pharmaceutical clinical trials** (CRO mCTA)
    October 2007
  - **Commercial medical device clinical investigations** (mCIA)
    Autumn 2008
- **Integrated Research Application System**
  launched UK-wide in January 2008
- **European regulatory horizon scanning strategy**
  implemented September 2006

BACKGROUND

Streamlining the regulatory and governance arrangements for research was one of the biggest challenges to be addressed when the UKCRC was formed in 2004. It was agreed that lack of consistency and standardisation between the different organisations involved, and variation in the interpretation of regulations or advice, was having a detrimental effect on health research in the UK.

The UKCRC Partners and stakeholders, including the regulatory and governance bodies, have been working together to reduce the administrative burden and introduce consistent approaches. The R&D strategies of the four UK nations and pressure from the research community itself have helped to drive these initiatives forward.

Between 2004 and 2006, the UKCRC Partners and stakeholders took on an ambitious programme of collaborative work which laid the foundations for recent achievements. Milestones in the first two years included gaining the endorsement of the major Regulatory and Governance bodies for the development of a single IT platform for permissions and approvals, piloting of the UKCRC R&G Advice Service to provide consistent and authoritative advice, and pilot studies of the Research Passport for Honorary Contracts.

Significant progress has already been made, but the full impact of individual changes to the regulatory environment will only be realised when all of them are implemented and embedded as standard practice.

UKCRC Regulatory and Governance Advice Service

A UKCRC review of advice provision on regulatory and governance issues revealed confusion and inconsistency. It was clear that a reliable mechanism for UK-wide consolidated regulatory and governance advice was needed. In response to this review and as part of the Department of Health in England's R&D Strategy, *Best Research for Best Health*, the UKCRC Regulatory and Governance Advice Service was created. The service is jointly delivered by the NIHR Clinical Research Network Coordinating Centre and the Medical Research Council Regulatory Support Centre.

The Advice Service forms part of the local and national regulatory and governance advice provision in the UK for those involved in health research. It was primarily set up to support advice providers, such as NHS/HSC R&D departments and university research managers or Clinical Trial Unit staff who may not have access to reliable sources. The Advice Service aims to deliver consistent and authoritative advice on regulatory and governance issues by providing:

- A route for resolving complex queries in consultation with national regulatory authorities
- A range of web-based resources, including toolkits, best practice and Q&As.

The Advice Service was piloted over six months in several sites before it was launched throughout the UK via a series of roadshows between April and July 2007.
Web: http://www.ukcrc-rgadvice.org

UKCRC R&G Advice Service resolution of a complex query

The UKCRC Regulatory & Governance Advice Service provides a route for answering complex queries, such as those involving several regulatory bodies. One such example, received by the R&G Advice Service in late 2006, involved three regulatory bodies and a complicated situation involving indemnity of research.

The situation: A clinical trial of an investigational medicinal product was being conducted at a number of sites in England, one of which was a prison setting. It was sponsored and funded by the Department of Health and had received approval from a Research Ethics Committee and the Medicines and Healthcare products Regulatory Authority. NHS Research & Development permission from one relevant Trust would only be granted subject to satisfactory indemnity arrangements.

The problem: The research team comprised NHS employees, the prison staff, and staff employed through contracts with outside agencies. This presented a problem with provision of indemnity for negligent harm. For clinical trials involving medicines it is a legal requirement that there should be insurance and indemnity arrangements to cover the liabilities of sponsors and investigators. Her Majesty's Prison Service does not provide insurance policies for staff and it was not considered appropriate for the NHS Trust to issue honorary contracts to prison staff as the duty of care for the participants lay with the prison.

The outcome: The R&G Advice Service was able to resolve this complicated query through coordination of advice from the NHS R&D Forum, a legal advisor within Her Majesty's Prison Service with regard to indemnity arrangements, and the Department of Health in relation to PCT responsibilities towards prison healthcare. The query was particularly complex in nature and required a high level of coordination, but the R&G Advice Service was able to work through it and reach a satisfactory consensus within six weeks.

Streamlining Permissions and Approvals

By 2004 it was recognised that complex permission and reporting requirements were putting an administrative burden on research; a fact which was acknowledged in England's R&D strategy *Best Research for Best Health*. The UKCRC Partners agreed to work towards developing a single gateway for research applications. The aim was to make life easier for researchers and to harmonise and streamline the flow of information between organisations, thus reducing much of the bureaucracy involved.

In May 2006 a UKCRC working group was formed to look at this issue, composed of the major NHS statutory bodies and other relevant stakeholders, including funders and sponsors of research. The group, chaired by Sir John Lilleyman, then Medical Director of the National Patient Safety Agency, rapidly agreed that administrative processes needed to be simplified and standardised.

The UKCRC Working Group tasked the National Research Ethics Service (NRES) with leading a Department of Health-funded initiative to develop a web-based system which would allow researchers to make a series of applications whilst entering data about their project only once. Swift progress was made, owing to NRES's previous experience of developing an online ethics application system and collaborative working with the NHS R&D Forum and other regulatory and governance bodies. The resulting Integrated Research Application System (IRAS) was launched for consultation-in-use between January and June 2008.

IRAS
INTEGRATED RESEARCH APPLICATION SYSTEM

The Integrated Research Application System (IRAS):

- Is a single, web-based system for applying for the permissions and approvals for health and social care / community care research in the UK
- Enables researchers to enter the information about their project once instead of duplicating information in separate application forms
- Uses filters to ensure the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
- Helps researchers to meet their regulatory and governance requirements.

IRAS can be used to capture the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Justice (National Offender Management Service)
- NHS/HSC research offices
- NRES/NHS/HSC Research Ethics Committees
- Patient Information Advisory Group (PIAG)

In May 2008, functionality was added to IRAS that enables researchers to make applications to MHRA Medicines for research involving Investigational Medicinal Products. Additionally, a Management

Board, chaired by the Department of Health in England, was established to oversee the ongoing management and review of IRAS. After further improvements, the aim is for IRAS to become the preferred system for applications to all of the partners. It will also be linked to other systems and processes including the NIHR information systems supporting the new NIHR Coordinated System for gaining NHS Permission.
Web: www.myresearchproject.org.uk

Model Agreements

Sponsors of research and host institutions need to have appropriate agreements in place before a piece of research can start. The UKCRC Partners and stakeholders, led by the Department of Health in England, are developing a suite of model agreements, which can be used 'off the shelf'.

- **Commercially Sponsored Pharmaceutical and biopharmaceutical trials (mCTA)** – launched in October 2006, this agreement is designed to be used without modification for pharmaceutical and bioscience industry-sponsored contract research trials in patients in NHS hospitals throughout the UK.
- **Commercially Sponsored Clinical trials employing a contract research organisation (CRO; tripartite mCTA)** – this is a tripartite agreement between a pharmaceutical or bioscience company sponsoring a trial, the contract research organisation (CRO) managing it and the NHS hospital where the trial takes place. It was launched in October 2007.
- **Commercially Sponsored Clinical investigation of medical devices (mCIA)** – this agreement is designed for use in industry-sponsored medical device clinical investigations and was launched in October 2008

These agreements will be reviewed on a regular basis and revised as and when it is appropriate.

Use of the model Clinical Trial Agreement in Scotland

In Scotland, use of the unmodified mCTA has almost halved the average study start-up time to 64 days compared with 114 days when modifications are requested. By October 2007, all Scottish sites were using the unmodified mCTA.
Source: ABPI

Streamlined systems for gaining NHS permissions

The four UK Health Departments have each sought to streamline the administrative processes associated with research, in reaction to concerns raised by the research community about the increasing burden of regulation and legislation. Those responsible for managing research at a local level have also been involved in this process. Different systems are being developed across the UK in order to deal with the different statutory provisions, organisational structures and sizes of each nation. However, the Health Departments are committed to ensuring compatibility to facilitate UK-wide studies and have signed an agreement of mutual acceptance. This allows the countries to accept one another's systems so that activities are not duplicated.

The Health Service R&D approval systems in the four UK nations

Northern Ireland

Northern Ireland has developed a common consistent regional research governance system with standardised policies and procedures and common underpinning research management software. The re-organisation of the Health & Social Care (HSC) system has significantly reduced the number of HSC Trusts. This has enabled closer working and a higher degree of consistency. A Memorandum of Understanding (MoU) approach for approvals and permissions is being developed to ensure that each Trust accepts approval work undertaken by other HSC Trusts, eliminating the need for duplication of this work. Under the MoU, a lead HSC Trust will be identified for each study, leaving other Trusts to address site specific issues.

Scotland

A coordinated system for multi-centre research (NHS Research Scotland) has been developed. This process is managed by a coordinating centre (NRS CC), which is the main point of contact for applicants undertaking such studies, and is responsible for liaising with NHS Board R&D offices to facilitate Board management approval prior to study initiation. The NRS CC receives and collates the agreed valid national document set and assigns a unique study identifier. The researcher therefore only has to provide the information on their study once. The NRS CC also registers the study on the national web-based research database. The system separates out criteria that are reviewed once centrally by a generic reviewer to comply with NHS research governance standards, from those which are reviewed locally at each site.

England

A process for NIHR portfolio studies is being tested, called the NIHR Coordinated System for gaining NHS Permission (NIHR CSP). This system will give researchers a single point of contact. It will also collate evidence of approvals, agreements and resources so that those responsible for granting permission to begin a study at a NHS site in England can have ready access to it, and need not duplicate checks already completed. This managed system will integrate with the activities of the NIHR Comprehensive Local Research Networks which will facilitate the local permission process, and help to ensure the NHS is ready to provide the support needed by a study after it begins.

Wales

A project has been started to streamline the review and approval process for Wales. Plans are well underway to establish a central Research Management and Governance office for primary care.

The Research Management and Governance Office will be piloting the primary care review and approvals process in January 2009 and will aim for full roll-out across Wales in April 2009. For secondary care, a baseline assessment and stakeholder consultation has been completed. Options are currently being assessed, with a view to beginning development and implementation work in late 2008.

Research Passport

The UKCRC Partners and stakeholders have developed and implemented a consistent and efficient approach to issuing honorary research contracts - the 'Research Passport'.

The Research Passport is a streamlined system for issuing honorary research contracts to researchers who do not have a contractual relationship with the NHS. It was originally piloted and launched in the north-west of England by the North West Strategic Health Authority working in partnership with local NHS organisations and universities. Following this success, and after discussion with universities and the Medical Schools Council, it was developed for UK-wide use, and was introduced across the UK from October 2007.

Before the roll-out of the Research Passport, researchers working across multiple NHS sites often needed to get a new contract from each host organisation. Each contract required several pre-engagement checks, for example occupational health and Criminal Records Bureau checks. The Research Passport is designed to shorten study start-up times and save valuable time and resources of Human Resources, R&D departments and researchers by relying on existing pre-engagement checks and assurances from substantive employers. It also promotes consistent use of honorary research contracts by the NHS and its partners, and provides clear guidance on their use.

> *"The research passport is especially useful in primary care where multiple-site working is the norm. It has hugely reduced the amount of time researchers spend negotiating the bureaucracy of several different organisations which means more time for research and less paperwork. It also gives Trusts peace of mind when working with researchers and enhances patient safety.*
>
> *Devolved nations in Wales and Scotland have also embraced the research passport scheme and training is underway for staff in these areas to take the initiative forward."*
>
> Dr Julia Miller, Senior Scientific Administrator, NIHR School for Primary Care Research.

The Passport benefits researchers, NHS organisations and universities because it:

- Promotes the consistent use of honorary research contracts by the NHS
- Provides clear guidance on their use
- Provides a streamlined standard system to apply for the contracts
- Avoids repeat checks for each contract
- Clarifies responsibilities of NHS hosts and Higher Education Institution employers.

The Research Passport forms part of the *Research in the NHS – Human Resources Good Practice Resource Pack*. The pack also describes other standardised procedures for handling the HR arrangements for researchers and was developed under the umbrella of the UKCRC by the four UK Health Departments and the NHS R&D Forum. Further information can be found at:
http://www.nihr.ac.uk/systems_research_passports.aspx

The Research Passport

The Research Passport is designed to streamline the system for issuing honorary research contracts, saving duplication of work and speeding study start-up times.

An example of the impact that the Research Passport can have is reported by Rhian Hughes, Deputy Director of the Primary Care and Health Sciences Research Institute at Keele University, who was involved in a pilot project on the system between August 2006 and April 2007. This pilot involved both NHS host sites and University substantive employers.

Before: One randomised controlled trial of acupuncture or physiotherapy for knee pain across 21 NHS Trusts in the West Midlands required 147 honorary research contracts for a small group of seven research staff. The average time taken to get the honorary research contract from each trust was 21 weeks, and the maximum time was 30 weeks.

After: A study four times larger than the one described above, a complex intervention which involved screening patients who presented with back pain in general practice, took just four weeks to set up. All eight staff were issued with research passports to cover their research activity in 12 GP practices and Primary Care / NHS trusts within only two weeks, without the need for any additional checks or induction training.

The UK-wide roll-out of the Research Passport is being led by the NIHR Clinical Research Network Coordinating Centre via the NIHR Comprehensive Local Research Networks in England, NHS Research Scotland via NHS Scotland Health Boards and Higher Education Institutions in Scotland, Wales Office of Research and Development for Health and Social Care in Wales and Joint Health and Social Care (HSC)/University working group in Northern Ireland. Elements of the Good Practice Resource Pack will be revised as the relevant policies and practices develop.

European Biosciences Intelligence Coalition (EBIC)

Of all new regulations, 80% now come from the European Union. The European Biosciences Intelligence Coalition (EBIC) provides a forum for members to share intelligence on new regulations emerging from Europe and routes of influence, to share their analysis of the likely impact on research, and, where appropriate, coordinate their efforts to inform the development of new regulations. As the scope of intelligence is potentially very broad, EBIC members agreed to initially focus on: EU research regulation; EU public health regulation; EU commercial regulation and EU research funding policy.

The EBIC strategy was jointly developed by the UKCRC, including the UKCRC Secretariat, Cancer Research UK, Wellcome Trust, the Bioscience Futures Forum with the BioIndustry Association and the Department for Business, Enterprise and Regulatory Reform. Agreement of the strategy represented unification of UKCRC and Bioscience Futures Forum ambitions to develop European regulatory horizon-scanning capabilities.

The current EBIC member organisations include: the Association of Medical Research Charities;

BioIndustry Association; Cancer Research UK; the Department of Health for England; the Department of Business Enterprise and Regulatory Reform; the Medical Research Council; the Association of British Healthcare Industries; the Association of the British Pharmaceutical Industry; and the Wellcome Trust. EBIC is facilitated by the Department of Business Enterprise and Regulatory Reform, the UKCRC Secretariat and the BioIndustry Association. Implementation of the EBIC strategy was formally initiated at the inaugural meeting of the EBIC members in September 2006.

Coordinated approach to regulatory and governance training

Many organisations provide training in the regulation and governance of research, however, training is often provided by one organisation to a specific audience. The benefit of sharing and coordinating resources has already been demonstrated by the National Research Ethics Service, universities and the MRC working together to roll out a national programme of ethics training days for researchers and ethics committee members, based on a model first used in Manchester. Led by the MRC, the UKCRC has set up a small team of individuals drawn from some of the organisations providing regulatory and governance training. The remit of the group is to explore and identify opportunities for a joined-up approach to training, bringing together, for mutual benefit, the different audiences involved in research regulation and governance. This initiative is joined up with other linked activities, such as the UKCRC Regulatory and Governance Advice Service, the Integrated Research Application System (IRAS) and the UKCRN Training Programme.

LOOKING AHEAD

Much progress has already been made to streamline the UK regulatory and governance environment, but as stated in the introduction to this chapter, the full impact of individual changes to the regulatory environment will only be realised when all of them are implemented and embedded as standard practice. Looking ahead, there are several activities and developments on the horizon:

- The outcomes of activities to streamline R&G processes in the UK will be re-evaluated in 2009. This will include a formal review of the Research Passport, the Advice Service and UK R&G advice provision in general
- Following the successful streamlining of the research approval process through IRAS, partners will be able to revisit the possibility of streamlining funders' and regulators' reporting requirements.



Building up the Research Workforce

Strengthening the workforce which underpins clinical research is a vital part of establishing a strong and sustainable clinical research infrastructure across the UK. Since 2006, the UKCRC's long-term aim to develop a high quality research workforce has started to be realised as barriers to pursuing a clinical research career are broken down and new training posts are taken up.

Key Achievements

- Continued roll-out of clinical academic training programmes across the UK for doctors and dentists as outlined in the report of the Academic Careers Subcommittee of Modernising Medical Careers and the UKCRC
- Appointment of 932 NIHR Academic Clinical Fellows and 442 NIHR Clinical Lecturers: three rounds of applications now launched
- Continued investment in Clinical Senior Lectureship schemes by the Higher Education Funding Council for England (HEFCE): 74 Senior Clinical Lectureships in post and 40 more posts awarded in the third round of funding in June 2008
- In Scotland, development of the Scottish Clinical Research Excellence Development Scheme (SCREDS), which encompasses opportunities at all levels including Clinical Lectureships, Clinical Fellowships and Senior Clinical Fellowships
- Plans underway in Northern Ireland to create three Foundation Year Programmes, eight Academic Clinical Fellowships, and three Clinical Lectureships per year, based on recommendations of the Academic Careers Subcommittee report
- Publication of The *Report of the UKCRC Subcommittee for Modernising Nursing Careers (Workforce): Developing the Best Research Professionals* following public consultation
- Funding agreed from Department of Health England, NIHR, HEFCE and the Economic and Social Research Council (ESRC) to establish the Clinical Academic Training Pathway for nurses, midwives and allied health professions in England, and implementation group formed to take this forward

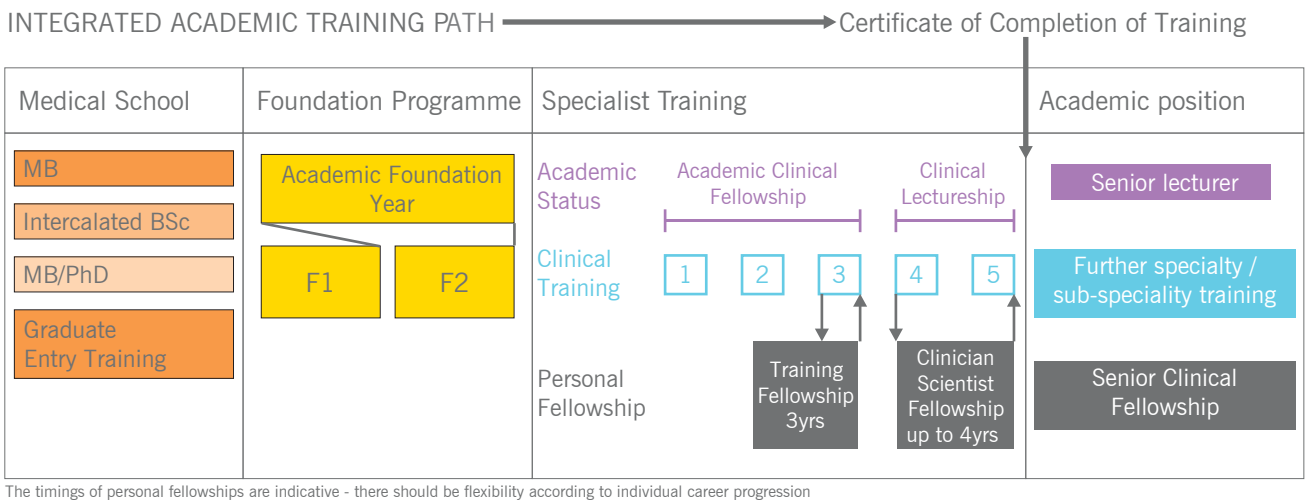
BACKGROUND

By 2004, there had been a decline in numbers of doctors and dentists who carry out research, despite an overall increase in numbers of these professionals in the UK. Factors thought to be contributing to this decline included cultural changes in the NHS, a lack of transparency in route of entry or career structure, and a shortage of properly structured and supported posts after training was completed. These deficits also existed in other parts of the UK clinical research workforce, such as nurses involved in clinical research. The Research for Patient Benefit Working Party recommended that the UK should focus some of its activities on developing the research workforce in the UK.

The UKCRC worked in partnership with NHS Modernising Medical Careers (MMC), to make recommendations on how to remove barriers and encourage research at all stages of clinical training. A clear and integrated training pathway was developed and this is illustrated in **Figure 1**. Since 2004 new schemes and initiatives have been established across the four UK nations to boost opportunities for doctors and dentists who wished to combine clinical careers with clinical or educational research.

In 2006, it was recognised that nurses, midwives and allied health professionals faced similar deterrents to pursuing a clinical academic career, and much needed to be done to ensure that there would be sufficient expertise and capacity of nurse researchers to benefit the UK clinical research environment of the future. Building on the model established for medical clinical academic careers, a UKCRC Subcommittee started work to identify barriers and solutions for training and careers for nurses in clinical research and new initiatives are now being established across the UK.

Figure 1 Integrated Academic Training Path for Researchers



The timings of personal fellowships are indicative - there should be flexibility according to individual career progression

Clinical Academic Careers for Doctors and Dentists

Building on the strong foundations put in place between 2004 and 2006, much has been achieved over the last two years to develop academic clinical careers in the UK. The approach to implementing the recommendations of the Academic Careers Subcommittee has differed across the four UK nations.

England

In October 2005, the NIHR Integrated Academic Training programme was developed and launched by the NIHR in England. Administration is provided by the NIHR Coordinating Centre for Research Capacity Development.

Partnerships between universities, local NHS trusts and postgraduate deaneries host training programmes, which are awarded through a competitive process. The programmes currently provide approximately 200 **NIHR Academic Clinical Fellowships** and 70 **NIHR Clinical Lectureship** training opportunities each year. These are for trainee doctors and dentists who are about to enter specialist training, or for specialist registrars with potential to become future leaders in clinical research and education.

Separately, the Higher Education Funding Council for England (HEFCE) has committed up to £50 million over ten years to develop 200 'new blood' **Clinical Senior Lectureships**, in partnership with the NHS. These posts last up to four years and are for doctors and dentists with a PhD/MD (or equivalent) who already have specialist training experience.

The NIHR Integrated Academic Training programme is now well established. Three rounds of competition have taken place to host the new training posts. In the first round, programmes of posts were agreed based on an open competition, and selection of 202 trainees to NIHR Academic Clinical Fellowships and NIHR Clinical Lectureships took place between May 2006 and March 2007. The second round, in January 2007, targeted specialties that were endangered in terms of clinical and academic capacity, and geographical gaps identified in the first round.

The three rounds of HEFCE-funded 'new blood' Clinical Senior Lectureship schemes were made in May 2006, April 2007 and June 2008.

In February 2007, **NIHR In-Practice Academic Fellowships** for General Practitioners and General Dental Practitioners were launched, supporting six GPs for Masters level training. A second round followed in February 2008 and successful candidates are expected to start training in Autumn 2008.

Wales (2007 – 2008)

Until 2007, the Wales Office of Research and Development for Health and Social Care (WORD) funded the Integrated Academic Training programme jointly with the Department of Health in England. However since 2007, the schemes have been funded and developed separately in the two countries. WORD funds 16 **Academic Clinical Lectureship** posts and 16 **Clinical Lectureship** posts per year in Wales.

Following an assessment of the current scheme in Wales, WORD is developing a new approach to Clinical Academic Careers policy. This exercise is in its final stages, and after completion, work will get underway to begin implementation.

Northern Ireland

In response to the recommendations of the report of the Academic Careers Subcommittee of Modernising Medical Careers and the UKCRC, a new Northern Ireland Clinical Academic Training Scheme has been introduced. This scheme is intended to nurture a cadre of research-led clinical academics capable of being leaders of research within their disciplines.

A HEFCE Clinical Senior Lecturer's view



Dr Shamima Rahman is head of the Mitochondrial Research Group within the Clinical and Molecular Genetics Unit at the Institute of Child Health, London. She was awarded a HEFCE-funded Clinical Senior Lectureship in the first round of competition in 2006, and here she describes the benefits of the CSL scheme.

"I trained as a paediatrician straight from medical school and after an SHO post at Great Ormond Street Hospital I won a scholarship to the Royal Children's Hospital in Melbourne to do a year of research into mitochondrial diseases– that really gave me a taste for research and that's why I've pursued a clinical academic career ever since. Following a PhD, I was appointed to a clinical lectureship at the Institute of Child Health in metabolic medicine. That was the springboard that allowed me to set up my mitochondrial research group, here at the Institute of Child Health, currently within the clinical and molecular genetics unit. I did the lectureship for six years, and the obvious next place to go was the Clinical Senior Lectureship.

The advantage of the Clinical Senior Lectureship for someone like me is that there is a huge pressure to do either clinical or academic in the current climate and this is a wonderful opportunity to do both. I'm someone who really enjoys everything I do: I really love the research but also very much enjoy the clinical work.

Another great advantage is that it gave my colleagues and I an opportunity to provide a niche service combined with research which neither the NHS nor Universities would normally have funded - a national service for patients with rare mitochondrial diseases. The service is based at the National Hospital for Neurology in London and two other centres, in Oxford and Newcastle, and it was funded by national commissioning money from the Department of Health. Although I'm a paediatrician I did this in partnership with the Institute of Neurology, which is an adult hospital. Without this scheme, funding a collaboration between the Institute of Child Health and the National Hospital for Neurology would have been much more difficult – it provides scope for the formation of unusual partnerships and allows you to think outside the box.

The scheme is also a good chance for the Department of Health and HEFCE to appoint emerging leaders in their field, who might otherwise be pressurised into opting for either a purely clinical or a purely academic career. So hopefully, if breadth is provided across a number of specialties, it will be a way of securing high quality clinical research in the UK for the next generation.

I'd strongly recommend the clinical senior lectureship to anyone who is considering applying."

The scheme provides a competitive training pathway starting with a Foundation Programme with nine four-month Foundation year 2 (F2) posts. These placements with senior academic mentors are designed to develop knowledge, skills and aptitudes, and an interest in academic medicine. A subsequent Fellowship programme allows four trainees to be appointed each year as pre-doctoral **Academic Clinical Fellows** or post-doctoral **Academic Clinical Lecturers**. The Fellows are initially appointed for two to three years during which time they will complete third and fourth year Specialist Training and academic research training and apply for an external PhD funding fellowship.

Academic Clinical Lecturers will finish their clinical training while continuing academic development at post-doctoral level, leading to an application to a major funding body. The Northern Ireland Clinical Academic Training Scheme involves a partnership with Queen's University Belfast, the Belfast Health & Social Care Trust and the Northern Ireland Medical and Dental Training Agency. The HSC R&D Office is reviewing its doctoral fellowship programme to facilitate the development of this new approach. This complements the existing General Practice Academic and Research Training Scheme (GPARTS) which integrates research training with vocational training at GP Registrar level.

Scotland

In Scotland, the Academic Careers Subcommittee recommendations have been taken forward as the Scottish Clinical Research Excellence Development Scheme (SCREDS). This is a flexible scheme which comprises several integrated components.

The first of these is the **Medical Clinical Lectureship** level of training posts, which are mainly funded by NHS Education for Scotland. These posts are broadly equivalent to the Academic Clinical Fellowships in England and Wales, and comprise 80% clinical time and 20% research time. The training posts are open to candidates at any point in their training after Foundation level, and up to 125 posts are part of the scheme. These posts are entered at the pre-doctoral level and initially give individuals the chance to prepare for competitive entry into a peer-reviewed Fellowship leading to a PhD/MD. After completing the Fellowship, individuals can then re-enter clinical training in a Clinical Lecturer post in order to achieve their Certificate of Completion of Training. The Medical Clinical Lectureship level also includes an educational training option called Additional Cost of Teaching (ACT)-funded Clinical Teaching Fellowships.

The second component of SCREDS is the **Research Fellowship** level. Funding for these can come from a range of sources, including the Chief Scientist Office, Universities and Charities. These posts last three or four years and some funders allow up to 20% of the individual's time to be spent on clinical commitments to make sure that their clinical skills are retained during academic research. The Chief Scientist Office Clinical Academic Fellowship scheme is now in its third year, with ten Fellows in post, and another round of applications under consideration.

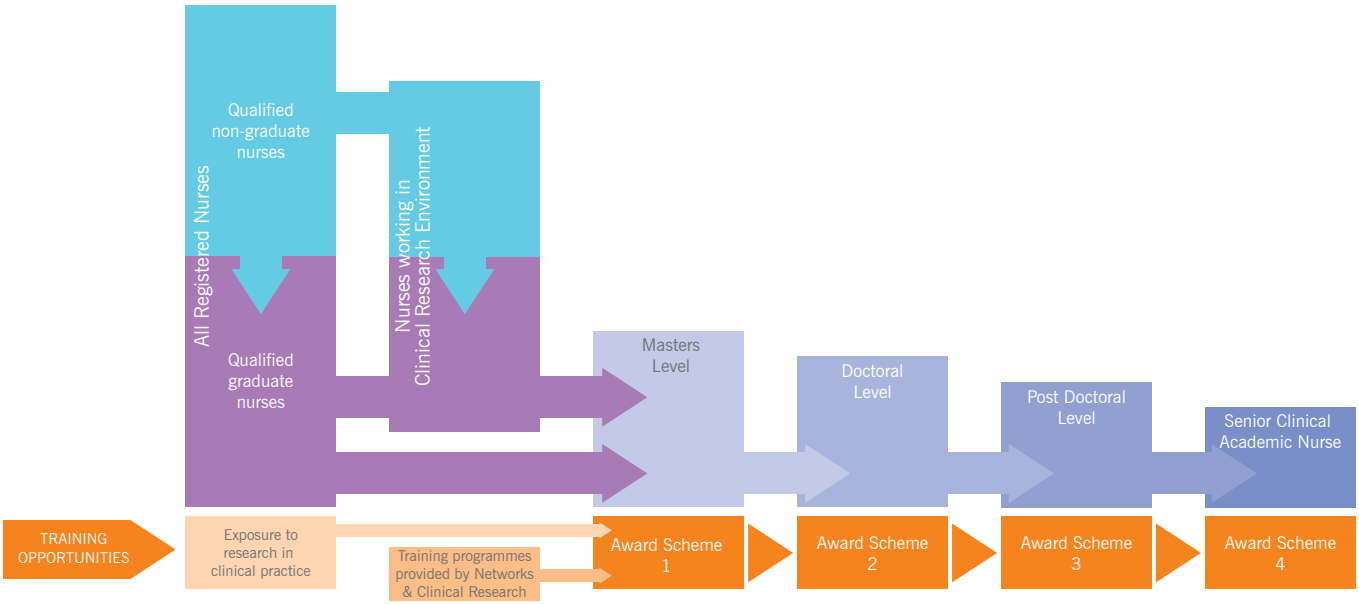
Thirdly, at the more senior level, **Clinician Scientist** posts, for those with a PhD or MD, have been available competitively in Scotland for several years at the pre-CCT level. Further applications were invited in Spring 2008 and are under consideration.

Nurses, midwives and allied health professionals

In 2006, a UKCRC Subcommittee for Nurses in Clinical Research (Workforce), chaired by Professor Janet Finch, conducted work to identify barriers and make recommendations for training and careers for nurses in clinical research.

In late 2006, the UKCRC published a draft report of the Subcommittee's findings, *Developing the*

Figure 2 Clinical Academic Training Pathway



Best Research Professionals. The report made recommendations on preparing and supporting clinical academic nurses of the future and addressed the need to develop a clear career pathway for nurses involved in clinical research. Its recommendations addressed three main areas: education and training, facilitating careers, and better information on nursing research.

The report was the subject of a public consultation between January and March 2007. This included a public event in February 2007 at which attendees were able to ask questions and voice their opinions on the report. The response to the report was overwhelmingly positive, and most of those who were consulted wholeheartedly endorsed the recommendations. The consultation responses were considered by the Subcommittee, and used to modify the final version of the report which was published in August 2007.

As part of the consultation process, the allied health professions (AHPs) were also invited to comment on the applicability of the recommendations to their research careers. Most respondents agreed that the recommendations substantially applied to the AHPs and similarities were identified between nursing and the AHPs in many areas.

Figure 2 demonstrates the career structure recommended by the report.

In a similar manner to the Integrated Academic Career programme put in place for doctors and dentists, the approach to implementation of the recommendations will differ across the four UK nations, with each country using different sources of funding and developing different, but complementary, structures. Work in this area is being led by the Chief Nursing Officers.

England
NIHR and the Chief Nursing Officer for England, in collaboration with the Economic and Social Research Council and HEFCE are launching the Clinical Academic Training Pathway for nurses, midwives and allied heath professions. Funding has been secured to implement four levels of integrated training:

- Masters in Research or Masters in Clinical Research
- Doctorate by Research
- Clinical Lectureships
- Senior Academic Clinical Lectureships

An implementation group has been established which met initially in August 2008. The implementation group is developing transparent application processes to establish the schemes which will be launched in open competition. It is expected that the Clinical Academic Training Pathway will be launched in autumn 2008 with successful candidates taking up posts from September 2009. The scheme will be administered by the NIHR Coordinating Centre for Research Capacity Development.

Scotland
A Nurses, Midwives and Allied Health Professionals (NMAHP) Research Training Scheme has been underway in Scotland for a number of years. This scheme has funded Fellowships at both PhD and postdoctoral level and is now coming to an end. In addition, the Chief Scientist Office funds a NMAHP Research Unit and, along with partners, provides funding for three NMAHP Research Consortia. Along with the Chief Nursing Officer Directorate, NHS Quality Improvement Scotland and the Scottish Funding Council, the Chief Scientist Office will be reviewing the ways in which it can continue to support research careers for NMAHPs.

Northern Ireland
The HSC R&D Office is working with the Chief Nursing Officer, other stakeholders in nursing and the Allied Health Professions to define new clinical academic training pathways in line with the recommendations of the *Developing the Best Research Professionals* report. It is expected that the new arrangements will be in place for the 2009-2010 academic year and will integrate with the existing capacity building initiatives. These include a new PhD top-up scheme to encourage graduates in HSC disciplines to undertake research.

Wales
The Higher Education Funding Council for Wales has committed funding to carry out the recommendations from the report. Related funding has also been secured through the Wales Office of Research & Development (WORD) and the Department for Public Health & Health Professions. This funding is for seven 'first into research' awards, seven Master of Research Awards, 14 PhD fellowships, one post doctoral award and a career scientist. Discussions are ongoing to gain further funding through collaboration with key stakeholders. This will enable the development of a sustainable infrastructure to take forward the implementation of clinical academic careers for nurses, midwives and AHPs in Wales. The award programme, managed by the University of Glamorgan, is known as the Research Capacity Building Collaboration for Nursing and Allied Health Professionals.

LOOKING AHEAD

In England, the NIHR will continue to work with stakeholders to ensure successful implementation of the proposals for clinical academic careers for all healthcare professionals. The allocation of further posts for doctors and dentists is currently being considered by the NIHR.

In Scotland, future opportunities at the most senior level will be Senior Clinical Fellowships. These posts will be broadly comparable to the Senior Clinical Lectureships in England, and will be offered competitively at post-CCT level with expectation of permanent academic postings for exceptional candidates. Such posts might also be funded by the NHS or external funders. The first call for applications was made in September 2008.

In Northern Ireland, plans are being developed to take forward the Subcommittee's proposals and Queens University Belfast also plans to increase uptake of intercalated degree pathways. This may be made more attractive by offering student scholarships/bursaries during the additional year of study to encourage students to consider academic medicine as a career.



Coordinating Research Funding

The UKCRC partnership has encouraged a culture of communication and coordination between the main funders in the UK to maximise the impact of the health research they fund.

Key Achievements

- Adoption by health research funders of the Health Research Classification System, which was developed as part of the 2006 *UK Health Research Analysis*, for ongoing research management
- Publication of *From Donation to Innovation*, an analysis of the research activities of medium and smaller sized members of the Association of Medical Research Charities
- Establishment of five UKCRC Public Health Research Centres of Excellence through a £20m joint initiative
- Launch of a £16.5m jointly funded UKCRC Translational Infection Research Initiative which has included establishment of two Infection Research Consortia.

BACKGROUND

To make the most of the investment and the opportunities available in health-related research in the UK, there are areas where a joined-up approach is helpful. The UKCRC has facilitated this process in two ways. It has mapped the UK-wide health research portfolio to create an evidence base that funders can use to inform future strategic planning. It also acts as a forum for linking up funders in targeted areas to encourage communication and coordination.

The first ever analysis of health research in the UK was published by the UKCRC Partners in May 2006. The *UK Health Research Analysis* provides a breakdown of the distribution of spending by the 11 largest Government and charity health-related research funders across all types of research activity and covering all areas of health and disease in the UK. Underpinning the analysis was a bespoke Health Research Classification System (HRCS), developed by the UKCRC. The HRCS links the science to its associated funding and allows research spending patterns to be meaningfully compared between different portfolios and organisations.

The UKCRC Partners have also brought together funding organisations to review specific areas of research interest using a Strategic Planning Group model. The Strategic Planning Groups are designed to identify any gaps or opportunities and advise funders how best to implement activities to address them. In July 2005 the major funders of public health research in the UK came together to form the UKCRC Public Health Research Strategic Planning Group, chaired by Professor Ian Diamond, and in 2006 the UKCRC Strategic Planning Group on Microbiology and

Infectious Diseases Research (MIDR), chaired by Sir John Lilleyman, was established.

ACTIVITIES AND ACHIEVEMENTS

Adoption of the Health Research Classification System

The Health Research Classification System (HRCS) was developed by the UKCRC Partners to categorise the full spectrum of their health-related research activities. It is designed to be used as a strategic tool to analyse funding in different research areas. This creates an evidence base to inform planning and facilitate discussions. Use of this common coding system allows meaningful comparisons of research spending patterns to be made between different research portfolios and different organisations, facilitating coordination between funders.

Since the two health research analysis reports were published, many of the participating funders have adopted the HRCS to classify their health research portfolios. The UKCRC has also worked with funding agencies outside the UK to help them to use the HRCS to analyse their research portfolios.

Feedback on the use and impact of the HRCS and health research analyses on strategic discussions has been obtained from 29 organisations that participated in the analyses or received training in the use of the HRCS. The findings show that 22 (76%) are using the HRCS to classify their research or intend to use it in the future. The feedback also revealed that 23 organisations (79%) are planning their own analysis of research using the HRCS or would do so with further help.

The UKCRC is supporting the wide range of organisations interested in adopting or evaluating the HRCS by making the classification system publicly available and providing training, advice and support tools.

> *"The UKCRC classification system was a real innovation which proved its worth in helping to bring funders closer together. It is now a central part of the Medical Research Council's own information systems."*
>
> Declan Mulkeen, Medical Research Council

> *"The Health Research Classification System has been very useful in helping us to study the pattern and trends in our research funding over the last five years."*
>
> Edwin Low, National Medical Research Council, Singapore

> *"The UKCRC classification system and analyses have been most helpful during the development of ideas about how to collect and analyse our own data."*
>
> Peter Sneddon, National Institute for Health Research

> *"We have found the report and coding methodology both interesting and useful and hope to make it part of funding analysis and priority setting (as appropriate to the policy context and strategic aims of our organisation) in the future."*
>
> Michael Bowdery, Wales Office of Research and Development, Welsh Assembly Government

> *"This was a valuable exercise, and the ability for different organisations to classify their research consistently will be of increasing importance in future."*
>
> Jeremy Pearson, British Heart Foundation

Publication of *From Donation to Innovation*

Medical research charities play a key role in funding health research in the UK. The *UK Health Research Analysis* included the major government funders of health related research and the three largest medical research charities in the UK: the Wellcome Trust, Cancer Research UK and the British Heart Foundation. To build on this work, the UKCRC, in collaboration with the Association of Medical Research Charities (AMRC), carried out a further analysis of the research funded by 29 medium and smaller-sized medical research charities.

The report, *From Donation To Innovation*, published in 2007 used the Health Research Classification System and the same methodology as the original *UK Health Research Analysis*. It provides a breakdown of the spending by the participating research charities across all types of health research. **Figures 3 and 4** are taken from the report and show the distribution of the total spend of the participating charities across different types of research activity and areas of health and disease.

> *"I have found the experience of the analysis and resulting insights fascinating, helpful and positive."*
>
> Lee Saunders, BUPA Foundation

> *"We felt this was an extremely useful exercise and are looking forward to seeing how we can develop and use this in the future."*
>
> Julia Ambler, Muscular Dystrophy Campaign

Figure 3 Proportion of Participating Charities' Total Spend by Research Activity

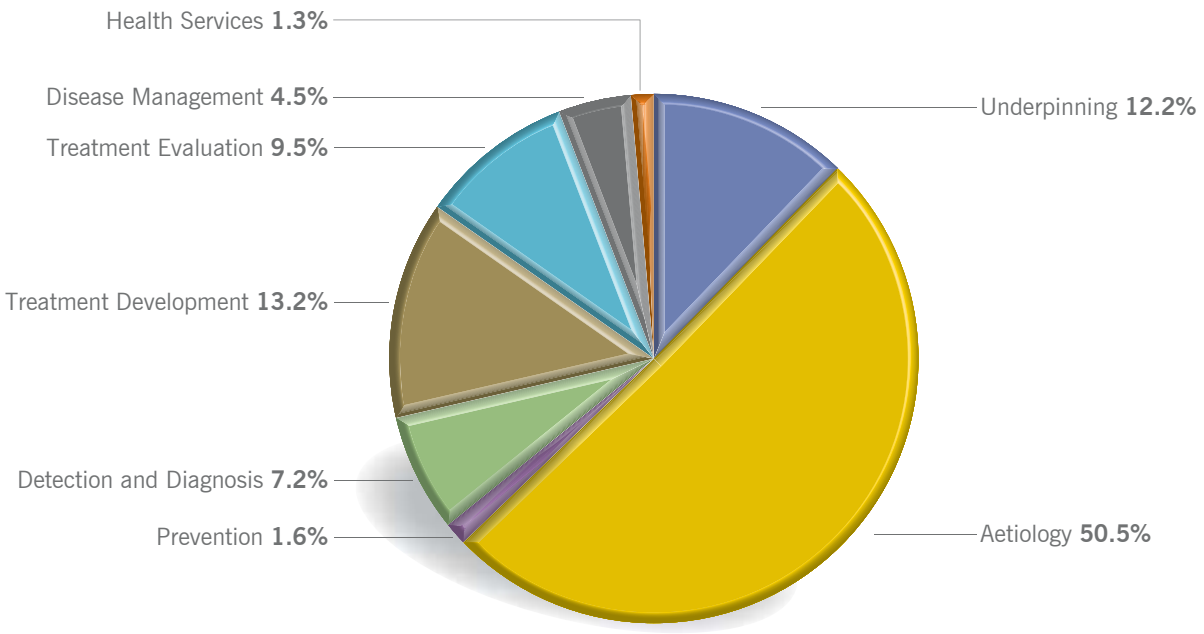
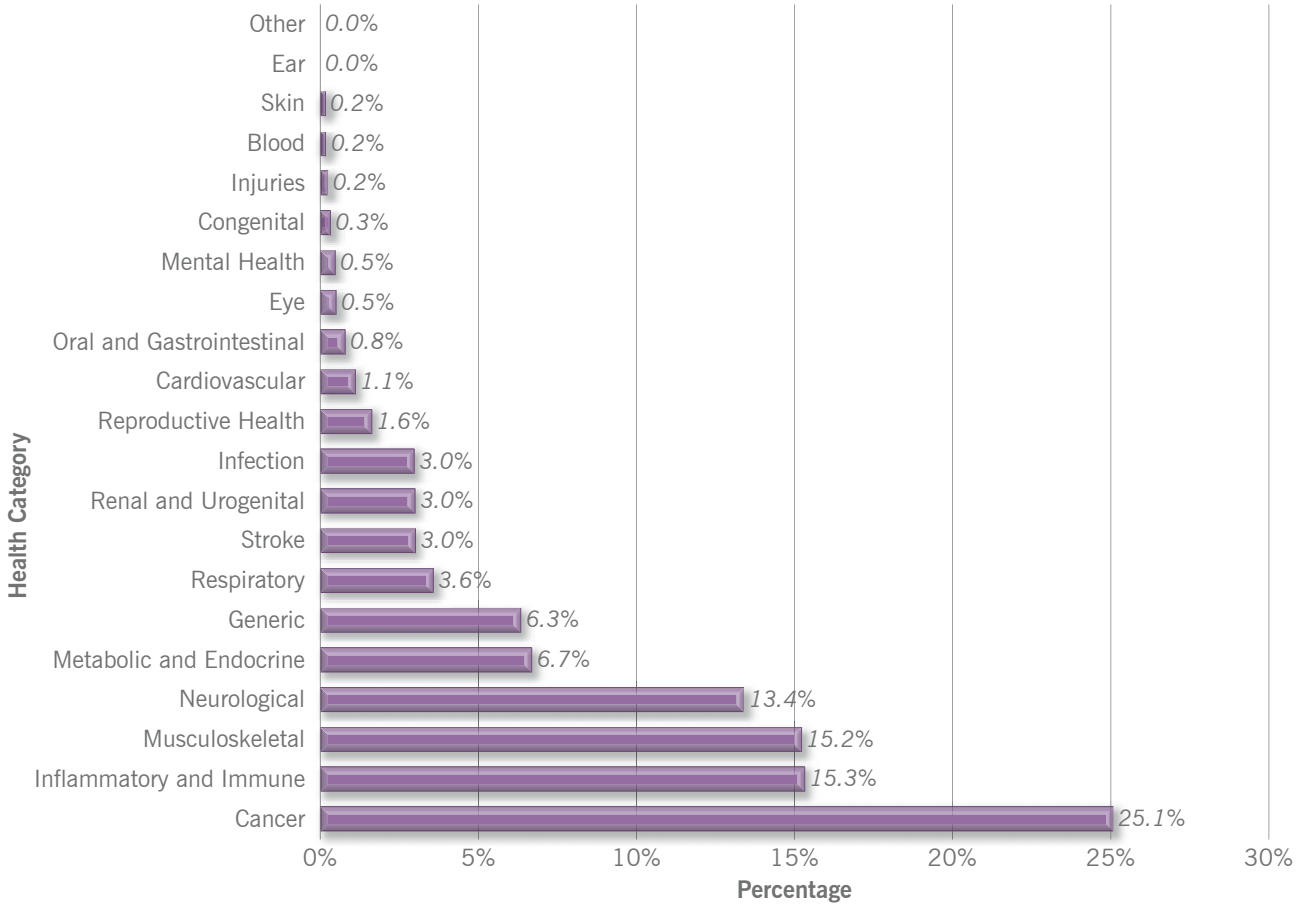


Figure 4 Proportion of Participating Charities' Spend in All Health Categories



The report adds to the picture of how the charity sector contributes to the overall landscape of health research in the UK. Charities who took part were able to review their own portfolio and to compare it with the activities of other funders. The findings also provide valuable information for donors, patients, charity staff and researchers and those involved in policy and strategy development.

The full report can be downloaded at: **www.ukcrc.org/pdf/From_Donation_to_Innovation_Report_07.pdf**

Taken together, the original *UK Health Research Analysis* and *From Donation To Innovation* give an accurate overview of the majority of government health research funding and 96% of AMRC members' research funds.

UKCRC Public Health Centres of Excellence

In January 2008, £20m funding was announced to establish five UKCRC Public Health Research Centres of Excellence. The Centres were created through a joint funding initiative by a consortium of eight major public health research funding organisations.

The joint initiative was established as a result of the UKCRC Public Health Research Strategic Planning Group, chaired by Professor Ian Diamond. The strategic aim of funding the centres is to increase infrastructure, boost academic capacity and encourage multi-disciplinary working in public health research in the UK. The Centres are designed to bring together leading experts from a range of disciplines working in partnership with practitioners, policy makers and wider stakeholders to tackle public health issues which are likely to have a significant impact on the health of the nation.

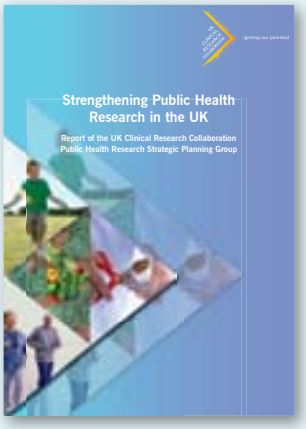
The five successful Centres were:

- North East Centre of Excellence for Translational Research in Public Health, Newcastle University
- Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement, Cardiff University (in collaboration with Swansea University and Bristol University)
- UKCRC Public Health Research Centre of Excellence, Queens University Belfast
- Diet and Physical Activity Public Health Research Centre, University of Cambridge
- The UK Centre for Tobacco Control Studies, University of Nottingham.

Awards were made on a competitive basis with each centre receiving up to £5m over five years. Administrative management of the Centres is being provided by the Economic and Social Research Council. The eight funding partners in the initiative are: the British Heart Foundation; Cancer Research UK; Department of Health; Economic and Social Research Council; Medical Research Council; Health and Social Care Research and Development Office, Northern Ireland; Wales Office of Research and Development for Health and Social Care, Welsh Assembly Government; and Wellcome Trust.

In Scotland, the Medical Research Council and Chief Scientist Office are co-funding the Scottish Collaboration for Public Health Research and Policy which was launched in August 2008. This initiative will receive £3.5m over five years, and aims to come up with fresh strategies to tackle Scotland's poor health record.

The UKCRC Public Health Research Strategic Planning Group carried out an evidence-based review of the status of public health research in the UK, which included examining recent reviews in the area, mapping relevant activities and initiatives of the funding bodies and extensive consultation with experts and stakeholders in the field. Several common themes emerged from the evidence, including the need to address the cross-cutting issues such as training and career structure; multi-disciplinary and collaborative working; maximising the use of existing data; and methodological issues.



The activities and outcomes of the Strategic Planning Group are documented in its report, *Strengthening Public Health Research in the UK*, which can be downloaded at: **www.ukcrc.org/pdf/PH_Report.pdf**

Launch of UKCRC Translational Infection Research Initiative

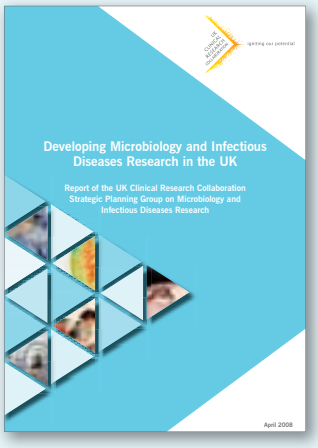
In June 2007 the UKCRC Translational Infection Research Initiative was launched with funds of up to £16.5m provided by seven partners. The Initiative has two strands of competitive funding, the first of which established two Consortia. These are new collaborative research groups focusing on high quality translational research in the field of infectious diseases. The other strand is the award of Strategy Development Grants which are intended to enable the development of improved research proposals and bids in this field.

The initiative is the major outcome of the UKCRC Strategic Planning Group on Microbiology and Infectious Diseases Research (MIDR), which was chaired by Sir John Lilleyman. It will provide a direct boost to the field by providing new infrastructure, supporting multi-disciplinary research projects and establishing training programmes.

In January 2008, five nine-month Strategy Development Grants were awarded, and in June 2008, two Consortia were established with £9m funding from the Biotechnology and Biological Sciences Research Council, Medical Research Council, National Institute for Health Research and Wellcome Trust.

Each Consortium will be funded for a five-year period. One of the Consortia is based at Oxford University and is concentrating on the use of technology in microbiology to detect unrecognised outbreaks of infectious disease and to rapidly identify the strains of infection involved. The other Consortium is based at Imperial College London. It focuses on the key public health priorities in hospitals and healthcare associated infection as well as antibiotic resistance and aims to develop an organisational approach to improving health systems and healthcare delivery.

The Initiative is managed by the Medical Research Council on behalf of the other six partners: the Biotechnology and Biological Sciences Research Council; National Institute for Health Research; Health and Social Care Research and Development Office, Northern Ireland; Chief Scientist Office of the Scottish Government Health Directorates; Wales Office of Research and Development for Health and Social Care, Welsh Assembly Government; and Wellcome Trust.



The UKCRC Microbiology and Infectious Diseases Research Strategic Planning Group carried out a review of the area which included an examination of previous reports and current funding patterns and consultation with key stakeholder groups. From the evidence based review work, a number of common areas for action emerged, grouped under the following headings: Clinical and Translational Research; Medical Intelligence; Communication and Collaborative Working; and Workforce, Training and Career Structure.

The Strategic Planning Group detailed its activities and actions in a report called *Developing Microbiology and Infectious Diseases Research in the UK*. The report can be downloaded at: **www.ukcrc.org/pdf/MicroB_Report.pdf**

LOOKING AHEAD

A number of activities are underway to build on the foundations put in place over the first four years of the UKCRC. These include:

- Investigating the feasibility of an analysis of UK-based pharmaceutical and bioscience industry health research
- Further promotion and training to encourage wider adoption of the HRCS by national and international organisations. This includes a workshop for European health research funding organisations to be held in early 2009
- Creation of an online version of the HRCS including help texts, answers to common questions and a search mechanism
- A second competitive round of Consortium funding under the UKCRC Translational Infection Research Initiative which will begin in January 2009.



NHS IT Systems and Research

New developments in managing patient data open up enormous opportunities for research which can improve patient safety and enhance the effectiveness of clinical treatments in the UK.

Key Achievements

- Engaging industry, academia, the public and the public health community in the work of the UKCRC R&D Advisory Group to NHS Connecting for Health
- Providing the evidence for integrating research into the NHS IT programme through a series of research simulations
- Ensuring a UK-wide approach to taking forward the recommendations of the UKCRC report on research simulations
- Gaining Government endorsement to the recommendations, which in response established a programme for enabling research as part of the NHS Connecting for Health activity with funding from the NIHR.

BACKGROUND

The academic research community and industry have long recognised the unique opportunity electronic patient records provide for interventional and observational health research. The challenge has been to raise Government and public awareness of how research using healthcare records can benefit the population's health.

In December 2005, the Chancellor announced a commitment to develop the capability of the NHS IT systems to facilitate recruitment of patients to clinical trials and gathering of data to support ground-breaking work on the health of the population and effectiveness of health interventions. The Government health research strategy, *Best Research for Best Health*, reaffirmed this commitment.

In 2006, the UKCRC and NHS Connecting for Health (NHS CfH) began a joint programme of activity to move the dialogue beyond principle and generalities via a series of simulations to test the feasibility of using the NHS Care Record Service for research applications.

ACTIVITIES AND ACHIEVEMENTS

Leading a response to the challenge

With sponsorship from Professor Sally Davies, the Department of Health's Director General of R&D, and Richard Jeavons, the then Director of IT Service Implementation, the UKCRC brought the research community together with colleagues from NHS CfH

in the UKCRC R&D Advisory Group to Connecting for Health. This Group's membership comprised opinion leaders from academia, research funders, patient and public representatives and industry and was chaired by Professor Ian Diamond, Chief Executive of the Economic and Social Research Council, and Chair of Research Councils UK.

The Group commissioned a series of paper-based research simulations to test how feasible it would be to use the developing NHS Care Records Service as a platform for research and identify issues that would need to be addressed to make this possible. Simulations were conducted in four areas:

- Surveillance – in particular pharmacovigilance, post-marketing assessments, drug interaction and utilisation studies
- Interventional clinical trials – including feasibility assessment, identification and recruitment of patients and electronic data capture
- Prospective tracking of an identified cohort – based on the requirements of the UK Biobank project
- Observational epidemiology – based on retrospective analyses of data using case-control and cohort study design.

These simulations, although based on the developing NHS IT system in England, also tested how well the NHS IT systems across the UK could operate with one another, to enable both clinical and research activity to take place right across the UK. As part of this objective, the group also reviewed the similarities and differences in the approaches in the four UK Nations.

The simulations were conducted between October 2006 and February 2007, and the findings were showcased at an event for the research community in February 2007. Following feedback from the wider research and public health community, the group published its report of the research simulations in June 2007. The report can be downloaded at: **www.ukcrc.org/pdf/CfH_Full_Report.pdf**

> *"The new electronic health record will enable us to achieve better linkage of databases in order to answer complex or unexpected public health questions.*
>
> *For example, in Denmark and Sweden such linkage has allowed these countries to obtain rapid, precise and unbiased answers to important public health questions such as the safety of blood transfusions.*
>
> *Another example is where linking of information on a mother's health to that of her children creates important opportunities to explore the safety of medicines which need to be taken during pregnancy for the health of the child."*
>
> Professor Carol Dezateux, Institute of Child Health, University of London.

Recommending Change

The research simulations documented in the Report revealed several required characteristics for data and systems such as:

- Access to comprehensive data covering as wide a population as possible
- Strict governance of data access and associated services
- A federated system of linked data sources.

Fundamental to the Report's recommendations was recognition that research is integral to patient care, with both clinical services and research sharing the same mission of improving patient care and safety. The report offers some compelling examples of how access to routinely collected data supports research for patient benefit. For example, these data can alert

a doctor as to whether an individual patient shows characteristics that might make a particular medicine or mode of treatment dangerous. Data can also be analysed rapidly to look for emerging patterns of disease or adverse reactions.

The report also examined the requirements for data linkage, and for the quality and completeness of data. The role of a neutral intermediary, or 'honest broker', is identified as a way forward to ensure patient confidentiality and security, and the report also looked at the integrity of the scientific data delivered for research and public health activities. The Report's main recommendations were to:

- **Mandate use of a common patient identifier** in all NHS records and activities to allow linkage of data sources at the patient level
- **Communicate the relevance of research to healthcare**. At the heart of this is recognition that research is a core, not secondary, component of the development of the NHS Care Records Service because it directly benefits patients
- **Federate existing databases** to ensure that the data made available are as comprehensive as possible. This could function as a data switchboard linking NHS Care Record data to other data sources and also provide an effective infrastructure with optimal governance systems in place. Services such as removal of identifiers and data quality checks could also be delivered
- **Improve data quality** to ensure that data are accurate and based on a set of standards for recording and processing. Incentives might be needed to ensure completeness and quality of data
- **Initiate governance discussions** to ensure appropriate access to, and use of, data for research purposes. Data governance must be robust yet capable of facilitating research
- **Engage key stakeholders** to communicate the joint benefits of using patient data for research and clinical care. Involvement of professional audiences is key to enhancing data quality and improving data access.

Throughout its work, the UKCRC R&D Advisory Group to NHS Connecting for Health collaborated with the Care Record Development Board's Working Group on secondary uses. This joined-up approach and cross-referencing between the two Groups' Reports is important because robust information governance will be essential in order to respond to the needs of research.

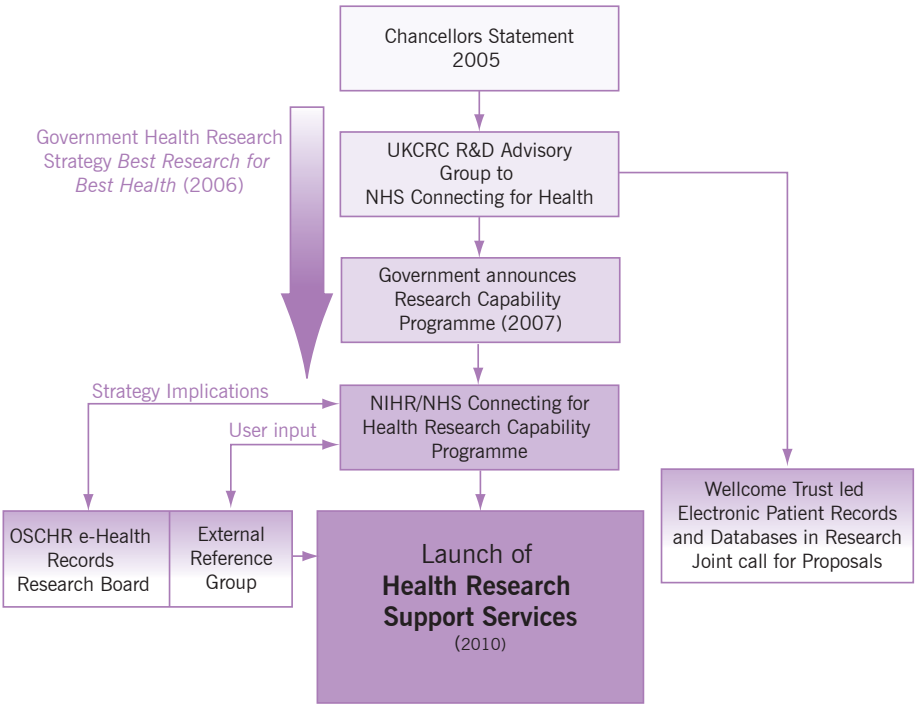
To maintain momentum in the wake of the report, in May 2007, the Wellcome Trust and the UKCRC held a Frontiers Meeting on the use of patient records for research and health benefit. The meeting gave researchers and clinicians the opportunity to discuss the potential of using electronic patient records to improve the health of the UK population and to look at what has been happening in other countries. In parallel, members of the UKCRC R&D Advisory Group and representatives of the simulations teams gave evidence at the House of Commons Health Select Committee's third evidence session on the electronic patient record, using this opportunity to get across the messages in the report of the UKCRC research simulations.

UKCRC Partners - delivering change

The reaction to the report was swift and significant. In June 2007, Lord Hunt, the then Minister of State for Quality at the Department of Health, welcomed the recommendations of the UKCRC report. He agreed a formal programme of work to take the recommendations forward (see **Figure 5**).

In response, the Department of Health, as a programme within NHS Connecting for Health, are building a new Research Capability Programme for

Figure 5 Developing the e-Health Research Landscape



England. Professor Sally Davies, Director General of Research and Development, is leading this programme within the Department of Health.

The primary aims of the programme are to:

- Enable research to achieve its full potential as a 'core' activity for healthcare
- Facilitate use of NHS data to lead to improvements in the quality and safety of care of patients and the public.

The Programme responds to the recommendations made by the UKCRC Research and Development Advisory Group to NHS Connecting for Health and fulfils the intentions set out in section 4.2 of the Government's R&D strategy, *Best Research for Best Health*, which is to ensure that data collected via the NHS Care Record Service meets the needs of the research community and public health practitioners. Professor Sir Alex Markham has been appointed Chair of the Research Capability Programme Board. The Programme is directed by Peter Knight.

The initial enabling phase of the programme allowed the development of a Strategic Business Case describing the infrastructure and related support services that will be needed to support Health Research. This phase is now complete, and the implementation phase started at the end of June 2008. Researchers, including those based in industry, patients and funders are providing input to the programme through an External Reference Group.

This group also functions as the Office for Strategic Co-ordination of Health Research (OSCHR) E-Health Records Research Board, which has a wider UK focus. The remit of the group is to align the strategies of the UK's research funders to provide the funding to meet the needs of the e-health records research community throughout the UK.

In addition to the work of the Research Capability Programme, another of the report's recommendations is being taken forward through new funding for research on electronic patient records and databases. This funding is being provided by the Wellcome Trust, working in partnership with the Economic and Social Research Council, the Engineering and Physical Sciences Research Council and the Medical Research Council. The aim of this initiative is to stimulate and support the use of electronic databases for health research, taking advantage of the new electronic technologies that are under development across the UK.

NHS IT systems and research in Wales

Informing Healthcare (IHC), the national programme for NHS IT in Wales, is a key organisation in the reshaping of the information and communication technology systems of NHS Wales. The Health Information Research Unit (HIRU), commissioned and funded by WORD as part of the Clinical Research Collaboration Cymru, has established a close working relationship with IHC which has resulted in the establishment of new research facilities to conduct health informatics research.

The Health Information Research Laboratories, funded in partnership between IHC and the School of Medicine at Swansea University, are focused on:

- testing and evaluation of healthcare ICT technologies to determine safety, user acceptability and compliance with technical standards
- the development and piloting of new informatics products and services to meet the needs of users and patients
- providing a focus for collaborative and cooperative working for experts in academia, the NHS, IHC and industry, to work on joint projects that will lead to innovative ICT solutions for healthcare problems.



Patient and Public Involvement in Research

The UKCRC is working to promote active involvement of patients and the public in developing and sustaining a thriving clinical research environment in the UK, to improve the health and well-being of all.

Key Achievements

- Continued UK-wide development of patient and public involvement in the research networks
- Launch of **People in Research**, a web-based resource for involving patients and the public
- Launch of a pilot scheme, involving patients and the public as members of UKCRC advisory groups, Board Subgroups and the UKCRC Board
- Development of a database of current activities researching, evaluating or reflecting on the impact of patient and public involvement in research
- Development of UKCRC Strategic Plan for Patient and Public Involvement 2008 – 2011

BACKGROUND

The UKCRC is one of many organisations across the UK that shares an interest in contributing to the development of patient and public involvement in research. UKCRC Partners have always been keen to involve patients and public in their research activities and to raise their awareness of clinical research, but the resources to do this are limited. Working alongside their own organisational approaches to patient and public involvement, the UKCRC Partners have committed to working together on issues that cannot easily be tackled by a single organisation and where a collaborative approach is most effective.

By 2006, the UKCRC had established a project group overseeing the delivery of several joint initiatives for patient and public involvement, many of which have come to fruition over the past two years.

ACTIVITIES AND ACHIEVEMENTS

Growth of patient and public involvement in the research networks

In 2007, a survey of UKCRC Board members identified the UK clinical research networks as an area of UKCRC activity which would benefit from increased patient and public involvement. The four UK Health Departments are all providing resources to support the development of patient and public involvement within the networks. Links are being made with the broader framework of patient and public involvement in health and social care and working partnerships are developing with voluntary sector organisations and patient groups.

In July 2006, Involving People: Cynnwys Pobl was set up specifically to support the development of patient and public involvement in research in Wales. As part of Clinical Research Collaboration Cymru (CRC Cymru), it provides input into the strategy, development and implementation of health and social care research. Currently over 100 members of the Involving People Network are participating in CRC Cymru's activities. Involving People: Cynnwys Pobl coordinates opportunities for involvement, providing information, support and training, and also provides researchers with advice on good practice.

In England, the goal of the National Institute for Health Research is for patient and public involvement to become embedded in all its work including the networks. A specific example of the progress being made was provided by a 2007 survey of activity in the Stroke Research Network in England. It identified 15 patients/public members involved with the national coordinating centre and a further 37 people involved with the local research networks. The different ways in which people were being involved included: membership of clinical studies groups; website development; publicity and presentation at local events; and working alongside researchers to develop research questions.

In Scotland, the Chief Scientist Office has a Public Involvement Group, established in 2002, whose members sit on all of its advisory committees and take part in ad hoc activities. Participation is widening through involvement of patients in the work of the topic-specific networks. For example, the South East of Scotland Cancer Research Network worked in partnership with a clinical network to take forward a project developing a clinical trial information brochure and patient poster that was designed and written by patients. A further example of involvement, at a strategic level, is the inclusion of two patient/public members on the Advisory Group to the Scottish School of Primary Care which hosts the Scottish Primary Care Research Network.

Northern Ireland's HSC R&D *Strategy Research for Health & Wellbeing 2007-2012* highlights patient and public involvement as one of five strategic priorities. Patients are already involved in the management of the Northern Ireland Clinical Research Network (NICRN) and a full-time manager post, with specific responsibility for patient and public involvement, has been created in the NICRN Coordinating Centre to ensure patients and the public contribute to all aspects of the NICRN. A specific post with patient and public involvement responsibility has also been designated in the HSC R&D Office to coordinate the wider implementation of this activity.

People in Research

People in Research (**www.peopleinresearch.org**) is a web based resource for patients and the public providing information about organisations that want to actively involve members of the public in their research activities. INVOLVE, an NIHR programme, led the development of People in Research on behalf of the UKCRC. The design and content of the site was significantly shaped by the input of 18 members of the public who were involved in different aspects of the project. When the pilot site was launched in February 2007 it provided information about ten organisations. This number has grown steadily and there are now 27 organisations listed on the site. An evaluation of **People in Research** is currently underway and will make recommendations for its future development.



Jean Cooper Moran, Senior Programme Manager, Patient and Public Involvement, at the National Institute for Health Research Central Commissioning Facility (NIHR-CCF), explains how the People in Research website benefits NIHR-CCF programmes:

"Being represented on the **People in Research** website means that we can make our needs for patient and public involvement visible to the lay community, and offer them the chance to develop or exercise a new skill-set, and gain new contacts. In the last year 2007-2008, we found approximately 17 new volunteers through People in Research, and recruitment is constant.



We benefit because **People in Research** carries links which visitors to the website can follow straight into the patient and public involvement area of the NIHR-CCF site. This means that the information that the volunteers receive is always timely and they can see updated information about the programmes they wish to know more about.

People in Research attracts both new volunteers and those who have reviewed scientific proposals before, and we regard it as a valuable asset."

"I got involved with the UKCRC because its goal of achieving through collaboration was an exciting ambition to be part of and I thought it would be very interesting to work alongside talented people in the health research world.

Patient and public involvement is really important because it's easy for academics and those involved in research to forget about the priorities of the public. Re-asserting a public perspective makes sure that research has its feet on the ground.

People should not be intimidated about getting involved; we all pay for the NHS and we have the right to be involved in the decisions made."

Jenny McKibben, Patient/Public Member of UKCRC Board and Board Subgroup for the UKCRN.

Measuring the impact of public involvement

Considering how to measure the impact of patient and public involvement in research is a growing area of interest and of research. The UKCRC is helping to coordinate the process of gathering this evidence base as it grows. The Collaboration has developed a UK-wide database that provides brief information about any current activities that are in some way researching, evaluating or reflecting on the impact of patient and public involvement in research. The database, which can be downloaded from the UKCRC website, is regularly updated and promotes information-sharing amongst researchers. It complements existing work being undertaken by INVOLVE (through invoNET) and the NHS Centre for Involvement.

UKCRC Advisory Groups

In 2006, a small pilot project was set up to recruit and provide ongoing support for patient/public members in UKCRC advisory groups. In April 2007, following an open recruitment process, eight people were selected to join four advisory groups. Additional patient/public members are now being recruited to newly formed UKCRC advisory groups.

There are currently patient/public members in several UKCRC groups including the UKCRC Board, UKCRN/UKCRC Joint Communications Advisory Group and the UKCRC Board Subgroups for Patient and Public Involvement and for Public Awareness.

An evaluation of the pilot project will be completed early in 2009.

"INVOLVE takes the lead role in supporting and promoting active public involvement in NHS, public health and social care research in the UK.

Being part of the UKCRC has provided us with some valuable opportunities to work with other stakeholders to achieve these aims. For example, we have worked with the UKCRC, Involving People: Cynnwys Pobl, the James Lind Alliance and the NIHR Network Coordinating Centre to come up with a strategic plan to provide a framework for the UKCRC's future patient and public involvement activities."

Sarah Buckland, Director, INVOLVE – an NIHR programme.

UKCRC patient and public involvement strategic plan 2008-2011

Over the past two years, the UKCRC has continued to recognise the importance of patient and public involvement to the delivery of its overall mission. Initially, through its Patient and Public Involvement Project Group a number of projects such as the People in Research web resource were developed and delivered.

In early 2007, the UKCRC Partners identified the need to consolidate this project-based approach by developing a patient and public involvement strategy. Over the following year, through a process of consultation and collaboration with a range of stakeholders, a three-year strategic plan was developed. This plan creates the framework for future patient and public involvement activities in support of the UKCRC's objectives.

The three key strategic objectives outlined in the strategy are:

- To ensure that patients and the public influence and support the development of UK clinical research at a strategic level
- To improve public confidence in, and understanding of, clinical research through greater patient and public involvement
- To develop sustainable solutions to the barriers that can prevent or impede public involvement in research.

A UKCRC Board Subgroup for Patient and Public Involvement has been established to oversee the implementation of the plan. The Subgroup draws upon the expertise of organisations with a specific remit to support patient and public involvement in clinical research, such as INVOLVE and the James Lind Alliance, to ensure that relevant information is shared and resources are used effectively.

LOOKING AHEAD

The key challenge for UKCRC patient and public involvement activities over the next couple of years will be to remain focused on a moving target. Patient and public involvement in clinical research is inextricably linked to the continued and rapid development of patient and public involvement in many other aspects of healthcare. To operate effectively, the UKCRC will need to be flexible enough to respond as part of this dynamic environment.

The UKCRC has two clear roles to play. Firstly, it will actively support and promote the patient and public involvement activities of other groups and organisations, UK-wide. Secondly, where gaps and barriers are identified the UKCRC continues to be an agent for change through the collaborative endeavours of a number of organisations.



Raising Public Awareness of Clinical Research

The UKCRC Partners are working together to increase patient and public awareness of the value of clinical research.

Key Achievements

- Launch of generic information resources for patients and the public on clinical trials
  - *Clinical Trials: What they are and what they're not*
  - *Understanding Clinical Trials.*
- Launch of information materials and classroom resources on clinical research to support teaching of the national science curricula.

BACKGROUND

The UKCRC Partners all work individually to raise public awareness of their own research activities and highlight the strengths of the UK research environment. The recent publication of *60 Years of research in the NHS benefiting patients* is a good example of this. Several partners have also worked together to boost awareness and stimulate debate on specific issues, such as the use of hybrid embryos for research. This collaborative working towards the shared aim of improving public awareness of clinical research is increasing among the Partners as the environment for clinical research in the UK is transformed.

In 2006, the UKCRC established a time-limited Public Awareness Task and Delivery Group chaired by Professor Colin Blakemore, who was then Chief Executive of the Medical Research Council. The group's remit was to provide advice and develop ideas around raising public awareness of the value of clinical research and clinical trials. The group generated several innovative ideas and approaches, two of which have now been delivered.

ACTIVITIES AND ACHIEVEMENTS

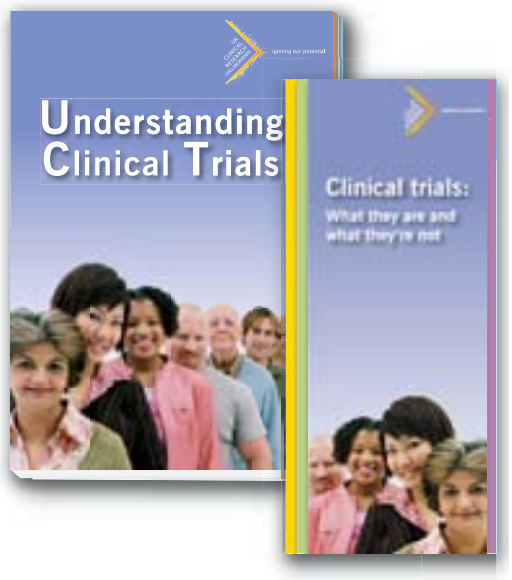
Developing information resources on clinical trials

Although detailed information on clinical trials is available in the UK, the majority is specific to certain areas such as cancer, mental health and HIV. The UKCRC has therefore developed two generic

information resources on clinical trials for patients and the public:

- *Clinical Trials: What they are and what they're not* – a leaflet which is designed to answer some of the basic questions patients and the public have about clinical trials
- *Understanding Clinical Trials* – a booklet which is aimed at people considering taking part in a clinical trial and provides detailed information about how clinical trials are designed and run.

The two resources were piloted throughout the clinical research networks and were launched more widely in November 2007. They have been well received and are fast becoming a primary information resource for those randomising into clinical trials taking place in the UK clinical research networks. Both the leaflet and the booklet have been reprinted three times and over 25,000 copies of each resource have now been distributed. Staff within the clinical research networks have been prime initial users, but since the resources have been highlighted in communications from the UK Chief Medical Officers, increasing numbers have been requested by staff working in NHS organisations not directly connected with the networks.



Developing educational resources on clinical research

The UKCRC Partners have been keen to raise awareness of clinical research to children and teenagers, both to highlight the importance of this type of research to the health of the nation, and to showcase the research environment as a possible career choice. The science curricula currently in use across the UK have little space for additional modules. However, the move towards knowledge and skills based teaching provides an opportunity to develop information materials and classroom resources on clinical research that can illustrate key parts of the science curricula.

The UKCRC has therefore carried out a project to develop a web-based resource on clinical research for students and teachers to support the national science curriculum from key stage 3 to 4. It has worked with the development team from the **Centre of the Cell**, who have a large experience of producing educational materials on cell biology, health and disease to support the national science curriculum. They have a well-established methodology to develop information and classroom resources for students and teachers and can call on the expertise of over 60 research scientists.

The project has been carried out in three stages – scoping of available resources produced by UKCRC Partners and other organisations; signposting to available resources with indications of target age groups; and development of new educational resources. Stages 1 & 2 were completed in 2007 and a list of available resources can be found at: **www.centreofthecell.org/centre/?page_id=234**

During 2008, the team at the Centre of the Cell has been working with the UKCRC to develop new educational materials on clinical research. The resources will be launched in November 2008, and include:

- A '**patient journey**' following a patient participating in a clinical trial for a new medicine. The journey details the process of a clinical trial and also highlights the job roles and careers of the individuals involved.
- **Classroom resources/activities** on:
  - Double blind trials
  - The application of science to create new medicines
  - Risk factors for disease
  - Disease detection and diagnosis
  - Development of new vaccines

The materials can be downloaded at:
www.centreofthecell.org

Centre of the Cell

The Centre of the Cell is a science education centre, an online resource and an outreach project aimed at schools, young people and families and is based at Barts and The London School of Medicine and Dentistry. Its mission is to inspire curiosity and learning by connecting science to everyday life.

"By working with the UKCRC we have been able to create a new set of information and classroom resources for students and teachers on clinical research, including how we develop new treatments and test them in clinical trials. The principles and techniques involved in clinical research are great way of illustrating some of the core aspects of the new science curricula being taught across the UK. These new resources really complement those we have already developed on cells, biomedicine and disease. We hope we have created a learning resource on clinical research which really engages children with the subject and may also inspire more of them to take up a career in research"



Professor Fran Balkwill, OBE, Director, Centre of the Cell

LOOKING AHEAD

As the Collaboration moves into its fifth year the Partners have agreed to increase the extent to which they work together on public awareness. To do this, they have established a UKCRC Board Subgroup on Public Awareness which brings together senior representatives from their organisations to develop a joint strategy for raising public awareness of clinical research. The first task of this group will be to identify a number of potentially high profile areas that would benefit from a joint working approach. One such area will be to develop a coordinated approach to the issue of public attitudes to the use of personal health information for research.



Working with Industry

Continued industry involvement in UKCRC activities seeks to ensure that the developing research environment will provide optimum conditions for the conduct of commercial research in the UK.

BACKGROUND

The bioscience, healthcare and pharmaceutical industries have been strong advocates for change to the research environment in the UK. *Bioscience 2015* – the 2003 report to the Government from the Bioscience and Innovation Growth Team clearly articulated industry's concerns about the future of clinical research in the UK and became one of the important drivers for the Government establishing the Research for Patient Benefit Working Party. This working party led to the establishment of the UKCRC and ensured that industry's issues and concerns would be at the heart of the UKCRC Partners programmes of change.

Industry is represented on the UKCRC Board by the Association of the British Pharmaceutical Industry, the BioIndustry Association, the Association of British Healthcare Industries and a senior industry R&D executive. From the beginning of the Collaboration these organisations have ensured that there has been appropriate industry input across all areas of UKCRC activity.

The UKCRC High Level Industry Reference Group, chaired by Sir David Cooksey, has provided strategic advice to the UKCRC Board. It has been influential in informing government policy in a number of areas related to the UKCRC agenda, notably on the unique opportunity that ethical access to electronic patient record data provides for health research. The Industry Road Map Group involves UK-based staff responsible for running industry trials in the UK and is playing a crucial role in helping the clinical research networks to develop the structures and processes that can best deliver industry contract and collaborative research.

In 2007, membership of the group was extended to include Clinical Research Organisation representation.

ACTIVITIES AND ACHIEVEMENTS

Industry's main concerns with clinical research in the UK remains the speed of approval/initiation of clinical trials and the ability to deliver on promised recruitment targets in a timely manner. These concerns are also shared by research funders in the public and charity sectors. In the eyes of the industry sector, improvements in these two factors are fundamental to the UK being able to offer a high quality and cost effective clinical research service proposition that is attractive both within the UK and internationally.

Industry involvement in the broad range of UKCRC activities has been vital to ensure that the solutions currently being implemented not only improve the environment for non-commercial research but also meet the specific needs of the different industry sectors. Delivery of a number of key pieces of work, discussed in more detail elsewhere in this report, has only been possible because of direct involvement by individuals from commercial organisations and their trade bodies.

A particular focus for industry has been the UKCRC Partners' work to streamline the regulatory and governance environment in the UK. Industry understands that the main benefits of this work will only be tangible once the new coordinated systems of health service R&D permissions have been implemented, but also recognises that implementation of a number of the initiatives designed to speed up trial initiation are already beginning to make a

difference. These include:

- Routine use, in unmodified form, of the suite of model agreements for commercial research in the NHS Hospitals in the UK, including the model Clinical Trial Agreement for pharmaceutical and bioscience research, the tripartite agreement for research run through a Contract Research Organisation and the model Clinical Investigation Agreement for studies involving medical devices
- Implementation in May 2008 of a transparent costings template and guideline tariff for contract research in the NIHR Clinical Research Network, designed to remove the inconsistency of working across multiple NHS sites, and reduce site-by-site negotiations
- Development of a model Confidential Disclosure Agreement to cover sharing of study protocols across the NIHR Clinical Research Network, designed to facilitate more rapid feasibility assessments, endorsed by the ABPI in July 2008 and now being rolled-out across networks and companies
- Implementation of a Memorandum of Understanding between a company and NIHR Clinical Research Network Coordinating Centre, specifying roles, responsibilities, timeframes and deliverables for studies.

The establishment of clinical research networks across the UK has been watched closely by industry. Representatives from industry have provided important input at key stages of development, both directly, and through the Industry Road Map Group. To date, over 129 commercial studies are running within the networks and metrics are available for the initial studies, which have now closed. Of the six studies which had network involvement in feasibility assessment, four met or exceeded their recruitment targets within the agreed timeline and the remaining two recruited over 80% of the target patients. In comparison, amongst studies which had no network involvement, only two out of eight reached their recruitment targets.

Another UKCRC initiative of value to industry is the **UKCRC Experimental Medicine Resources** website funded by the NIHR. This is a central information repository on the UK's capability and expertise in experimental medicine and early phase clinical trials. This website was developed partially in response to industry needs for a method for rapidly finding up-to-date information on available expertise, resources and techniques for early phase trials in the UK.

LOOKING AHEAD

Industry continues to play a vital role in the UKCRC Partnership – helping to shape the new infrastructure and systems that are being established, challenging the approach where necessary and holding the Partnership to account on delivery. Industry colleagues also have an important job to do in promoting the new environment being created in the UK, both within their own organisations and on the wider international stage. Several UK partners are engaged in the Ministerial Industry Strategy Group Clinical Research Working Group initiative to define the service proposition for commercial research in the UK. This will feed into the UK's Life Sciences Marketing Strategy coordinated by UK Trade and Investment. Persuasive metrics will be required to demonstrate that the UK can reliably deliver a high quality, cost effective research system. Industry's input into how these metrics are collected and used will continue to be important.

Taking the Agenda Forward

This report records the UKCRC Partners' achievements through four years of collective working, focusing on the key pieces of work which have been delivered over the last two years. Many of these improvements to the UK clinical research environment have been coordinated by the UKCRC Secretariat, but as the collaboration moves towards its fifth year, individual Partners are increasingly taking the lead. A prime example of this is the UKCRC's work to improve clinical academic careers. This work began with a group of Partners coming together under the UKCRC umbrella towards the end of 2004. Four years later, the integrated academic training programme is well established and is being taken forward by each of the UK health departments and HEFCE, while the UKCRC Secretariat's role in this activity is complete.

As the Collaboration goes forward and the planned reduction in the UKCRC Secretariat takes place, the UKCRC Partners will continue to work together using a number of different models for joint working and will increasingly take the lead on issues on behalf of the wider partnership.

The long-term future of the UKCRC will be reviewed again in 2009, but the intention is that the UKCRC way of working will become a permanent part of the UK clinical research landscape, long after the current UKCRC Workplan is complete.

Evaluation

The establishment of high quality infrastructure to underpin clinical research will allow us, for the first time, to accurately gather performance measures covering the clinical research landscape. The UKCRC Partners have agreed to bring these metrics together on a regular basis and monitor the health of the clinical research environment.

Annex 1
UKCRC Partner Organisations

The Association of British Healthcare Industries (ABHI)
http://www.abhi.org.uk

Association of the British Pharmaceutical Industry (ABPI)
http://www.abpi.org.uk

Association of Medical Research Charities (AMRC)
http://www.amrc.org.uk

Academy of Medical Royal Colleges (AOMRC)
http://www.aomrc.org.uk

The Academy of Medical Sciences (AMS)
http://www.acmedsci.ac.uk

BioIndustry Association (BIA)
http://www.bioindustry.org

Cancer Research UK (CRUK)
http://www.cancerresearchuk.org

Department of Health (DH)
http://www.dh.gov.uk/Home/fs/en

Department for Innovation, Universities and Skills (DIUS)
http://www.dius.gov.uk

Economic and Social Research Council (ESRC)
http://www.esrc.ac.uk

INVOLVE
http://www.invo.org.uk

Medical Research Council (MRC)
http://www.mrc.ac.uk

Medicines and Healthcare products Regulatory Agency (MHRA)
http://www.mhra.gov.uk

National Institute for Health and Clinical Excellence (NICE)
http://www.nice.org.uk

National Institute for Health Research (NIHR)
http://www.nihr.ac.uk

NHS Confederation
http://www.nhsconfed.org

Health and Social Care Research and Development Office, Northern Ireland
http://www.centralservicesagency.com/display/rdo

Chief Scientist Office of Scottish Government Health Directorates
http://www.sehd.scot.nhs.uk/cso

Strategic Health Authorities (SHAs)
http://www.nhs.uk/servicedirectories/Pages/StrategicHealthAuthorityListing.aspx

UK Higher Education Funding Councils
England: http://www.hefce.ac.uk
Northern Ireland: http://www.delni.gov.uk
Scotland: http://www.sfc.ac.uk
Wales: http://www.elwa.org.uk/elwaweb/portal.aspx

Wellcome Trust
http://www.wellcome.ac.uk

Welsh Assembly Government
http://www.wales.gov.uk/word

Annex 2
Statement of Internal Control

Scope of Responsibility

UKCRC Board

The UKCRC Board maintains strategic oversight of the activities of the UKCRC and is responsible for the governance of the UKCRC Secretariat.

The following accountability arrangements are in place:

- The UKCRC Board is comprised of representatives from all the UKCRC Partner organisations and meets three times a year. The Board sets and agrees an annual Workplan of UKCRC Activities. The UKCRC Chief Executive and the Secretariat provide reports to the Board at each meeting across all UKCRC Activities
- The Board has responsibility for authorising and monitoring the budget of the UKCRC Secretariat and for monitoring and evaluation of UKCRC Activities and overall performance against the agreed Workplan
- The Board holds the Chief Executive to account in terms of budget management through the mechanism of a Budget Committee.

Financial Accountability

UKCRC Budget Committee

The UKCRC has a Budget Committee comprised of representatives from the UKCRC Board, which meets on a twice yearly basis and is responsible for:

- Reviewing the establishment, management and implementation of an effective system of internal control and risk management
- Reviewing promptly all reports on the organisation and financial statements presented by the UKCRC Secretariat, before submission to the Board, focusing particularly on the following as appropriate:
  - Compliance with budget
  - Appropriate expenditure of budget
  - Security of income and cash-flow.
- Reporting to the UKCRC Board on the effectiveness of the financial reporting and internal control policies and risk management processes and statements

By virtue of the fact that the UKCRC is hosted within the MRC Head Office, it is covered by and complies with all MRC local and corporate financial procedures and regimes.



UK Clinical Research Collaboration
20 Park Crescent
London
W1B 1AL
United Kingdom
Tel: +44 (0)207 670 5452
Fax: +44 (0)207 637 6067
info@ukcrc.org
www.ukcrc.org