Industry Engagement in Wales

The National Institute for Social Care and Health Research
Foreword

This NISCHR policy document heralds a fundamental and ambitious change to the present approach to working with industry. Over the past year, significant changes have already occurred to support health research in Wales and many more are now planned or in progress. These demonstrate the commitment from Wales to deliver on this important agenda.

Following wide consultation with stakeholders from the NHS, industry, academia and government, the actions outlined in this document are the first steps towards establishing a dynamic and robust environment for the life science industry to undertake health and social care research in Wales. The exciting development of Health Research Wales – a ‘one-stop-shop’ providing a seamless all-Wales sign-posting and facilitation service, will rightly position and promote Wales in the arena of international R&D.

Proposed areas for action can be found throughout this document and focus on the following overarching ambitions:

- For the NHS to play a pivotal role in delivering research, development and innovation and develop a business friendly culture where engagement with industry is a core organisational activity.

- For engagement between academia and industry to become a natural process of innovative collaboration which results in addressing unmet clinical needs and economic growth.

- For Wales based researchers to play a greater role in securing funding from UK and European translational research schemes in order to meet future clinical unmet needs and, carry forward new and innovative ideas.

- For patients in Wales to be consistently offered the opportunity to participate in clinical research and play a greater role in global drug discovery programmes, new technologies and medical devices.

- For NHS R&D offices to build on existing strengths and consistently deliver commercial research studies in a competitive, global environment.

- For government to work together to promote Wales as a distinctive brand within UK PLC.

Director General for Health, Social Services and Children
1. The Strategic Setting

1.1 The National Institute for Social Care and Health Research (NISCHR) is the Welsh Government body that develops, in consultation with partners, policy on research and development to reflect the health and social care priorities of the Welsh Government. NISCHR delivers its strategy and policies through commissioning services, running research schemes and initiatives, and through strategic investment and partnership working with other funding bodies, the NHS, academia, industry and other key partners.

1.2 NISCHR’s strategic direction\(^1\) is complemented by the Science Strategy for Wales\(^2\) and the development of a life science strategy from the Department for Business, Enterprise, Technology and Science (BETS), both of which emphasise the importance of greater collaboration between the NHS, academia and industry to enhance opportunities for commercialisation and contribute to the economic development and prosperity of Wales.

1.3 NISCHR recognises the important contribution the life sciences sector makes to the health and wealth of Wales. This document highlights the renewed strategic focus between NISCHR and industry and outlines how NISCHR will facilitate an increase in research activity and innovation undertaken in Wales. It places particular emphasis on the importance of academia, industry and the NHS forging new, collaborative ways of working in order for Wales to remain competitive and capitalise on its strengths in the UK and international arena.

1.4 Over the last few years, a number of strategic documents from the Office for Life Sciences\(^3\), the Academy of Medical Sciences\(^4\), the Royal College of Physicians\(^5\) and a review of health research funding by Sir David Cooksey\(^6\) have highlighted the need to move away from traditional models of working towards a culture that promotes and supports new collaborative ways of working. All stress the value of changing and supporting the research environment to one that embraces creative engagement between the NHS, industry and academia and an understanding of the value gained from supporting symbiotic relationships between these partners.

1.5 The review of health research funding by Sir David Cooksey noted that whilst the UK Health Research system has many strengths, there was a risk of the UK failing to capitalise on investment in health research to generate economic, health and social benefits. Two key gaps were identified in playing a crucial role in the translational pathway: translating ideas from basic and clinical research into the development of new products and approaches to the treatment of diseases and illness and, using those products and approaches in clinical practice.

\(^3\) Life Sciences (2010) : Delivering the Blueprint : Office for Life Sciences
\(^4\) The Academy of medical Sciences (2011) A new pathway for the regulation and governance of health research
\(^5\) The Royal College of Physicians (2009) Innovating for Health: Patients, Physicians, the Pharmaceutical Industry and the NHS: The Royal College of Physicians
1.6 The recently published *Innovation, Health and Wealth* report identifies the significant role the NHS plays in the process of innovation, adoption and diffusion. As a major investor in science, technology and engineering, the participation of the NHS in a broader, multidisciplinary-research network enables the users of innovations to have an active role in the identification of unmet clinical need and, more importantly, to play a significant role in the development of products and services which meet those needs. This can be achieved through active engagement with collaborators, ensuring patients are offered the opportunity of participating in clinical research and through the adoption of evidence based technologies.

1.7 Since its inception in 2002, the All-Wales Medicines Strategy Group (AWMSG) have forged a strong partnership between NHS Wales and the pharmaceutical industry on the medicines management agenda, and in particular on access to new medicines. That partnership has supported the role of AWMSG in providing timely, independent and authoritative advice to Welsh Government and NHS Wales on new medicines and new licensed indications. A key achievement in 2012, borne out of collaboration with the pharmaceutical industry, has been the development of a Wales Patient Access Scheme which enables pharmaceutical companies to respond to the challenges of providing evidence of clinical and cost effectiveness for medicines being appraised by AWMSG in advance of an appraisal from the National Institute for Health and Clinical Excellence (NICE). This brings demonstrable benefits in the early access to new medicines deemed effective and cost effective.

2. Developing the Health and Social Care R&D Environment

NISCHR investment in health and social care research

2.1 NISCHR commissions and funds an infrastructure to support excellence and build capacity in health and social care R&D across Wales. Investment in the Clinical Research Infrastructure (CRI) supports 17 Registered Research Groups (RRGs), in a range of disease and topic areas, 4 Infrastructure Support Groups (in health economics, health informatics, Welsh language awareness, and medical image analysis and visualisation) and several Trials Units.

2.2 The NISCHR Clinical Research Centre (NISCHR CRC) provides an all-Wales expert research workforce with experience of direct patient and service user contact to support and deliver research. NISCHR CRC also provides a training and development function, a lay representative service ‘Involving People’ and maintains the NISCHR clinical research portfolio database.

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7 Department of Health (2011) *Innovation Health and Wealth – securing adoption and diffusion in the NHS: Department of Health*
2.3 More recently, NISCHR has invested in a substantial biomedical research platform designed to assist in addressing key translational gaps. The Biomedical Research Centre (BRC) and three Biomedical Research Units (BRUs) have been established to promote strong partnerships between higher education institutions (HEIs) and the NHS in Wales, bringing talent and experts together to translate research to improve patient care. The National Centre for Mental Health (the Biomedical Research Centre) at Cardiff University, will carry out research to better understand the causes and triggers of mental illness and to use this knowledge to improve treatments and services. The three BRUs focus on: medical image analysis and visualisation (Bangor University); biomarkers for the detection, prevention and treatment of thromboembolic disease (Swansea University); and translational cancer genetics research (Cardiff University). Several of the BRUs and the BRC have active collaborations with industrial partners and all will be expected to seek further collaborations with industry to work towards the translation of their research, where appropriate.

2.4 The NISCHR-funded Wales Cancer Bank and Wales Gene Park are key components of the infrastructure to support research in translational medicine. The Wales Gene Park (WGP) brings together genetics expertise in Wales and has a remit to facilitate knowledge transfer between the NHS and commercial sectors through providing key platform technologies, equipment and expert assistance. The Wales Cancer Bank (WCB) provides a resource of tissue/blood samples from patients in Wales who are undergoing an operation where cancer is a possible diagnosis. Samples are collected at 7 centres across Wales and used for further research into the mechanisms underlying cancer and the response of tumours to treatments.

2.5 NISCHR will continue to support the translation of research findings to patient benefit in Wales through the development of an experimental medicine policy. This will help to bridge the first of the translational gaps identified by the Cooksey report, by exploring how best to support experimental medicine research in Wales and ensuring that areas of UK industry strengths are adequately supported by a strong experimental medicine research base. Through involvement in the UK Clinical Research Collaboration (UKCRC) Experimental Medicine Funders Group, NISCHR will ensure that the policy is aligned with UK experimental medicine strategy and will encourage Wales based researchers to make use of UK-wide resources for experimental medicine research.

2.6 In 2011, following a report commissioned by NISCHR reviewing social care R&D in Wales, The All-Wales Academic Social Care Research Collaboration (ASCC) was established to pilot alternative approaches to capacity building in social care research. These initiatives will provide training in research methods and statistics to the social care workforce, develop closer links between academia and social care, and increase the involvement of third sector organisations in social care research. NISCHR will evaluate the relative successes of the models at the end of the 3 year grant period, and the lessons learned will inform the direction and design of future investments. It is recognised that the potential for commercial opportunity through technological innovation in social care is considerable, particularly in the context of

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a rapidly ageing population and associated concerns about the increasing number of older people with dementia. However, the development of innovative technological solutions that can help to mitigate and manage the effects of these and other challenges and enable people to live independently for longer is still in its infancy in the UK relative to Europe. New technologies designed to address social and medical benefits of remote monitoring, early intervention and the relevant cost benefits that would accrue from such an approach require engagement with industry.

2.7 In March 2011, the NISCHR Academic Health Sciences Collaboration (AHSC) was launched across Wales and was given the overarching aim of establishing an all-Wales collaboration between health boards, trusts and universities that will strengthen clinical research capacity through maximising the use of the NHS R&D funding administered by NISCHR. It was further tasked to build links with industry and other research bodies that will contribute towards the economic development of Wales.

2.8 During 2011, the NISCHR AHSC established a Task and Finish Group to shape the future landscape of partnership working between industry, academia and NHS Wales. This national forum provided an opportunity for representatives from the NHS, life science companies, clinical research organisations, academia, trade bodies and government to input into key issues and develop a framework proposal for interaction between NISCHR AHSC and industry⁹. The recommendations from the group have formed the framework by which the NISCHR AHSC is developing a range of initiatives to address a key ambition of NISCHR to foster a Welsh research environment where strong and sustained collaboration between industry, academia and the NHS is the norm.

2.9 Overall, the NISCHR research architecture has the capacity to contribute significantly to the collaborative, translational research agenda. Currently, researchers are encouraged to explore collaborations with commercial partners. However, NISCHR is committed to exploring ways in which strategic funding can facilitate and stimulate a dynamic research community where industry, academia, social services and the NHS work together.

**Actions:**

Through the development of the experimental medicine policy, NISCHR will support the translation of research findings to patient benefit in Wales and improve the alignment of the Experimental Medicine research base to UK industry strengths.

Through developing closer links between industry and social care, NISCHR will continue to explore ways in which collaborative arrangements can lead to improvement and innovation in the organisation, delivery and quality of social care services.

NISCHR will look at opportunities to develop a model of working which formally integrates alliances with industry into the NISCHR infrastructure.

3. **NHS Wales**

3.1 The NHS is a unique health system. It is the largest publicly funded health service in the world offering ‘cradle to grave’ care for all UK residents. It is also one of the largest purchasers of life sciences products in the world, spending at least £15 billion each year on goods and services. In Wales this equates to an annual spending budget of £800 million, giving companies and investors access to an important resource of clinicians, patients, clinical research and an array of disease specialisms.

3.2 The purpose of the NHS and everyone working within it is to promote health and wellbeing, and to provide high-quality healthcare, free at the point of delivery, to everyone who needs it. In short, the NHS is tasked with alleviating the burden of ill-health and transforming patient outcomes, all within a difficult financial climate. However, as highlighted in the Cooksey report research addressing unmet clinical needs is no longer linear and unidirectional, starting from the ‘bench’ and moving to clinical discovery. Translation of ideas can and does occur from bedside to bench and more often than not, this involves many journeys in both directions. The NHS therefore has a significant role to play in this process.

3.3 The way the NHS operates in Wales, combined with demographic trends creates an environment that is highly conducive to health research. Wales has a relatively stable population of around 3 million, reflecting an urban, rural and ethnically diverse mix of people. The electronic data collection developed by NHS Wales Informatics service (NWIS) provides opportunities for both service improvement and research. This architecture will enable the collection of routine data linked to individual health records, with NWIS providing analytical services. Groups like the NISCHR-funded Health Information Research Unit (HIRU) have the capacity and the capability to make use of this data, and other relevant data sets, for health research purposes using the Secure Anonymised Information Linkage system (SAIL).

3.4 The recent success of a Welsh-led research centre of excellence CIPHER (Centre for Improving Population Health through E-Health Research), demonstrates Wales’ position at the forefront of e-health research. The Centre will undertake cutting edge research that links e-health records with other forms of research and routinely collected data, playing an active role in engaging with the public to promote better understanding of the benefits of e-health records research, offering career development and training opportunities, and acting as a vital point of contact for industry partners.

3.5 Recognition of the need to drive culture change to make research and innovation a core activity in the NHS is reflected in the Quality Delivery Plan for the NHS in Wales\(^\text{10}\) which, reiterates that research and innovation is not only necessary to create better therapies in the future but also brings immediate benefits to patients who participate in studies. Besides potential for saving and improving lives, research and development has additional value in terms of creating economic development and in attracting the best expertise into the Welsh health service.

3.6 The integrated Welsh NHS provides an excellent basis for research and innovation. The recently launched five year strategic vision for NHS Wales\textsuperscript{11} clearly identifies the need for the NHS to be ‘much more active in searching out and applying evidence in generating and promoting research where it is lacking’. There is a clear commitment from the Minister for Health and Social Services and the Chief Executive for NHS Wales that research and innovation should be valued and is central to the future development of the NHS. Through the implementation of this policy, NISCHR expects NHS organisations to place a greater emphasis on innovation, knowledge transfer, commercial trials, new technologies and the use of patient data for research.

\begin{quote}
\textbf{Actions:}
\begin{itemize}
  \item NISCHR will continue to actively work with the NHS to develop a business friendly culture where engagement with industry is a core organisational activity.
  \item NISCHR will support approaches for more effective use of data and data linkage to maximize the value to commercial research in Wales.
\end{itemize}
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4. Patients and Service Users

4.1 Patients are pivotal to translational research; they have a key role to play, either through involvement in focus groups or as a service user. It is also widely accepted that patients taking part in clinical trials have better health outcomes than those not involved. Additional benefits mean that they have potential early access to the newest forms of treatment together with the highest standards of medical care at no additional cost to the NHS.

4.2 Clinical trials conducted in the NHS require the involvement of a research sponsor and the health service. In later stage trials, the relationship is likely to be transactional. However, earlier trials and translational research are more likely to involve true collaboration between clinician, academia and industry. In some cases patients may also be required to provide feedback and opinion for proof of concept work which requires them to take a more active role in the translation of an idea in order to answer a specific research question.

4.3 Clinical research is an essential part of the medicine development process and provides more than data on proof of safety and efficacy. Resultant data provides a source of information to all medical researchers and it affords scientists the opportunity to examine, question and utilise trial data. The importance of this has been captured by leading UK healthcare organisations including the medical royal colleges and senior representatives of the pharmaceutical industry who have joined together to support best practice in transparency and publication of data arising from clinical research studies\textsuperscript{12}.

\textsuperscript{11} Welsh Government (2012) Together for Health – Five year vision for the NHS
\textsuperscript{12} The Ethical Standards in Health and Life Sciences Group (2012) Clinical trial transparency principles and facts
4.4 As part of driving culture change, NISCHR intends to make the most of new opportunities and awareness raising of relevant resources such as the development of the Clinical Trials Gateway, which allows patients and doctors to search a number of different international trial registries to find clinical trials that are taking place in the United Kingdom. NISCHR also supports a recent publication from NHS Wales, which provides information to patients on the benefits of health research and its potential impact on service delivery.

4.5 Involving patients and members of the public in research design can lead to better research, clearer outcomes, and faster uptake of new evidence. As part of the NISCHR CRC, Involving People has the function of recruiting and training a network of patients, carers and service users and providing them with opportunities to be involved in research development with NISCHR RRGs and subsequent funded projects. The recent NISCHR CRC Involving People Action Plan highlights key objectives to increase Patient Public Involvement (PPI) in research, which includes supporting a diverse network of service users prepared for active involvement in research, raising awareness of PPI in research throughout Wales and supporting researchers to actively involve patients, carers and service users in their work.

Actions:
NISCHR will explore opportunities to increase patient participation in industry related clinical trials and will work with primary care practitioners to raise awareness of the Clinical Trials Gateway.

NISCHR intends to continue working to develop an approach to ensure that public, patient and user involvement is considered in all NISCHR work programmes, including industry initiatives.

5. THE LIFE SCIENCE INDUSTRY

5.1 Life Sciences companies are a crucial element of a broader UK life sciences ecosystem which includes academia, the NHS, patient groups, research councils e.g. the Medical Research Council (MRC) and government funders such as NISCHR, the National Institute for Health Research (NIHR) in England and the health departments of Scotland and Northern Ireland.

5.2 Working with the life science sector is of increasing importance to NISCHR. The UK Life Sciences industry is a world-leading, high tech industry employing over 150,000 people and investing at least £5 billion in research and development (R&D) in the UK every year. It also has an annual turnover of nearly £50 billion, making it a significant sector for investors. Although life sciences includes non-medical subsectors, for the purposes of this paper, the sector is defined as comprising the following three sub-sectors: pharmaceuticals, medical biotechnology and medical technology.

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13 www.ukctg.nihr.ac.uk
5.3 Focusing on Wales, the life sciences sector is made up of over 250 companies employing over 15,000 people with a contribution of £1.3 billion to Welsh GDP. The industry is well recognised as a strong driver of economic growth, provides highly-skilled employment opportunities and, through the development of innovative medicines and medical technologies, contributes to the delivery of high-quality healthcare.

5.4 These subsectors of life sciences are often research led, carry significant technical risk, and rely heavily on intellectual property (IP) development and management. This is especially relevant for pharmaceuticals, where it can take a long time and very significant investment before therapies enter the market, and the failure rate is very high. However, life sciences businesses have access to a global market with relentless growth, driven by emerging markets, lifestyle and demographic changes. Additionally, from a policy perspective, life sciences is distinct from other sectors in that it has the ability to deliver much needed economic benefits and prosperity whilst also improving public health and reducing healthcare costs.

5.5 Life Sciences companies also represent a major potential revenue source to parts of the health service and medical academia as customers for contract research, clinical trials, and research and development collaborators. The sector is also highly receptive to licensing opportunities for products that stem from IP originating from individuals within the NHS.

5.6 Important differences exist between the pharmaceutical and medical technology sectors in terms of product development and the regulatory pathway. To better understand these differences and to recognise the contribution the medical technology sector makes to the economy of Wales, NISCHR commissioned MediWales to review the barriers to clinical access. The report highlighted that there are a number of major challenges hindering the development of innovative medical devices such as: the lack of available clinical expertise during early product idea evaluation; the lack of knowledge of funding opportunities and pathways, and lack of access to specialist advice for proof of concept testing.

5.7 Over the past year, NISCHR has forged strong links with the Association of the British Pharmaceutical Industry (ABPI) and MediWales, the forum representative for the life sciences industry based in Wales. Much of the work undertaken has enabled a greater depth of understanding on how NISCHR initiatives related to translational research, IP, knowledge transfer and social care can be strengthened through working with the life science industry.

Action:
NISCHR will continue to work with industry partners to ensure that the benefits derived from working with the life science sector are embedded into core R&D workstreams e.g. through adequate representation of stakeholders on the NISCHR AHSC Industry Advisory Group.

16 Office for Life Sciences (2010) Life Sciences in the UK - Economic analysis and evidence for ‘Life Sciences: Delivering the Blueprint’
17 MediWales (2010) Barriers to Clinical Access: MediWales
6. Academia

6.1 Scientific research and the development of modern techniques are crucial for improving patient care in a society that is increasingly demanding the highest quality health services. Effective patient care requires the continuous improvement of knowledge on the pathophysiology of the diseases, diagnostic procedures and therapeutic tools available.

6.2 Fundamental changes to drug discovery and a reduced capacity within industry to undertake research in-house heralds a change in the way industry now operate. Bridging the gap between discoveries achieved at the ‘bench’ and interventions and therapies at the ‘bedside’ remains a challenge. This gap has been singled out as having an unwelcome effect not only on patient care but, more broadly, economic development.

6.3 Translational research is an area of fruitful collaboration across academia and industry, where the UK has historic strength. This is a consequence of the aim of researchers on both sides to deliver efficacious interventions and therapies to benefit human health. In most cases, both want the same goal and progressively need each other to achieve this. Increasingly, academia are finding that there are opportunities for deeper industrial collaborations, not just involvement with drug discovery, but also in supporting and enabling activities such as bio-marker identification and development and imaging science. NISCHR currently supports translational research projects in a variety of clinical academic specialties and over the past year this workstream has broadened to include a new partnership with the Science and Technology Facilities Council (STFC).

6.4 Voluntary collaboration between academia, industry and other research partners can drive a sustainable model of innovation. Partnerships between academia and industry are becoming increasingly prominent. By pooling research, resources and expertise developing new drugs, therapies and medical technologies can be a joint achievement resulting in shared revenue. In addition to this, recognition of research impact is also an important area of assessment within the Research Excellence Framework (REF) which assesses the demonstrable benefit of research undertaken by HEIs to society, public policy, quality of life, culture and the economy.

6.5 This new collaborative approach to research represents a significant change in culture to traditional ways of working. However, the value and benefit it affords is emphasised by research funders including the Technology Strategy Board (TSB), MRC, NIHR and the Wellcome Trust who actively encourage multidisciplinary teams to work together to address the clinical unmet needs and grand challenges that presently impact society.

Actions:
NISCHR will continue to encourage academics to engage in commercial collaborations where appropriate opportunities exist.
NISCHR will work to increase available funding opportunities for academics who wish to work with commercial collaborators.

18http://www.ref.ac.uk/background/
7. **Facilitating the Commercial Research Environment**

7.1 NISCHR has invested significantly in a research environment that makes Wales an attractive place to undertake research. The NISCHR AHSC Permissions Coordinating Unit (PCU) has been set up to provide a number of advantages, not least reducing the time it takes to gain NHS R&D permissions. The unit provides a single point of entry for research permissions, consistent decision making and a supportive environment to enable NHS R&D offices to provide the best service possible. The Permissions Coordinating Unit is ideally placed to capture all commercial contract research undertaken in Wales.

7.2 The development of a NISCHR commercial research register will replace current processes in place, and remove the need for a formal adoption process for commercial contract research. It will also provide a framework to collect data sets that go beyond those collected during the permissions process in which to inform the evolving industry workstream.

7.3 Metrics assessing set up times, recruitment and completion of studies to time will enable NISCHR to monitor commercial outputs across NHS Wales and provide data to assist in marketing Wales effectively. NISCHR will continue to breakdown barriers to providing timely NHS R&D permission for industry. The commercial research register will also support the focus of this activity by providing up-to-date, accurate detail on the commercial activity coming into Wales and provide assistance in ensuring that where possible, appropriate coverage and support is available. NISCHR AHSC will manage and maintain the commercial research register for all industry studies which will act as a platform for monitoring commercial research activity taking place in Wales.

7.4 Practical, operational assistance is also required to support a new culture of commercial research activity in the NHS. Industry Managers will be recruited to support the needs of industry. Working closely with colleagues in NHS organisation R&D offices, researchers, support departments, HEIs and industry employees, the post holders will be responsible for supporting the feasibility assessment, set up, recruitment of patients and delivery of commercially sponsored clinical research studies across Wales. A key element of the role will involve identifying, building and managing relationships, liaising across all relevant stakeholders and sectors with the purpose of strengthening and growing high quality commercially sponsored research studies in Wales.

7.5 NISCHR CRC research network staff, e.g. clinical studies officers, research nurses and research facilitators, will continue to play a role in supporting the commercial research agenda. Additionally, through changes to the NHS R&D funding policy, opportunities exist to ensure that revenue accrued from commercial trials is used strategically to build a stronger commercial research workforce in Wales. There is therefore greater scope to broaden the skills base of research professionals to embrace studies sponsored by pharmaceutical and medical devices companies.
7.6 Investigators with a significant interest in undertaking commercial research are crucial to the success of the initiatives outlined. There is a need to actively support our current investigators and draw out new investigators who want to participate and lead studies from Wales. Providing protected clinical time for commercial research, via initiatives like the recent NISCHR AHSC Clinical Research Time Competition (2012/13) is one method of ensuring that capacity for increased commercial contract research is available to those professionals with a specific interest in undertaking commercial research.

Actions:
By building on the existing strengths of NISCHR AHSC, NISCHR will continue to ensure that the remaining barriers to timely NHS R&D permission, as reported by the Academy of Medical Sciences Review (2011) continue to be addressed.

Industry Managers will be recruited by NISCHR AHSC to provide a clear communication route and facilitation service for delivering commercial research studies in Wales. This will be delivered under the newly established Health Research Wales portal.

The commercial research register will replace formal adoption of commercial research studies in Wales and will be managed and maintained by NISCHR AHSC.

NISCHR will review opportunities to develop a foundation of investigators experienced in commercial research and support less experienced professionals to gain the skills required to lead and participate in commercial studies.

By learning from existing good practice, NISCHR will explore ways in which the workforce in commercial research can be strengthened.

8. The Role of NHS Research and Development

8.1 Ultimately, the development of new medicines and their introduction into clinical settings demands a receptive and responsible system of research approval that facilitates the initiation and completion of clinical trials which is a core responsibility for NHS R&D organisations. Traditionally, NHS R&D funding allocations have been ring-fenced for non-commercial research, and whilst the new NHS R&D funding plan continues to support a high-quality portfolio for non-commercial research studies, allocations can also be used to conduct commercial research activity where cost recovery models are utilised.

8.2 In order for commercial research to be embedded in the R&D culture of organisations in Wales, it is important it is not seen to stand alone but to be closely linked to the more developed non-commercial R&D environment in Wales. It is therefore vital that commercial research is integrated into NISCHR policies and workstreams and hence measures of the success of this policy document have been and will be introduced across the spectrum of NISCHR’s activities.
8.3 The recently published NHS R&D allocations Delivery Framework 2012/13 outline the new R&D performance management arrangements for NHS organisations. In this document, NISCHR has set a national objective ‘to create a research environment which promotes and encourages commercially funded research activity within the NHS’. Key indicators and targets have been introduced through the NHS R&D Monitoring Framework which include local targets on research permissions, set-up and delivery and levels of engagement with commercial research. As well as collecting data for local management purposes, NISCHR will use this information to feed into National UK targets on commercial research and to market Wales both within the UK and internationally.

8.4 In line with the NISCHR industry policy and the NISCHR AHSC work programme on industry engagement, there is an enhanced focus in 2012/13 on the commercial R&D agenda. The role of Health Boards and Trusts, and in particular NHS R&D offices cannot be underestimated to position NHS Wales at the forefront of commercial R&D. This can only be achieved by all NHS organisations working in partnership with the NISCHR AHSC to collectively address issues and break down the barriers that currently exist.

8.5 Although NHS R&D offices are autonomous in their decision making, the modifications outlined represent a significant change in culture which lends itself to greater engagement with commercial stakeholders. A key aim of NISCHR is to encourage senior leaders in R&D management in Wales to embrace and consider the potential that commercial research offers within their organisations and to their patients.

8.6 Through this industry policy, there is an expectation that Wales will be recognised as a key player in commercial research. The life sciences sector in Wales is predominantly made up of medical device and diagnostic companies that increasingly require a strong evidence base which will be captured through clinical trials. There is therefore a real opportunity for R&D departments to cultivate additional expertise in this area, which will support the local economy.

**Actions:**
Embedding commercial research into the NHS through the provision of NHS R&D funding will be considered by NISCHR in future funding model formulas.

A range of performance indicators to assess the delivery of commercial research across NHS Wales will be monitored by NISCHR.
9. Building a Reputation – Promoting Wales

9.1 Recognition that Wales is part of a competitive landscape has been an important consideration which has underpinned this policy agenda. As evidenced throughout this document, a variety of separate components are required to work together to ensure that the profile of Wales is raised as a place that welcomes collaborations with industry and commercial contract research.

9.2 *Health Research Wales* will be established to provide industry with a central access point, where all interested stakeholders can access relevant information quickly and easily. This includes access to model agreements, costing templates and directories of expertise. In essence this will be a ‘one-stop-shop’ providing a seamless all-Wales sign-posting and facilitation service, advice on the requirements required to undertake clinical research in Wales as well as promoting the strengths and capabilities of Wales.

9.3 The uptake of medical technologies with good evidence of clinical and cost-effective benefits needs strong engagement by companies with relevant NHS healthcare professionals, both during the product development stage and post marketing. Small and Medium-sized Enterprises (SMEs) tend to operate within their local health economy in establishing initial interest in their products. Contact with clinicians to gain feedback is therefore vital to this process.

9.4 *Health Research Wales* will act as a repository for an up-to-date directory of expertise providing access to clinicians and academics with a stated interest in commercial research. Effective examples of commercial collaboration and institutions that exemplify a willingness to support mutually beneficial relationships with industry provide a platform for Wales to build on. Therefore, links to Higher Education Institutions, trade bodies and support services will also feature as part of this comprehensive package.

9.5 The key strengths of Wales are well documented in a variety of strategic documents from the Welsh Government, sector representatives and Higher Education Institutions. However, these assets have not always been obvious in a global environment. Strong brand identity is crucial to ensure that Wales is marketed effectively both at a national and international level. *Health Research Wales* will provide recognition to consumers making purchasing decisions about appropriate research partners and expertise which will assist this new dynamic structure to grow and prosper.

**Actions:**

*Health Research Wales* will be the external facing brand of NISCHR AHSC’s signposting, facilitation service and communication function with industry.

*Health Research Wales* will serve as the main communications vehicle to Industry nationally and internationally and, promote Wales as an attractive place to do research.
10. Building Research Connections

10.1 The development of partnerships with industry in research is a key part of the Welsh government’s strategy for science, which acknowledges that there are benefits to be derived from working in collaboration with universities where complementary research interests exist. Furthermore, a recent analysis of biomedical publications from the National Endowment for Science, Technology and the ARTS\textsuperscript{20} (NESTA) suggests that the UK impact in biomedical sciences is high relative to other countries, and that collaborative papers have a greater citation impact than purely academic papers. In practical terms, such collaborations can be fundamental to moving basic research forward across translational gaps, enabling it to become a real benefit to patients and a realistic contribution to economic renewal.

10.2 In recent years, NISCHR has shown its commitment to translational research through involvement in initiatives that support collaborative working. The Severnside Alliance for Translational Research (SARTRE)\textsuperscript{21} is one such example. Originally established in 2009 with funding from the MRC and Welsh Government, SARTRE was set up to drive cooperation between the Universities of Bristol and Cardiff and to develop a mechanism for driving joint translational projects forward. Over time, this remit has been extended to acknowledge the role that the physical sciences such as engineering and biomedical sciences play in collaborative research.

10.3 Through the development of SARTRE, and UK-wide initiatives such as the Translational Research Partnerships overseen by the NIHR Office for Clinical Research Infrastructure (NOCRI), multi-disciplinary models between industry, NHS and academia have been established. However, NISCHR recognises that there is a need to identify an optimal approach that will capitalise on the strengths of the NHS, academia and the industry sector based in Wales and, learn from deficiencies that have occurred from past collaborations.

10.4 Through NISCHR and BETS, the Welsh Government has commissioned a consultative review of translational collaborative models\textsuperscript{22} that appraises and reviews best practice across the UK, Europe and internationally in areas of pharmaceuticals, medical technology and biotechnology.

**Actions:**

NISCHR will consider how recommendations from the recent review of translational research models can shape policy direction.

NISCHR will work with key stakeholders to identify and establish a translational research forum, the aim of which will be to actively facilitate opportunities for collaboration between industry, academia, social care and the NHS.

\textsuperscript{20} NESTA (2011) All Together Now - Increasing cross sector collaboration in the UK biomedical Industry: http://www.nesta.org.uk/

\textsuperscript{21} http://www.sartre.ac.uk

\textsuperscript{22} Hecht and Sundstrom (2012) International Review of Best Practice in Translational Research: forthcoming
11. Access to Research Funding

11.1 Through membership of the UK Office for Strategic Coordination of Health Research (OSCHR) and the UKCRC, NISCHR maintains a high profile on the UK research funding scene. NISCHR works with a range of UK funding partners including the MRC, the Economic and Social Research Council (ESRC), the medical research charities, and counterparts in the other UK Health Departments, participating in a wide range of UK programmes which open significant funding streams to researchers based in Wales.

11.2 In line with an overall strategic objective across the Welsh Government, there is a need to increase the proportion of UK research funding into Wales. The ‘open’ innovation model of research and development, where companies engage with the wider research environment, is also an opportunity to strengthen the life sciences sector in Wales and enhance collaboration.

11.3 Over the past year, NISCHR has sought to develop the involvement of Wales based researchers in schemes that provide funding to assist in the development of innovations that address a clinical unmet need. Both the product development call and the surgery call; badged under the NIHR i4i (Invention for Innovation) programme support and advance the research and development of innovative healthcare technologies and their translation into the clinical environment for the benefit of patients.

11.4 Work has also been undertaken to capture the important contribution the NHS can make to the conception of the clinical unmet need. The INVENT patent and proof of concept scheme was developed by NISCHR in 2011 to support technological innovations conceived by NHS employees in Wales. However, more recently, in recognition of the important contribution that innovation plays in the delivery of social care, INVENT has been extended to social care employees based in Wales.

11.5 Initiatives that directly support translational research for a clinical unmet need with a view to producing a marketable product and associated Intellectual Property (IP) have increasingly become core work for NISCHR. Other UK funding initiatives, for example the Small Business Research Initiative (SBRI) and the TSB, also support collaborative partnerships to address potential clinical unmet needs.

11.6 A number of schemes also exist within other Welsh Government departments to support Research and development. BETS supports an innovation support programme that encourages collaboration between HEIs and business through knowledge transfer, Intellectual Property and commercialisation. Working in partnership with other Welsh Government departments, NISCHR will clarify available funding opportunities for Wales based researchers and companies involved in translational health research.

11.7 To ensure the ongoing viability of their work, researchers in academia, the NHS and industry need to consider how they will continue to fund their activities. Exploring all available funding options and careful planning will assist in ensuring
future financial sustainability. Increasingly, funders now expect researchers to have considered the potential scientific, societal and economic impacts of their research. Therefore, applicants are required to consider how to maximise the impact of their work which may include advancing the innovation to the point where it becomes attractive for others, for example, venture capital firms, industry or public-private partnerships.

### 12. Adopting Innovation

#### 12.1 Innovation

Innovation is the development of a new idea, service or product, which can significantly improve the quality of health and social care wherever it is applied. Innovation is widely recognised as a key driver of economic growth and job creation and makes a significant contribution to the improvement and sustainability of the health service and services to patients. In recognition of this, the Welsh Government has recently launched an innovation programme and is presently considering the results of a consultation on this subject to raise Wales’ performance in innovation. NISCHR will play an important role in the development of an all-Wales innovation strategy in which the NHS is already recognised as a significant component.

#### 12.2 Turning new ideas into products

Turning new ideas into products that health and social care services can adopt is fundamental for patient and public benefit. Stimulating ideas from the NHS and local authority social services departments and, ensuring appropriate conditions for the development of Intellectual property so that industry can readily take up those ideas is an important consideration for NISCHR.

#### 12.3 INVENT proof-of-concept fund

The initial INVENT proof-of-concept fund was a pilot scheme to provide funding for staff in the NHS who wanted to develop an idea that addressed an unmet clinical need. The early indications from this scheme and from similar activities in other areas of the UK suggests there is potential to increase technological and IP-related product innovation from within the NHS in Wales. NISCHR will continue this scheme and broaden it to encompass innovation arising in social care institutions.

#### 12.4 Well managed IP

Well managed IP can improve the innovation and commercialisation environment considerably. To address this NISCHR is developing a set of principles for IP issues associated with its funding and template IP policies for NHS organisations in Wales. These will seek to demystify some of the misconceptions surrounding IP, incentivise staff in the NHS and social care organisations to engage in innovation activities and to ensure that both industry adopters and the organisations and individuals who have created and developed IP are rewarded fairly.

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23 Welsh Government Innovation Strategy for Wales – Call for evidence 2012
http://wales.gov.uk/newsroom/businessandeconomy/2012/120430innovationstrategy
12.5 Poor adoption and diffusion of a new innovation or medicine can have a significant impact on potential benefits to patients. NICE provides national guidance on promoting good health and preventing and treating ill health. It is also internationally recognised for the way in which it develops its recommendations and utilises a process that focuses on the best available evidence. This includes the views of experts, patients, carers and industry. In Wales, the AWMSG appraise new medicines that are not due to be considered by NICE within 1 year. This process has been accredited by the NICE accreditation system and has significant benefits to patients in Wales.

12.6 Furthermore, in Wales, the application of evidenced based research into patient care is underpinned by the proviso that all medicines approved by NICE or AWMSG must be made available to patients within 3 months of a positive recommendation. AWMSG are currently working with health boards and trusts to monitor compliance with AWMSG guidance and technology appraisal recommendations from NICE.

12.7 Wider considerations for the uptake of new innovations are currently being evaluated through a number of initiatives across the Welsh Government. A Health and Wellbeing Good Practice and Innovation Board has been established to enable evaluation of the potential impact of innovations and facilitate and accelerate their adoption by the NHS, social services and third sector organisations in Wales. In addition to this, the National Assembly for Wales’ Health and Social Care Committee will be reviewing the uptake of medical technology in Wales and the possible barriers to effective new technologies being more accessible to patients.

12.8 It is widely recognised that public procurement has a strong role to play in driving innovation to pull through new ideas. Procurement services are well placed to provide insight into the product gaps or clinical unmet needs that exist in the NHS and have a clear role to play in encouraging the market to propose new solutions before specifications for tendering are announced. Consideration of relevant health economic data can also provide context to purchasing decisions. In order for NISCHR to achieve its goals and maximise its impact on patient care, active engagement exists with officials from NHS procurement.

Action:
NISCHR will promote innovation by supporting funding schemes that focus on patient facing research and clinical unmet needs, with a clear aim to advance the translation of healthcare technologies for increased patient benefit. By working with stakeholders and partners in Welsh Government and further afield, NISCHR will work to ensure the research it supports is recognised and captured through effective horizon scanning processes.

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13. Delivering Research

Contracts and agreements across Wales

13.1 A series of model agreements have been drawn up by the UK Health Departments and relevant industry bodies to help speed up the contracting process for clinical trials and clinical investigations of medical devices carried out in the NHS. These agreements support the contracting process for research partnerships involving the pharmaceutical and biotechnology industries, universities and NHS organisations. In many cases they remove the need for individual site reviews and local legal agreements to be drawn up. Speed of delivery remains an important consideration for funders and industry in terms of timely trial setup and impact on time to market. Un-modified model agreements enable clinical trials to start earlier, which in turn provides patients faster access to innovative treatments, therapies and medical technologies.

13.2 In response to the growing participation in collaborative research, the model Industry Collaborative Research Agreement (mICRA) is the first model agreement to support collaborative commercial clinical research involving pharmaceutical and biotechnology industries, academia and NHS organisations across the UK. The mICRA was developed by a working group led by NOCRI and the MRC. Representatives from industry, universities, the NHS, and the Intellectual Property Office, worked together with expert legal opinion to develop a model agreement that can support all collaborative research scenarios. A statement of endorsement from all organisations involved in developing the agreement encourages its use in streamlining the contracting process for collaborative research.

Action:
Greater promotion of model contracts and agreements and the development of new documents to address outstanding needs will become a core feature of the industry programme.

Commercial costing templates

13.3 Transparency, consistency and predictability are the declared goals of the national costing templates for commercial research in the UK NHS. The templates address a recommendation from Sir David Cooksey’s 2006 report on health research funding to accelerate negotiations for trials in the UK. By providing clear and consistent costs, the templates ensure that the NHS is fully reimbursed for any associated activities and, identify standard rates, acceptable to all parties for staff time, overheads and investigations borne by NHS departments that support research.

25 http://www.ukcrc.org/regulationgovernance/modelagreements/mctaanddownloads/
13.4 A suite of commercial costing templates\textsuperscript{26} has been developed to support research taking place within secondary care and primary care and includes specific studies involving a medical device. They provide a starting point for clear negotiation helping to minimise time delays. Updated versions also provide data to assist with invoicing which in turn can assist with tracking patient recruitment.

13.5 NISCHR acknowledges that smaller companies within the medical technology sector are challenged by the costs required to undertake clinical trials. Opportunities should be taken to support ways in which medical device studies could be appropriately costed to support companies based in Wales.

Action: NHS R&D departments will be required to adopt cost recovery models to ensure the fair distribution of commercial research income across all departments involved in a research study.

14. Contributing to a Life Sciences Ecosystem

14.1 Collaboration, funding and a supportive infrastructure are vital if Wales is to make the most of its strengths. The life sciences sector panel, established in 2011, advises the Minister for Business Enterprise Technology and Science on the most promising areas for future business growth and strategic interventions which will deliver economic benefit to Wales. One element of the approach recommended by the panel is supporting the development of an integrated ecosystem for life sciences in Wales, which will bring people, ideas, knowledge and experience together in one place. This is complemented by the announcement of a £100m Welsh Life Sciences Investment Fund, and significantly increased support for overseas trade and investment activity from 2012 onwards.

14.2 There are also areas of overlap across Government Departments. Whilst the Department for Business Enterprise, Technology and Science (BETS) has a clear remit to market Wales from a life sciences perspective, NISCHR is committed to ensuring that the strengths of the health sector dovetail seamlessly with this activity and where appropriate a joint approach to marketing Wales will be undertaken via appropriate publications, conferences and trade shows.

14.3 Marketing Wales should also include a celebration of its successes. Over the past three years, NISCHR has worked with MediWales to introduce two new innovation awards that specifically recognise new technologies and developments within the NHS and collaborative partnerships between Welsh companies and the NHS. These and other examples of successful research projects set an established pattern for further collaborative developments. In the future, such examples will be showcased, demonstrating the benefit conferred to patients, not just within Wales and the UK, but globally. In addition to this, exemplars will show case successful set-up and delivery of health research in Wales.

\textsuperscript{26}http://www.crncc.nihr.ac.uk/Life+sciences+industry/tools/costing
14.4 High-profile liaison events with industry, academia, social care and the NHS will be supported by NISCHR. This will provide potential industry partners the opportunity to become familiar with the expertise that exists within Wales and the increased value Wales places upon the life sciences sector within the UK and globally. This will include working closely with UK departments e.g. NOCRI and UK Trade and investment (UKTI) to ensure that the strengths of Wales are included when promoting the UK to global audiences.

**Actions:**
NISCHR will continue to work closely with the Department for Business Enterprise, Technology and Science to ensure that on-going workstreams are integrated into the proposed life science ecosystem.

A communications plan will be developed, highlighting a signposting function, facilitation and engagement process with industry and the wider R&D community.

To ensure consistent process and promote Wales as part of a UK package, working with England, Scotland and Northern Ireland will continue to be a key priority for NISCHR.
## List of Acronyms

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABPI</td>
<td>The Association of the British Pharmaceutical Industry</td>
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<tr>
<td>ASCC</td>
<td>All-Wales Academic Social Care Research Collaboration</td>
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<tr>
<td>AWMSG</td>
<td>The All-Wales Medicines Strategy Group</td>
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<tr>
<td>BETS</td>
<td>Department for Business, Enterprise, Technology and Science</td>
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<td>BRC</td>
<td>Biomedical Research centre</td>
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<td>BRU</td>
<td>Biomedical Research Unit</td>
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<td>CIPHER</td>
<td>Centre for Improving Population Health through E-Health Research</td>
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<td>CRI</td>
<td>Clinical Research Infrastructure</td>
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<tr>
<td>DHSSC</td>
<td>Department for Health Social Services and Children</td>
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<td>ESRC</td>
<td>Economic and Social Research Council</td>
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<tr>
<td>HEI</td>
<td>Higher Education Institute</td>
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<td>HIRU</td>
<td>Health Information Research Unit</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<td>mICRA</td>
<td>model Industry Collaborative Research Agreement</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<td>NIHR</td>
<td>National Institute for Health Research</td>
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<td>NISCHR</td>
<td>National Institute for Social Care and Health Research</td>
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<tr>
<td>NISCHR AHSC</td>
<td>NISCHR Academic Health Sciences Collaboration</td>
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<tr>
<td>NISCHR CRC</td>
<td>NISCHR Clinical Research Centre</td>
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<td>NOCRI</td>
<td>NIHR Office for Clinical Research Infrastructure</td>
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<td>NWIS</td>
<td>NHS Wales Informatics Service</td>
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<td>OSCHR</td>
<td>Office for the Strategic Coordination of Health Research</td>
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<td>PCU</td>
<td>Permissions Coordinating Unit</td>
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<td>PPI</td>
<td>Patient Public Involvement</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>REF</td>
<td>Research Excellence Framework</td>
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<td>RRGs</td>
<td>Registered Research Groups</td>
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<tr>
<td>SAIL</td>
<td>Secure Anonymised Information Linkage System</td>
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<td>SARTRE</td>
<td>Severnside Alliance for Translational Research</td>
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<td>SBRI</td>
<td>Small Business Research Initiative</td>
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<td>SMEs</td>
<td>Small and Medium-sized Enterprises</td>
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<td>STFC</td>
<td>Science and Technology Facilities Council</td>
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<td>TSB</td>
<td>Technology Strategy Board</td>
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<tr>
<td>UKCRC</td>
<td>UK Clinical Research Collaboration</td>
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<td>UKTI</td>
<td>United Kingdom Trade and Investment</td>
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<td>WCB</td>
<td>Wales Cancer Bank</td>
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<td>Wales Gene Park</td>
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