Institution: Cardiff University (CU)

Unit of Assessment: UoA3

a. Context

Structure and Research Activity: In the latter stages of the REF period, under the leadership of the new Vice Chancellor Professor Colin Riordan, Cardiff University was re-structured into three colleges each led by a Pro-Vice Chancellor. Cardiff's UoA3 unit (the 'Unit') lies within the College of Biomedical and Life Sciences (the 'College'). The Unit comprises researchers from six groups, which are aligned in most cases to University Schools: Dentistry [D]; Health Care Studies [H] and Nursing and Midwifery Studies [N] both now within a newly formed School of Health Care Sciences; Molecular and Experimental Medicine [M] - representing investigators working in cardio-metabolic, ionic signalling, matrix biology and pharmacology research from the School of Medicine; Optometry and Vision Science [O]; Pharmacy and Pharmaceutical Sciences [P].

Research is inter-disciplinary spanning the full translational spectrum across three overlapping spheres of operation:- Molecular to systems level Preclinical research which addresses mechanisms of disease, therapeutic targets and interventions (e.g. drugs, diagnostics, tissue regeneration) in a range of disease areas (dental, cancer, cardiovascular, endocrine, immune, infection, musculoskeletal, neurological, ocular); Clinical Research which either integrates with the Unit's preclinical studies or is conducted as independent investigation. It is performed in external clinics or within the Unit itself accessing particular patient cohorts; Public Health/Healthcare Delivery research involving epidemiological, quality of life (QoL), pharmacoeconomic, workforce and practice-based investigations.

Non-academic beneficiaries and types of impact: Research is ultimately aimed at benefiting human health and welfare. During the translational path there will be a range of different beneficiaries and impact types.

Commerce (e.g. Cases 1,2,3,4,5,8) - Partnerships exist in all of the Unit's spheres of research and involve mainly the pharmaceutical, biotechnology and life sciences sectors, including global multinationals and UK/overseas SMEs. Impacts include improved commercial performance and employment of highly-skilled individuals through, for example, commercialisation of the Unit's technologies. Research also allows commerce to better understand and improve their own treatment modalities.

Practitioners (e.g. Cases 4,5,6,8) - Research by clinical academics (often in conjunction with the service) leads to change in practice guidelines and standards, and improvements in clinical training in cognate professional groups (e.g. physicians, dentists, dieticians, nurses and midwives, occupational therapists, optometrists, pharmacists, physiotherapists and radiographers/therapists).

Government and public-sector bodies (e.g. Case 7) - Research stimulates policy debate and its implementation by Government and devolved public-sector bodies. Epidemiological research impacts on NHS/professional workforce planning and leads to new service models.

Public Interest groups (e.g. Case 6) - Public understanding of the Unit's research and its societal impact stimulates evidence-based debate, for example, patient groups as advocates for change. It directs the campaign strategies and public relations of medical charities. It involves both organisations (medical charities, patient groups) and groups of individuals (general public, schools) across small and large (e.g. National Eisteddfod) audiences.

b. Approach to impact.

Strategy, facilities and expertise in the Unit and broader University promote interactions with non-academic users who partner the design of the Unit's research and/or develop the Unit's accrued knowledge in applications which lead to impact.

Unit's approach to interactions and evidence of their nature to deliver impact:

Commerce - the assessment period saw multiple commercial partners (78 different bodies) investing in joint research facilitated by a number of mechanisms. For example, co-funded PGR scholarships develop skilled researchers and foster later more strategic collaborations with a commercial partner. Joint studentship funding mechanisms have included e.g. RCUK-Case awards, Knowledge Economy Skills Scholarships (KESS), European consortia grants, as well as Unit/University PGR initiatives (see 'Enablers' below). For example, preclinical models of asthma were developed in a series of PhD programmes (Supervisors Broadley, Ford, Kidd [P]) and later

used in research collaborations toward candidate drug selection (e.g. Respivert WO2010-067130A1, Topigen US 2009/0087425 A1). Knowledge Transfer Partnerships (KTPs) directly target expertise to meet business needs. The Unit has hosted four KTPs in the period, e.g. Maillard [P] developing screening assays for biocide resistance at Steris Ltd. In 2012 Cardiff University was among the top 5 UK HEIs with respect to numbers of KTPs hosted.

Other approaches have involved co-funding by multiple agencies (charities, RCUK and industry itself) toward the development of products, e.g. peritoneal dialysis (Case 5 [M]). Similarly, co-sponsorship (DOH, A4B, University seed corn) has led to new detection technology for urinary catheter biofilms (clinical trials Q4 2013 - Williams [D]), technology which is undergoing exploitation by a University spin-out, MBI/Technovent. This spin-out is a vehicle to commercialise polymeric biomaterials research and is a strategic partner framing the research direction of not only the above catheter technology but also a number of the Unit's other biomaterials projects.

Industrial consultancy offers opportunity to explore mutually beneficial relationships. For example, interactions of Thomas [D] acting as a consultant to US company Algipharma (wound biology and biofilms) led to the company's adoption of Cardiff's polymer technology (Phase IIa study - OligoG NCT00970) and its subsequent lateral exploitation by the USA Dept. of Defence ($1.3 million).

Co-generation or acquisition of the Unit's intellectual property (IP) can bring longer term commercial R&D investment to the Unit that supports 'proof of concept' and later stage investigations (e.g. Case 2 [P]). Out-licensing of IP may be through new spinouts via the University or through the creation of independent entities (e.g. Case 1 [P]). Out-licensing may also be granted to an established industrial leader (e.g. Case 4 [M]) able to rapidly progress the technology to market. Such activity cross-fertilises opportunities (e.g. Cases 1 and 2).

Infrastructure investments maintain world leading facilities which attract industrial collaborators who aim to better understand their products (e.g. Case 8 [H]). For example, Fresenius-Kabi have a long term (>10 years) funding arrangement (staff appointees) within the Unit and benefit from the Unit's research infrastructure investments in formulation science and particle analysis to address practice-related issues around their Total Parenteral Nutrition products (Cosslett, Davies [P]).

Practitioners and Practice - Clinical engagement with practitioners and patient groups are critical. For example, the NHS hospital clinics and the School of Optometry's own public access eye clinic (the latter >10,000 patients per annum) allows researchers access to distinct patient cohorts (e.g. Case 6 [O]). Vortruba [O] has also used these facilities in the study of inherited optic neuropathy and mutations in the OPA1 gene. Working with the NHS UK Genetic Testing Network, Vortruba's work has led to national uptake of a more accurate genetic screen that is benefiting prenatal/pre-implantation diagnostic services. Patient interactions are also central to the Unit's 'rehabilitation' research (e.g. Case 8 [H]). One such example is the work of Busse [H] examining the benefits of physical therapy in Huntington's Disease which is revealing outcome measures that are informing practice recommendations and the design of international clinical trials.

Government and devolved policy-making bodies - Direct engagement with policy-making bodies allows effective input into the strategy of such bodies (e.g. Case 7 [D]). The Nursing group's work on career frameworks with Welsh Government, and the significant level of joint clinical academic appointments (20 staff) with the local NHS health boards, is forging influential partnerships. Initial research by Ryan [O] (now also Chief Optometric Advisor to Welsh Government) showed deficiencies in patient access to low vision and acute eye care services in Wales, and directly led to the establishment of a national government-funded community care service (PEARS) which is informing a similar approach in England. Epidemiological research (Chadwick, Chestnutt, Treasure [D]) with the Office for National Statistics found inequalities in child dental disease prevalence in Wales compared to that in England and Northern Ireland. This research led to a new All-Wales national care pathway which is also informing the commissioning of services in England.

Public Interest groups - Engagement with medical charities and patient groups is aligned with research activity (e.g. Case 6 [O]). For example, Lowes [N] (Vice Chair for Diabetes UK Wales Advisory Council) has explored parents' emotional response to their child's diagnosis of diabetes. The intensity of parental feelings was not previously appreciated and Lowes' research and engagement changed the peer-support training programme of Diabetes UK's to better address the grief-reaction. The promotion of the public understanding of science is underpinned by the Unit's

research. For example, licence income and external sponsorship allowed Campbell [P] to establish 'The Darwin Centre' (www.darwincentre.com) as a residential facility allowing public and pupil access to laboratory suites and hands-on research experiments. The centre continues to grow and now employs two educational (F/T) and two research officers (joint PhD scholars in the Unit) and runs over 150 public engagement events each year.

Enablers in the Unit and Institution for delivering Impact: One strength is the clinically-informed nature of the Unit's research involving clinical academics and NHS practitioners embedded within its operations. Partnerships such as NISCHR-Academic Health Science Collaboration consolidate this culture integrating NHS research strategy with that of the University's. Clinical facilities in both the NHS and the Unit promote researcher-patient interactions.

Sustained strategic alliances are best founded upon an external partner's engagement with the full breath of institutional expertise. The University's College structure provides its researchers and partners access to a wide range of modern facilities (see REF5). Research interactions with non-academic partners are leveraged through a number of mechanisms, e.g. matched (50% funding) PhD programmes such as President's Research Scholarships (£4M University investment) or Government initiatives such as Sêr Cymru Life Sciences Health Network in Drug Discovery (£7M).

Contractual and commercial issues arising from external engagements are supported through the University's Research, Innovation & Enterprise Services (RIES), which also hosts the 'Cardiff Partnership' seed corn funds and the "Innovation Network" which fosters links between industry and Cardiff researchers. The University's IP exploitation and investment group (Fusion IP) provides business support and start-up funds for spin-outs. The Welsh Government and Business (£100M) Life-Sciences Biotechnology Centre based in Cardiff (McGuigan [P] seconded as 0.2 FTE Director) is translating discoveries to the commercial sector through start-up investments.

c. Strategy and plans The strategy for research and impact is co-developed with the expectation that all researchers in the Unit undertake work that is not only of the highest academic quality but will also be work informed by non-academic partners. Importantly, the research should have the capacity to contribute to transformative international societal impact. Strategic goals naturally overlap with the research strategy, and include:

Prioritisation of inter-disciplinary working to address the more complex societal challenges in the biomedical and healthcare environments. Achieved through:

- Integration the Unit's research within new University-level Research Institutes (ca £200-250M investment) that will concentrate on major global challenges, and expand internal research synergies and external user network opportunities.
- Strengthening cross-HEI research collaborations to improve access to, and sharing of, specialised facilities, expertise and resources. Initially developed through the newly formed Great Western 4 (GW4) research alliance (Bath, Bristol, Cardiff, Exeter) and will include cross-institutional GW4 appointments and secondments. The objective will be developed in other initiatives within the USA, BRIC countries and Europe via both Institutional-led agreements and PI-led working. Participation in European academic - industrial consortia will be a priority.

Increase share of research informed by non-academic users. Achieved through:

- Exploiting cross-discipline links to appoint key non-academic users to the Unit's internal advisory boards to inform the research and its translational strategy. Conversely promote greater researcher engagement with the advisory bodies of external organisations. This to be facilitated by College level processes and through senior staff already holding such positions.
- Increased membership and strategic influence on research-user networks such as NISCHR, NIHR, South East Wales Academic Health Science Partnership (SEWAHSP). Identify non-academic users whose needs align to the Unit's research capacity and direction. Develop partnerships to access infrastructure, expertise and patient and funding resources.

Promote a culture where research is developed against a framework of benefits to society. Achieved through:

- Identifying and fostering on-going research that has potential to deliver impact. This includes incentivisation of impact activities through academic appraisal and workload models. The appointment of accountable 'impact champions' (managerial/professional support) to identify mechanisms and facilitate bridging of translational gaps (e.g. funding sources, IP, access to

policy fora) and for the effective dissemination of outcomes. Economies of scale and professional effectiveness to be realised through College and/or Institutional level roles.

- Extend the established model of entrepreneurship training (Cardiff's Presidents Scholars) within the career development of PGRs and postdoctoral researchers.

d. Relationship to case studies

Supporting impact through IP licencing and/or spin-out activities:

Case 1: Anti-VZV agent [P] - Relates to discovery of a potent anti-shingles (VZV) agent. Following multi-agency funded pre-clinical 'proof-of-concept' studies the Unit invested in patents and pursued out-licencing with business entrepreneurs (via commercial networks and the University's RIES). This led to the formation of an independent overseas spinout with the Unit retaining involvement in research throughout the clinical testing programmes. The agent has been subject to three acquisitions (>$30M R&D investment) and is poised (2013) to enter Phase III trial.

Case 2: Protide Technology [P] - Relates to prodrug technology with proven capacity to generate new drug candidates for anti-viral/-cancer indications. Commercial interest was stimulated by a series of collaborative research agreements with multinational companies. The outcomes inspired others to pursue the technology. Cardiff out-licenced the IP to a number of collaborating commercial partners, with licence payments to the Unit reinvested in facilities to expand the programme and meet milestones. ProTide entities have progressed to clinical trial (Phase I-III).

Case 3: Inhaled medicines [P] - Relates to a specialist University drug delivery spinout whose research base is closely aligned to academic scholarship and facilities within the Unit. The Unit supported the research and scholarship base (funding facilities and PGRs) of the respective staff aiding research diversification that translated into business activities. This has secured University IP and yielded improved business performance for the spin-out and its global partners involved in international development (UNIDO) programmes for specialist product development.

Case 4: Chemiluminescent technologies [M] - Relates to discovery of chemiluminescent dyes that addressed a technology need for nucleic acid amplification-based clinical assays. Following proof-of-concept and University patenting, the technology was co-developed by the Unit and a University spin-out (MLT) together with a commercial market leader in the field. Previous successful relationships between the Unit and the commercial partner expedited IP licencing and accelerated the path to global commercial and clinical practice impacts.

Supporting impact through the clinical research environment:

Case 5: Peritoneal Dialysis Fluids [M] - Multiagency funding and capacity to undertake both preclinical and clinical research in the Unit delivered significant findings on the biological effects of peritoneal dialysis (PD) solutions. Engaging the major manufacturers in collaborative investigations led to the redesign of commercial PD solutions with improved clinical safety and patient tolerability. Commercial, economic and direct patient health benefits have been delivered.

Case 6 Eye care and learning potential [O] – The Unit supports an eye clinic [O] that is a UK centre for referral and training in special needs Optometry. Clinical research over 20 years has led to evidence-based guidelines and improved eye care in children with special needs. Impact has been realised by researchers engaging with patients, professional bodies and medical charities.

Case 8 Quality of life and chronic wounds [H,M] - The Unit supports an internationally renowned wound healing clinical research facility managing an extensive commercial and practice research portfolio. Clinical academics in the Unit identified a need for Quality of life (QoL) instruments appropriate to measure the benefits of wound healing products and other interventions. The Cardiff QoL instruments developed are delivering commercial, economic and patient benefits.

Supporting impact through engagement with policy-makers:

Case 7: Preventing violence [D] - Clinical epidemiological research allowed multi-agency collaborations (police, local government, NHS, voluntary sector) toward a new model of violent crime prevention. The model involves multi-agency data sharing of Emergency Unit information. Early engagement with relevant sectors led to policy uptake with implementation initially at local level, and thereafter by UK and overseas governments. The work was recognised by the 2010 award of the Queen's Anniversary Prize. Strategic appointments to the research theme have expanded its capacity and the influence of its research.