Institution: Queen's University of Belfast

Unit of Assessment: 1

a. Context: The School of Medicine, Dentistry and Biomedical Sciences was radically restructured in 2008. A key driver was the need to promote research impact on healthcare, clinical practice and commerce, both nationally and internationally, through translationally oriented medical research. Resources were concentrated in 4 Research Centres: the Centre for Cancer Research and Cell Biology, the Centre for Infection and Immunity, the Centre for Experimental Medicine and the Centre for Public Health*. These focused on diseases of clinical importance in areas of research strength, forming the Institute of Health Sciences (IHS). The goals set emphasised research impact and included facilitating high quality co-ordinated research programmes *"focussed on a number of key health-related areas*", enabling strategic alliances with *"pharmaceutical and biotech industries"* and enhancing *"the development of the bioindustry for the 21st century".* Major infrastructure investments such as the Wellcome-Wolfson funded Clinical Research Facility and the UK Research Partnership Infrastructure Fund (UKRPIF) Centre for Experimental Medicine have been paralleled by a translation strategy that emphasises the sharing of expertise at the interface between basic and clinical scientists. This exploits our juxtaposition to, and close managerial relationships with the major teaching hospitals in Belfast. Research from the School has resulted in improvements in patient care and changes in clinical practice. The development of translational expertise has facilitated partnerships with both the NHS and commercial companies, while research based technological innovation has resulted in several spinout companies. These outcomes, as illustrated in the related Case Studies, demonstrate the current effectiveness and future potential of the strategies adopted to promote research impact. (* Returned under UoA2.)

b. Approach to impact: This has been characterised by dissemination of research outcomes to non-academic stakeholders and promotion of a strong translational focus. Working alongside our partners in the NHS, the Department of Health, Social Services and Public Safety, the Public Health Agency and the Northern Ireland Medical and Dental Training Association, our goal has been to place improvement in wellbeing and healthcare through the translation of research into clinical practice at the heart of the University and Health Service agendas. We have emphasised engagement with policy makers and the wider public and site visits by Westminster MPs, NI Assembly members and the NI Minister of Health have allowed us to emphasise the importance of biomedical and clinical research. The IHS has hosted high profile public events such as "Medical Research at Queen's: Discovery to Recovery", an evening of talks emphasising the clinical relevance of key research groups, and laboratory visits for key stakeholders (e.g. CRUK, Society for Translational Oncology, British Heart Foundation, Fight for Sight, and Cystic Fibrosis Trust). Staff are encouraged to act as ambassadors for the "Science, Technology, Engineering and Maths Academy" at Queen's, engaging with the next generation of researchers and research users.

The IHS focusses research strength around clinical problems of global significance. Our strategy emphasises the importance of establishing effective translational partnerships with NHS colleagues. Co-location of the Northern Ireland Clinical Cancer Centre beside the Centre for Cancer Research and Cell Biology, and establishment of the Cancer Registry within the Centre for Public Health has both promoted new research opportunities and also increased awareness of current research among clinicians. The impact of this, as indicated by improved patient outcomes, was recognised in 2011 by the award of Her Majesty the Queen's Anniversary Jubilee Prize to the University-led 'Comprehensive Cancer Care Centre' (http://www.royalanniversarytrust.org.uk/news/winners-announced). Research expertise in retinal imaging led to the establishment of the Central Angiographic Resource Facility, a joint initiative between Belfast Trust and Queen's University, which manages the UK's Network of Ophthalmic Reading Centres, facilitating image grading for commercial, research council and NIHR funded trials. Respiratory researchers in the IHS also partner NHS colleagues in clinical trials through the Critical Care Network, the Northern Ireland Clinical Research Network for Respiratory Medicine and the European Cystic Fibrosis Clinical Trials Network. The societal benefit of this work was recognised in the award of a CBE to Prof. Stuart Elborn in the 2013 New Year's Honours list.

The importance of translational partnerships with commercial companies is clearly exemplified in each of the 3 Research Centres returned to UoA1. These crucial links help ensure the clinical and economic benefits of research are realised, and the IHS has engaged with partners of global reach, including Astra-Zeneca, Pfizer, Novartis, Alcon and Roche. For example, GSK have

established a collaborative partnership with Prof. Alan Stitt (Centre for Experimental Medicine), allowing them to benefit from his research expertise with pre-clinical disease models as they seek to develop new treatments for diabetic retinopathy and macular oedema. This approach has already resulted in clinical trials of novel drugs. Cancer research has yielded over £50 million in income in the REF period, with the development of diagnostic products such as the *ColoDX* test for colon cancer, and ongoing validation of a number of experimental drugs. The close ties with biotechnology have been further cemented through the appointment of Prof. Richard Kennedy from Almac Diagnostics as a clinical scientist and McClay Professor in the Centre for Cancer Research and Cell Biology. The respiratory research group in the Centre for Infection and Immunity is one of only nine UK research centres in the industry-academia collaborative Translational Research Partnership for Inflammatory Respiratory Disease, funded by NIHR. They also work with the clinical research company Celerion and have completed five Phase 1 trials bringing more than £5 million into the local economy. Research based innovation has also resulted in spinout companies, with benefits in terms of jobs and income (Fusion Antibodies, TruCorp, Almac Diagnostics, PathXL and Lewis Fertility). This has been supported through the University's Knowledge Exploitation Unit and QUBIS, a University company established to commercialise research activities (http://www.qubis.co.uk/about-us). The combined turnover of spinout companies from the IHS, which employ over 200 people, was £7.3 million in 2012/13.

c. Strategy and plans: We seek to maximise research impacts on health and welfare, healthcare practice and the local and national economy. Our strategy will build on the approach outlined above, with an emphasis on a translational research culture and strong translational partnerships.

1. A Translational Research Culture: Maximising research impact requires a change in research culture through challenge, training and support. The annual appraisal process now emphasises the importance of maximising societal benefit to all research staff. The conceptual translation 'pipeline' is used as a basis for discussing the possible impact of research and any steps required to promote timely transition to the next phase (Fig.1). Relevant training needs are identified and met through the University Staff Training and Development Unit ('Intellectual Property Rights and Research', 'The Enterprising Researcher' and 'Applying your Research to Policy Agendas'). Appropriate, impact-related criteria will continue to be included in the academic profiles for probation and promotion, e.g. '*Establishment of links to appropriate commercial/industrial organisations' and 'Societal and Economic Benefit of Research'*. At Research Centre level, Directors report annual progress against relevant Key Performance Indicators, including *Knowledge Exchange and Commercialisation, Research Impact, Responses to External Stakeholder Strategies* and *Public Engagement*. Objective and measurable targets are agreed and outcomes reviewed, and any barriers to translation identified. The academic leadership of the IHS exemplifies the commitment to research impact both in commercial and NHS settings. The translational research led by Profs. Elborn and Stitt, both Research Centre Directors, has been outlined above. This is also a strong theme in cancer research. Prof. Paul Harkin is a founder and Managing Director of Almac Diagnostics, while 2 other Centre professors act as directors. Prof. Peter Hamilton, also in the Centre for Cancer Research and Cell Biology, is Vice-President for Research and Development in his spin out company, PathXL. As Head of School and Dean of Medicine, Prof. Patrick Johnston is one of the founders of two spinout companies, Fusion Antibodies and Almac Diagnostics, and acts as academic adviser to a number of leading international pharmaceutical companies (Pfizer, Amgen, Sanofi). This commitment to translation has been recognised in his appointment as Chair of the MRC Translational Research Group and Strategy Board member.

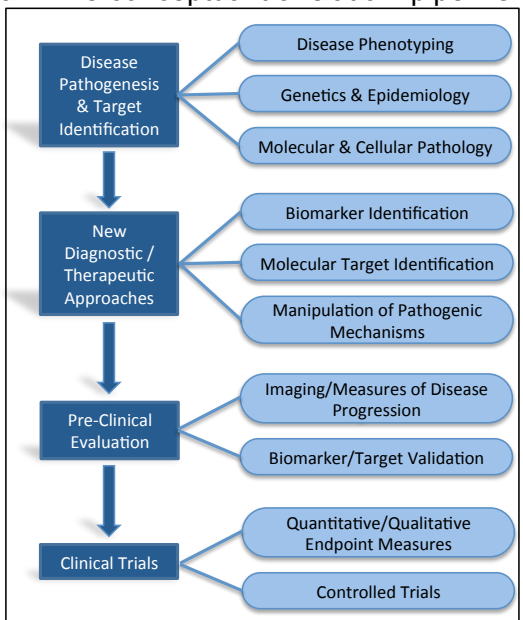

Fig 1: The translational pipeline within the Institute of Health Sciences

2. Public Engagement and Translational Partnership: The IHS will continue to promote the principles set out in the 'Concordat for Engaging the Public with Research' (http://www.rcuk.ac.uk/Publications/policy/Pages/perConcordat.aspx). Staff are encouraged to engage in public discussion and professional debate e.g. in formulating healthcare guidelines. This is crucial if research is to influence policy and clinical practice. Training is offered, e.g. through '*The Engaging Researcher*' event run by the Science Media Centre. Staff continue to engage with schools and some have acted as guest lecturers for W5, Belfast's award winning interactive science and discovery centre. Collaborative research with NHS colleagues is promoted through their appointment to honorary academic posts, allowing joint supervision of research students. These partnerships provide health service professionals with access to a world-class research infrastructure, not available within the service sector. The state-of-the-art Northern Ireland Molecular Pathology Laboratory (NI-MPL) was opened in the Cancer Centre in January 2013. This hybrid lab, developed in partnership with the Belfast Health and Social Care Trust, integrates molecular research and health service diagnostics under academic leadership, thus ensuring rapid translation of research into healthcare benefit. The campus also includes the Wellcome-Wolfson Clinical Research Facility (opened officially in 2013), as well as the Schools of Pharmacy and Nursing. This proximity will promote further interdisciplinary collaboration in applied healthcare research, as exemplified by ongoing studies into novel drug and vaccine delivery using pain-free micro-needle technology.

The next stage in infrastructure development is the projected opening in spring 2015 of the new home for the Centre for Experimental Medicine (CEM), with a total budget of £32m. Capital funding from a UKRPIF grant has been leveraged with additional funding from Atlantic Philanthropies, The Wellcome Trust and The Wolfson Foundation. The CEM brings together research in ophthalmology and vascular complications of diabetes, providing facilities in next generation sequencing and bioinformatics, cell and tissue imaging, proteomics and mass spectroscopy. We believe that, following major basic research disinvestment by large drug companies, there will be an increasing emphasis on true collaboration with institutions capable of delivering appropriate expertise. Our focus on building capacity in disease related research has already resulted in links with international companies such as Astra-Zeneca, Pfizer, Roche and GSK. Queen's plays a leading role in Knowledge Transfer Partnerships (KTPs), where the University has won 9 national KTP awards, including "Best KTP in the UK" in 2011. These initiatives place graduates within businesses to deliver innovative solutions for commercial programmes under academic supervision. The University has supported 15 KTPs in the health and life sciences sector in the REF period, fostering close partnerships between Small to Medium Enterprises and researchers. One agreement in 2013 will place 3 researchers from the IHS within Randox Laboratories Ltd, a Northern Ireland based clinical diagnostics company with an annual turnover of approximately £70 million. Moving forward, such links will help ensure that our research delivers economic and commercial impact locally, nationally and globally.

Table 1: Higher Education Business and Community Interactions-Survey (HEBCI-S) 2010/11

HEBCI-S Metric (2010-11)	*Rank in UK*
Best KTP	1
Sale of Spinout Shares	1
IP Income	3
Current Spinout Turnover	4
Patents Granted	7
Investment Raised by Spinouts	8
New Patent Applications	8
Cumulative Patent Portfolio	11

3. Direct Support for Commercialisation/Translation: Queen's has a strong track record in delivering economic impact through innovation, the creation of new jobs and dissemination of relevant skills. When measured against sector standard metrics, captured through the annual Higher Education Business and Community Interactions Survey, the university is consistently ranked in the top ten UK universities (Table 1). Funding is available to develop discovery projects before seeking more substantive awards from sources such as the MRC's Developmental Pathway Funding Scheme/ Developmental Clinical Studies or investment from commercial partners. This is underwritten by the Queen's Proof of Principle (PoP) Fund and a grant from the MRC Confidence in Concept (CiC) scheme, one of only 14 applications funded in 2012. Funding is further leveraged through Invest Northern Ireland (Economic Development Agency), which has already made a total investment of over £12m to the IHS. Queen's Research and Enterprise Directorate advise on IP protection and help develop licensing

agreements with commercial partners. The development of patented ideas to licensing is an important element in our impact strategy, as this promotes realisation of healthcare and economic benefits. Ongoing links with the spinout company Almac Diagnostics, which recently licensed a novel anticancer drug now being developed for Phase I trials, will act as a template for future partnerships with local biotechnology companies. Support at IHS and Institutional level has led to the development of 5 new biotech companies in recent years (Fusion Antibodies, Almac Diagnostics, PathXL, TruCorp and Lewis Fertility), with a total workforce of over 200, delivering ongoing commercial impact with the promise of future expansion.

d. Relationship to case studies: The 8 Case Studies for UoA1 all reflect the *'Translational Culture'* within the IHS that encourages staff to go beyond the simple publication of research findings in peer reviewed journals, with an emphasis on promoting research impact through public engagement and the translation of discovery into improved health outcomes and technological innovation.

Public Engagement and Translational Partnerships: Impacts on patient care and clinical practice require *professional and public engagement.* Evidence of benefit for a new diagnostic or therapeutic approach must not just be accumulated through research but also disseminated if the results are to benefit society. This process is clearly illustrated by the studies on '*Weaning from Ventilation*', *'Airways Disorders in Children'* and *'Difficult to Treat Adult Asthma'*, in which research influenced practice guidelines. In the last 2 of these cases, this was facilitated by the investigators' election to the relevant clinical sub-specialty panels responsible for promoting best practice, reflecting peer recognition of established research expertise. In the *'Erythrocytosis'* case study**,** identification of relevant mutations led to the development of appropriate diagnostic tests which are now offered as part of an international referral service, without which affected patients would be denied access to molecular diagnosis. The study '*Debunking MMR Vaccine Scares*' provides an important example of *public engagement* at the international level in a legal environment. Academic research expertise built up in molecular virology as applied to measles and mumps strain identification allowed Prof Rima to act as a credible and persuasive witness, helping refute the suggestions by Wakefield and colleagues that the MMR vaccine played a role in causing autism. Rima's testimony was vital in court cases both in the UK and the US, and protected the US Vaccine Injury Compensation Fund from potential bankruptcy in the face of large numbers of possible claims from the parents of children with autism.

Support for Commercialisation/Translation: '*Evidence based trials in Cystic Fibrosis (CF)'* demonstrates how internationally recognised expertise in cystic fibrosis (CF), including development of robust end-point measures for clinical trials for this disease, placed Elborn in the ideal position to partner with commercial companies to test new treatments. He co-led the international trial of Ivacaftor, the first therapy to directly correct the molecular defect in patients with a specific CF mutation. This resulted in licensing and funding for Ivacaftor's use in the US, UK and other EU countries, with improved outcomes for CF patients and commercial benefit for Vertex Pharmaceuticals, who developed Ivacaftor but needed clinical research expertise to test the drug. Such activities rely on legal *support for translation,* removing responsibility for costing and contracts from the researcher. The remaining two studies illustrate *full commercialisation* of research through the formation of spinout companies. As a full academic staff member, Prof. Hamilton has developed novel digital pathology image analysis solutions over the last decade, resulting in the establishment of 'PathXL', a company in which he is Vice-President for Research (see study on *'Digital Pathology'*). 'PathXL' has experienced continuous growth since it was first established and now employs approximately 30 people in the UK. It was awarded the "**European Web-based Software Platforms Enabling Technology Award" in** 2012 by **Frost & Sullivan,** and was ranked 13 in the '50 fastest growing Technology Companies in Ireland' in the 2012 "Deloitte Technology Fast 50" awards (see http://www.pathxl.com/). The study on *'Biomarker Discovery Innovation'* describes how this led to the establishment of Almac Diagnostics, a company that now employs 85 staff. This has patented, validated and licensed diagnostic tests for cancer biomarkers to US companies, helping inform both patient management and likely prognosis. The success of these ventures has been supported throughout by QUBIS, the University's vehicle for commercialisation of intellectual property (http://www.qubis.co.uk/).