Institution: Queen's University Belfast

Unit of Assessment: 3a Pharmacy

a. Context

The School of Pharmacy at Queen's has a long-standing translational research ethos, with health-related benefits for patients the intended ultimate impact of our research programmes. Our research structure and management, based on research divisions (clusters) with broader themes and individual research programmes, are designed to facilitate the generation of new ideas and promote collaborative working. Research activities encompass early stage fundamental studies in biomolecular/chemical-based sciences and in pharmaceutics, applied and near-market research (including technology transfer activities), clinical pharmacy practice, and informing/guiding evidence-based health policy and practice. Our approach to achieving impact from our research programmes is set in the context of our past history of close involvement with industry and experience of successful technology transfer from laboratory, via industry, to patient. An historical example of how this approach to impact was developed is the percutaneous anaesthetic product Ametop™, developed in the School of Pharmacy. Based on a patented tetracaine delivery system, it was licensed by the University to UK multinational Smith and Nephew plc. Ametop™ has been marketed in several countries since 1997 (www.timeshighereducation.co.uk/94012.article). This early example set the scene for a strong entrepreneurial drive within the School. A further influence was the long-standing relationship with the then local company Galen. In 1993, Queen's was the first Pharmacy School to run a Teaching Company Scheme (TCS, with Galen). Today, there are strong ongoing links with Galen's successor companies, Almac Group and Warner Chilcott Inc. The former is a licensee of the School's research on a novel anti-angiogenic drug, which is being developed for Phase I trials. US company Warner Chilcott have long-established links with the intravaginal drug delivery programme, which in turn generated our current programme of HIV prevention by vaginal microbicide delivery. The on-going connection with these companies, going back some 30 years, also resulted in their founders donating over £7 million to the School between 1998 and 2006, to further develop research and to build the School's McClay Research Centre for Pharmaceutical Sciences. As the School has developed a wider research portfolio over recent years, these experiences have strongly influenced the path to impact for laboratory science-based research. Concomitantly, a strong research ethos, local relevance and national/international connectivity has facilitated growing and successful primary care and clinical pharmacy research, including the establishment of academic practice units in local hospitals. For these aspects of our research, impact on policy and practice are among the key outcome measures.

b. Approach to impact.

The School engages with non-academic users and key stakeholders in the development of its research plans and forward research strategy. We have industry representatives on our 'stakeholder panel' as well as an active International Scientific Advisory Board. Past experience and external appointments have provided certain staff with a good awareness of issues relating to regulatory approval for both pharma products and medical devices. Together with our track record in commercialisation, this means we can talk with experience and confidence, for example, about product development challenges with a range of end-users. Key recent examples of the success of our approach include Donnelly's BBSRC Innovation Award and funding for microneedles commercialisation, and the award-winning new spinout company, ProAx-SIS. Practically, achieving beneficial impacts for patients from laboratory research typically involves seeking routes to market and, therefore, may also be associated with enhanced economic activity and employment. It therefore follows that the generation and protection of intellectual property (IP) is a key aspect of our approach to impact, with substantial experience in this area gained through past successful out-licensing and close interactions with industry. Exploitation of IP through spin-out activity or out-licensing, risk-sharing co-developments with industry and grant aid for commercialisation activities are key models that we currently employ to bring research with commercial potential into the technology transfer arena.

In a similar manner to engagement with industry as a conduit to ultimate patient benefits, there has been close and ongoing engagement with the practice community. Thus, the establishment of a successful academic practice unit in an acute Hospital Trust has facilitated the identification of key research questions of relevance to patient care, the environment in which the research can be

conducted, and where practice can be directly informed by the impact of that research. Close liaison with policy makers has been facilitated through policy seminars conducted by academics who have undertaken research that has direct relevance to health priorities e.g., infection control and antibiotic resistance, quality of care in dementia.

The Knowledge Transfer Programme (KTP) scheme is another aspect of our approach to impact, making our research expertise available to industry to solve real problems, generate new industry-identified products and enhance economic activity and employment. Following on from our past experience with the TCS, the forerunner of KTP, 24 Knowledge Transfer Partnerships worth £2.7M have been established nationally and locally with pharma and healthcare companies.

The School of Pharmacy has supported all of the research leading to impact though the allocation of DELNI (equivalent to UKRC) or School-funded studentships and investment in equipment and facilities measured in £Ms, in addition to external donations (£7M) through our industry links. The impact of the School's research over many years has been instrumental in leveraging further institutional support, notably in growing the academic and support staff complement. Thus, in REF 2014 the School is submitting 33 staff compared to 21 in RAE 2001 and 23 in 2008, while space has grown from 2000 square metres in 2001 to 5600 square metres currently. The impact described in our case studies and in those ongoing research programmes where impact will be fully seen in the future is an attraction for young doctoral students and postdoctoral researchers. Both of these cohorts grew substantially in this assessment period, with the School now having *ca.*160 research students, academic and postdoctoral staff working on its various programmes.

c. Strategy and plans

Research programmes in the School of Pharmacy have global relevance and connectivity, such that they are internationally competitive, with funding from BBSRC, EPSRC, MRC, NIH, EU.major development agencies, industry and others in this REF assessment period. A strong funding stream for early stage research is an essential pre-requisite to ultimately creating impact from research programmes and, in this REF period, the School has secured its largest ever research grant income. Strategically, we focus on areas where we have, through past investments and successful funding applications, established in-depth research strengths, and where we can also attract external interest based on our track record. Credibility is a key factor in securing external support for, and interest in, research programmes, Thus, the demonstrable impact of our earlier research is a significant driver of the impact agenda for current and future programmes as we seek to translate basic research into patient-focused products and services. One example of this is our preventative HIV microbicide drug delivery programme, where we work with leading agencies such as the US Centers for Disease Control and with EU Framework partners. Again, in our clinical and community-based research, we link with leading international health services, and with clinical and community pharmacy research centres. We also have two current MRC Developmental Pathway Funding Scheme Projects aimed at bringing late stage research through to clinical applications, exemplifying our commitment to take basic research along a well-developed route to clinical applications.

Practically, our work is supported by a significant institutional investment in the University's Research and Enterprise Directorate, providing business, IP and contractual expertise to support entrepreneurial activity, out-licensing and the formation of global research consortia. We have also established an International Scientific Advisory Board, with membership from leading Pharmacy academics in the UK and USA, who are advising us on our medium to long-term research strategy and ensuring that our work is of high quality, internationally competitive and relevant to the community at large. Supporting this is a patient group that regularly visits the School and keeps our research grounded in the reality of disease states and their debilitating effects on individual patients, plus close collaborations with a range of clinical colleagues, nationally and internationally. Key to all our research activities and our ability to deliver beneficial impact from our research is our staff, who we support in a variety of ways, including ensuring their visibility at major conferences, facilitation of links with leading national and international research centres and providing mentoring and other support for our early career and postdoctoral researchers.

For the future, we have several developing areas of research that we expect to yield significant impact. A prime example is our novel *polymeric microneedles controlled release trandermal delivery platform* (Donnelly,Woolfson), whose genesis is in the transdermal research that produced

Ametop™, and where commercialisation is being supported by BBSRC, who have featured the work as an example of 'how the science of the small will deliver big things'. Most recently (2013) BBSRC have provided over £700k of funding via the 'super follow-on fund' for commercialisation of the microneedles system (PCT/GB2008/003280), which has won numerous national awards (including 2013 'BBSRC Innovator of the Year' for Donnelly - http://miniurl.com/hWjW) and is attracting major interest and funding from industry. *ProAx-SIS* (http://miniurl.com/hWjN), a new QUB spinout company from Pharmacy (Martin, Walker), has developed novel small molecule, peptide-based inhibitors (Protease-Tags) as diagnostic/monitoring tests for chronic conditions such as CF, and won both the biotech category and overall 2013 NI Science Park Entrepreneurship Award. In biomaterials research, where there is a focus on medical device-related infection, a *novel multi-layer catheter surface that resists surface biofilm formation* (WO2010026433A3) has recently been out-licensed to a European manufacturer. In biomolecular-based research, McCarthy's IP on a *RALA peptide cell delivery system* (P106539GB00, filed Dec. 2012) has just been out-licensed (Oct 2013) to the biotech sector. Robson's novel (PCT/GB2007/002107) *FKBPL-based anti-angiogenic peptide drug* (ALM201), licensed to Almac Group, will commence Phase 1 clinical trials in early 2014 (http://miniurl.com/hWk1). Ongoing work in the clinical area has the potential to change future practice, such as Tunney's research on *anaerobic infection in cystic fibrosis*, funded by a unique tripartite scheme supported by NIH(USA), NHS(NI) and HRB (RoI), and McElnay's development of *dried blood spot analysis*, where his paper (DOI:10.1542/peds.2010-0807, the first such published study) was the basis for the recommended IV paediatric dose of metronidazole in 'Lexicomp Online', the main source of paediatric dosage guidance in the USA.

d. Relationship to case studies

Past experience of commercialisation and interactions with end-users is carried forward in current impact examples. Thus, the development by Jones of a bioadhesive stoma paste designed to cope with a moist skin surface in the presence of stoma exudate, was based on a long history of bioadhesive research in the School of Pharmacy and published work on periodontal disease delivery systems, where a similar problem of adhesion in a moist, exuding environment pertains. The resulting product, Cohesive Paste, developed by Jones, is now sold in some 26 countries by TG Eakin Ltd., a company that started locally but has now expanded into others areas of the UK and Europe, with a worldwide product portfolio in stoma care. In total, this company co-funded 4 KTP schemes in the School.

The long-term relationship established by Woolfson with the Galen Group and its two successor companies (Almac and Warner Chilcott) also led to the establishment of intravaginal drug delivery research in the School. Woolfson was closely involved in the development of Warner Chilcott's vaginal ring (VR) product Femring®, now marketed in the USA. The Femring® experience led to a world-leading expertise in VR delivery in the School of Pharmacy. This, and the realisation that the adoption of VR technology represented a paradigm shift in developing new strategies to control the HIV pandemic in the developing world, led to the Malcolm-Woolfson group in Pharmacy becoming the key player in the VR delivery of microbicides and candidate mucosal vaccines designed to control the HIV pandemic. A VR delivering the non-nucleoside reverse transcriptase inhibitor, dapivirine, developed by Malcolm and Woolfson with funding from the leading global development agency for microbicides (International Partnership for Microbicides) is currently in Phase III trials in Africa, a multi-million dollar investment in a transformative product for the protection of women from heterosexually acquired HIV infection.

The characteristic of long-term, mutually beneficial relationships with local companies that can then become global players is further exemplified by Scott's work with Fusion Antibodies Ltd. His development of Fusion Expression Technology (FET™), again via a KTP scheme, is today part of that company's key contract offering to the global biotechnology community. In a similar way, the mix between global and local applications of research is reflected in Hughes' development, with colleagues at Brown University, USA of a joint intervention model (the Fleetwood Model) to reduce inappropriate prescribing of psychoactive medications in nursing homes, where healthcare benefits for patients and economic benefits in relation to healthcare costs have both been demonstrated. This intervention has recently been commissioned locally.