Institution: University of Birmingham

Unit of Assessment: UoA1

a. Context

Clinical Medicine research within UoA1 at the University of Birmingham (UoB) is intended to impact on patients, users of health services, business, society in general, and the wider academic research community. Our audiences also include policy makers who dictate how health care is delivered and those bodies that arrive at decisions having an indirect effect on health. In the UK, these decision makers include the Department of Health (DoH) and the Department for Environment, Food and Rural Affairs (DEFRA). Internationally, they include other nations' equivalents of these organisations, such as the European Commission.

The research objective of UoB Clinical Medicine is to develop and promote excellence in basic and clinical science with an ultimate goal of improving human health. The key strength of our research in this area is an ability to move discoveries from basic mechanistic insight in the laboratory through pre-clinical models into clinical trials. The main longer-term beneficiaries are patients and the wider population, who gain access to improved treatments, knowledge, and industry wealth creation. Impact arises from this research through four main routes, ensuring involvement of as wide a range of potential stakeholders as possible: (1) Changes to health care policy and regulations impacting on health; (2) Changes to clinical practice and patient involvement in their own health; (3) Clinical trials and implementation of the outcomes; and (4) Design, commercialisation and implementation of novel diagnostics.

The four types of impact encompass the full range of research activity within UoA1, which includes expertise in basic cell and molecular biology, through in vitro cell and animal models (ranging from Drosophila through to rodents, including genetic and physiological models of human disease), to work on human samples and subjects. The research encompasses four key research themes: Cancer; Immunity, Inflammation & Infection; Hormones, Metabolism & Reproduction; and Cardiovascular Health. This research is carried out by non-clinical and clinical investigators in the Schools of Cancer Sciences, Clinical & Experimental Medicine, and Immunity & Infection based within the College of Medical and Dental Services (MDS), but also involves clinical staff in the associated NHS trusts, including Universities Hospitals Birmingham (UHB), Birmingham Children's Hospital (BCH), and Birmingham Women's Hospital (BWH), amongst others.

b. Approach to impact

The ultimate purpose of our Clinical Medicine research conducted is to benefit patients and health care users in the UK and internationally. The approach taken to support this purpose focuses on enabling engagement with all relevant external stakeholders at an individual and group level for academic researchers, as we believe significant, wide-reaching long-term impacts are most effectively driven through the ability to design, deliver and disseminate research with the widest audiences possible. By creating a culture in which researchers understand the variety and nature of groups that their research could benefit, and providing an infrastructure that makes engagement with these groups as simple as possible, we can focus organisationally on delivering long-term Impact while individual researchers focus on immediate research priorities and building specific engagement opportunities around them.

Support infrastructure specific for Impact delivery is embodied in and coordinated by the MDS Research & Knowledge Transfer (R&KT) Office. This office is supported by a strong administration involving a Head and Deputy Head, and School-embedded Research Facilitators, and is organised around: a) Research Development; b) Project & Partnerships Management; c) Graduate Research & Training; and d) Business Engagement. Academic steering comes from the Director of R&KT (Frampton), with input from senior management (College Board, including the Head of College (Jenkinson), Dean of Medicine (Adams), and the three Heads of School (Moss, Franklyn, Lord)), and leads for each of the research areas (Strategic Research Committee, SRC). The Research Facilitators are also members of SRC, ensuring practical support for research development is linked to planning and delivery of Impact. The Dean of Medicine's role is especially crucial for the delivery of Impact, as he ensures a seamless interface between basic science, translational research and integrated working with key NHS partners. This role is reflected in Adams' leadership of Birmingham Health Partners (BHP), which is a self-designated Academic Health Sciences Centre providing a joint UoB/NHS research infrastructure promoting joint strategic planning and delivery in clinical research between the College and our major NHS partners.

Our support for Impact planning can be framed around our key potential beneficiaries and collaborators, namely: healthcare organisations; business; the wider public; and 'academic' approaches supporting other beneficial impacts.

Healthcare organisations: Joint clinical and academic research administration and strategy between UoB and local NHS trusts are key for health-related outcomes from our research. The location of the University in the West Midlands, with its diverse ethnic and socio-economic population (>5.5m) and close ties to NHS partners, allows exceptional access to defined and well-characterised patient cohorts, providing an excellent environment for clinical research and trials.

The wide portfolio of joint research between UoB and its major NHS partners is focused largely through BHP, but also involves strong links to the Heart of England NHS Foundation Trust, Birmingham & Solihull Mental Health Foundation Trust, Sandwell & West Birmingham Hospitals NHS Trust, and the Royal Orthopaedic Hospital. These interactions include joint academic appointments, integrated training pathways, collaborative research bids and major co-investments.

Landmark successes in terms of Impact include the **Centre for Clinical Haematology**, which created a novel and highly effective early phase trial programme. This '**Therapy Acceleration Programme'** was flagged as a significant national achievement in translational medicine in the recent Government review 'Strategy for UK Life Sciences: One Year On' for reducing set-up time and costs per patient, as well as ratifying new trials that would not otherwise have taken place in the UK, including collaborations with eight pharmaceutical companies such as Novartis, who provided funding for additional trial centres and a biobank. The first trial that Novartis conducted under this scheme was set up in record time. As a result, the Novartis Oncology Business Unit in the UK not only managed to enrol the first patient globally into its trial (something they had not achieved before), they also saw a significant reduction in trial costs (from an average £11,000 to £3,600 per patient). Our **Cancer Research UK Centre**, the first of its kind in the UK, is a partnership between UoB, UHB and BCH, providing the infrastructure to enable clinical oncologists and basic researchers to work together. The **Birmingham Centre for Clinical Trials (BCCT)** brings together three clinical trials units to provide comprehensive, complementary expertise in trials in cancer and non-cancer, primary and secondary care settings, and early and late phase trials. The clinical trials capability encompassed under BCCT has delivered internationally recognised programmes for cancer, haematology, liver disease, renal disease and stem cell transplantation over the last two decades, resulting in significant patient care impacts. Our **NIHR/Wellcome Trust Clinical Research Facility (CRF)** comprises adult and paediatric facilities based at UHB and BCH that enables us to adopt an 'ageless' approach to research, providing high-quality clinical environments, including new gene- and cell-based therapy suites in which patients (approximately 80,000 so far) take part in experimental research studies. The CRF also has a **Health Research Bus**, a pioneering facility launched in June 2010 that comprises a bespoke, high specification, unit containing clinical research equipment, enabling research to be conducted in the community, providing ease of access for potential volunteers.

Other joint UoB/NHS translational initiatives driven through BHP include the **NIHR Liver Biomedical Research Unit**, **NIHR Surgical Reconstruction & Microbiology Research Centre**, and **NIHR Trauma Management Healthcare Technology Co-operative**. Our most ambitious vision for the future of Impact is embodied in the **Institute of Translational Medicine (ITM)**, which secured investment of £12M from the Government as part of the 'City Deal' for Birmingham (see 'c. Strategy and Plans').

We support many programmes of active dissemination to clinicians and policy makers. Individual researchers serve on policy bodies relating to clinical guidelines. Our UoA1 academic Piddock is the director of Antibiotic Action, a global initiative established by the British Society for Antimicrobial Chemotherapy, which serves as a forum through which Government, health professionals, industry and charities are challenged to identify and implement solutions within research, regulation and economic markets that will stimulate and regenerate interest in the discovery and development of antibiotic agents of the future. Antibiotic Action has already had international policy impacts and support from organisations such as the WHO.

Business: Proactive engagement with industry and support for commercialisation enables our researchers to ensure that their work can secure further investment and effectively reach patients and other users. Collaborative links with industry are fostered at both a strategic level and through individual researcher involvement within large companies such as GlaxoSmithKline and Novartis,

with each of whom we have been involved in more than 20 different research collaborations across all of our key UoA1 research themes, including royalty-free licensing of a Salmonella vaccine (Cunningham) for use in the Third World. We have also delivered a portfolio of collaborative industrial research and trials with the top 20 pharma/biotech companies including Bristol Myers Squibb; Pfizer; Lilly; GSK; Amgen; Novartis; Boehringer; Millennium; Sanofi-Aventis; Chugai; Roche; J&J; Novo Nordisk; Celgene; Schering Plough; Astra Zeneca; Bayer; and Abbott. MDS has established groups that oversee the commercialisation of research, including: (i) a dedicated **Technology Transfer Team** within the R&KT Office working with individual academics to assess IP and potential commercial development strategies; (ii) an **External Commercialisation Board** made up of top industry experts who advise on and support these processes; and (iii) a **Business Engagement Operations Group**, which implements the College's Business Engagement Strategy. The group is led by the Business Engagement Partner (Mountain) and includes academic 'champions' from the key research themes who encourage teamwork, identify and develop new engagement opportunities and scout proactively for IP amongst their peers.

The College-led commercialisation processes link to the dedicated UoB commercialisation company, **Alta Innovations**, which over the assessment period have supported 40 new patent filings (130 filings total), 35 licenses and 4 spin-out companies in UoA1. The UoB **Research & Innovation Services** provide further dedicated support for development of Knowledge Transfer Partnerships, Technology Strategy Board bids and other major industry-focused initiatives. UoB has a central team providing professional support for engagement with industry, and has recently launched a **business incubator** (BizzInn), through which we are developing a network of entrepreneurs, and been awarded £6.8M of European Regional Development Fund support to build an adjacent Biomedical Innovation Hub, which will provide wet lab facilities for biomed companies. Two members of this central team are based within MDS and have a specific healthcare remit. The effectiveness of this support for partnerships with industry is exemplified by **Bioscience Ventures Ltd** (BSVL), a joint venture with Abingdon Health around in vitro diagnostics, focused on our research in fields such as cancer and genetic-related diseases, as well as platform technologies that have wide reaching applications in many areas of medicine including infectious disease and drug testing. BSVL has won Praxis Unico and Lord Stafford awards for innovative academia-industry partnerships, a key example of which is **Serascience**, a BSVL company developed with our IP tested through clinical studies at UHB and BCH. Although Serascience was only formed in late 2010 its first product, a point-of-care test for myeloma, was launched in April 2013. We have just completed a £750,000 funding round for Serascience, in which the University and Abingdon Health each invested about £300,000.

We have also established regional vehicles for linking academics with business. **Birmingham Science City** is a region-wide partnership of public sector, businesses and the research bases, facilitating the use of science and technology to improve regional health and prosperity. **Science Capital**, a spinout founded by a UoA1 academic (Overduin), was established in 2010 to provide a healthcare focused forum bringing together academics, businesses, industry leaders and policy experts. Over the past three years, Science Capital has offered 12 quarterly networking events featuring 47 keynote speakers, with 44 academics and start-ups being given financial, business and legal advice in order to launch and grow new businesses. A panel of 52 professional advisors from leading patent, legal, and financial firms have given their support to entrepreneurs, with over 1000 participants having come to the events, and hundreds of thousands being exposed to the videos, presentations and web-content which UoA1 academics have continuously contributed to.

The wider public: Through active public engagement we aim to enable patients to manage their own health issues and seek help as necessary. The UoB **Public Engagement Working Group** brings together academic and administrative champions to share best practice, promote new activity, develop strategy, and award internal funding for innovative events and activities. This internal group links closely, through the R&KT Office, to the **National Centre for Coordinating Public Engagement**. We have delivered a concert based on UoA1 immunity research with the Birmingham Contemporary Music Group ('Resolution', March 2013) and supported the development of a new 'Medical Futures' gallery in Thinktank, Birmingham's science museum.

In terms of media engagement, beyond our central THE Award-winning Marketing & Communications team, we are one of thirteen UK HEIs supporting The Conversation, an open and free, not-for-profit independent news source that is focused on the latest research. UoB is also

host to the unique 'Ideas Lab', a team dedicated to working proactively with external media companies to stimulate new programmes based on academic research. Recent major press activity has included: hosting the BBC Science team and Remarkable Television for discussions with staff about future programming; winning the Sheffield International Documentary Festival 'New Talent' competition in 2012 (Banerjee); producing short videos about UoB research for partner organisations (e.g. Leukaemia & Lymphoma Research); and involvement of academics as staff writers on major TV series (e.g. McCabe, Embarrassing Bodies).

UoA1 researchers are major contributors to planning and delivery of institutional events such as the UoB annual 'Community Day' research showcase, and we will host the British Science Festival in 2014, which will have a major component around our Clinical Medicine research. Our CRUK Centre has been a national leader in local engagement and development. There is also a recurrent programme of 'Meet the Scientist' and 'Cafe Scientifique' events run in partnership between our scientists and the Birmingham Thinktank Science Museum.

Beyond simple dissemination, we have a very serious commitment to the involvement of patients in dialogue around research design. Our researchers provide a national model of good practice in rheumatology and arthritis care linked to research, with the key vehicle being the Birmingham Arthritis Resource Centre (BARC). Established in the City's central library over a decade ago, BARC promotes self-care and self-management, supporting people with chronic and painful conditions (26,200 people in 2008-12). In particular, the BARC team has developed strong links with regional South Asian communities, winning two national awards – the 2011 Pfizer-sponsored Nurse Award for 'Innovations in Rheumatology and Rheumatoid Arthritis' and the 2013 National Rheumatoid Arthritis Society 'Patients in Focus' Award. Other key examples of dialogue-driven engagement include the '1000 Elders' and 'Obesity Ambassadors' initiatives. These groups of volunteers take part in research studies, comment on research design (e.g. through bi-annual 'Age Well' days for older adults), and help us to develop communication strategies for research outputs.

Academic approaches supporting other beneficial impacts: MDS operates a strategic, internally designated 'Centre of Excellence' model, bringing together interdisciplinary academic groupings around key areas of excellence to support larger collaborative bids, but also develop new routes for Impact. These are described separately in the UoA1 Environment Template, but key examples that have focused on Impact include the **Centre for Healthy Ageing Research** and the **Centre for Obesity Research**. Evidence of external buy-in for this model for Impact delivery has been demonstrated through 4 years of dedicated funding for a Translational Research Manager for the Centre for Obesity Research through Bupa (2008-12, managed by Tomlinson), who were so supportive of the outcomes that they have become a committed partner, linking to their care home infrastructure, for future Impact delivery from the recently-awarded MRC-ARUK Centre for Musculoskeletal Ageing Research.

MDS has taken an extremely proactive approach to **international engagement**, ensuring that our research truly has reach. There is dedicated support for EU collaborative bid development through the UoB Research & Innovation Services, which also provides facilities to network effectively with international partners through a dedicated office in Brussels. At a strategic level, MDS has an **International Engagement Oversight Committee**, with specific academic champions for each continent, to monitor, promote and support new overseas links, particularly with industry, and to encourage international mobility of young researchers.

c. Strategy and plans

The UoA1 Research Impact Strategy (RIS) links to the overall UoB Impact Strategy (which will be in place by the end of 2013) and builds on the MDS and UoB research strategies, both in relation to generating Impact from research and through development of areas that can deliver the greatest Impact. The RIS is a focused but evolving approach, which builds on our College research support infrastructure and effectively embeds and prioritises health, wealth and social Impacts from basic and clinical research.

Goals

The overall goal of the UoA1 RIS is to maximise the significance and reach of Impact of research through achievement of the following objectives:

1. To provide the best training for early-career researchers around Pathways to Impact, particularly collaborations with the NHS, business and industry, and public engagement, involving regular training sessions and bespoke support from dedicated teams.

2. To ensure that, in generating new research proposals, investigators explicitly consider the likely Impact of their work and that this is taken into account our established 'Grant Clinic' model of very early in-person proposal review by senior staff can be used in deciding whether ideas should be pursued and the breadth of mechanisms to use in design, delivery and dissemination.

3. To continue to foster a climate of citizenship among senior academics within UoA1 in which active external collaboration with industry, the NHS and international partners is both expected and supported, ensuring that the routes to achieve such engagement are clearly defined.

4. To actively monitor Impact for all research projects.

5. To build strategic regional, national and international partnerships that have delivery of Impact as a core part of their remit and activity, and make these partnerships easily accessible to researchers across UoA1.

6. To deliver large-scale institutional and partnership strategic capital projects that can effectively act as Impact vehicles for the research undertaken in UoA1.

7. To continue and further develop support for public engagement activities, learning from best practice from UoA1, the wider College, UoB, and external groups.

Plans for supporting and enabling Impact

1. Further develop active Impact training programmes. These will be focused around developing and delivering different types of Impact, and will be provided across all levels of our researchers through the R&KT Office, which runs a series of dedicated workshops on external collaborative working and Impact generation. These workshops are open to all researchers, are presented jointly by academic and administrative staff that have relevant experience and expertise, and are recorded and made freely available internally. This training links with the Postdoctoral Research Committee-led training initiatives. Training will be monitored and further developed with input from MDS SRC, and the extent of its penetration within UoA1 will be evaluated through the newly developed UoB Personal Development Review (PDR) process.

2. Prioritise clarity of Impact planning early in proposal development. Within UoA1, all new research proposals are required to meet certain requirements, evaluated by a senior academic at least 12 weeks prior to submission, through the completion of an 'Intention to Submit' form and a subsequent Grant Clinic with two or more senior staff present. This process will be adapted to include information about aspects of the research relevant to Impact, including industry and public engagement activities. At this point, if Pathways to Impact are unclear, permission to submit the proposal will be declined and the researcher will be required to work with the R&KT Office to improve the clarity on this point.

3. Active development of new engagement routes. These will be encouraged through all MDS committees, particularly through the 'Centre' model described above, with financial resource committed to support new initiatives and provide recognition and reward. Leadership roles will be taken into account in allocating workload such as teaching, and participation monitored through the PDR process.

4. Active monitoring of Impact generation. Research projects will be reviewed on a monthly basis by the R&KT Office and SRC. All those leading research will be asked to notify the R&KT Office about activities undertaken that aim to increase research Impact, as well as evidence of any Impact achieved. Such information can be effectively captured and monitored through the online PURE system, and will be bolstered by a recognition and reward system for the most innovative Impact activities, particularly those that can inform best practice for other researchers.

5. Developing partnerships to achieve Impact. This approach is already underway, and the recent regional award of the West Midlands Academic Health Science Network (WM-AHSN) has been another crucial development to support delivery of future clinical medicine-related Impact. The WM-AHSN represents a region-wide partnership between NHS, social care, academia and industry, with the principal objective of transforming the health of the West Midlands population through efficient and effective translation of research and innovation into practice. This partnership provides a crucial influence on our forward-looking strategy, especially given that patient care is delivered by circa 110,000 healthcare professionals through 47 NHS organisations plus a range of private and third sector care providers, and that the region is home to over 550 medical technology companies employing over 9000 staff (more than any other UK region). The identified health challenges for the WM-AHSN are driven in the same way that ours are, that is, by local and

national needs and opportunities, especially around long-term chronic disease, the elderly population, obesity and diabetes, maternal and child health, and stratified medicine.

6. Deliver the Institute for Translational Medicine. The ITM will be operational in June 2015, and will combine bespoke clinical facilities with a hub for firms to engage with clinicians and academics. The ITM is also synergistic with Birmingham City's redevelopment plans that are already in motion to provide further serviced sites and accommodation for Life and Health Sciences-related business, expand jobs in this sector and increase national and international investment appeal. The ITM will therefore: i) Provide a fertile environment for outstanding clinical and scientific minds to come together to create the best clinical academic research; ii) Respond to national unmet need, unlock growth potential in the NHS and create a portal of resource for SMEs and pharmaceutical companies; iii) Benefit from world-class informatics and stratified medicine, providing an ideal environment to increase recruitment to and delivery of early- and late-phase trials; iv) Co-locate clinicians and academics with firms (both corporates and SMEs) developing and commercialising all types of healthcare innovations to provide opportunities for growth and employment while delivering major clinical benefits for patients; v) Accelerate discoveries 'from bench to bedside' enabling effective products to be tested and brought to market faster, yielding major health and economic benefits; vi) Create more than 2,000 high-value long-term jobs in clinical trials, diagnostics and adjunctive Life Science industries, including spin-outs, expansion of existing SMEs and inward investment; vii) Provide serviced office space for SMEs, and access to support, advice and finance from the City; viii) Offer opportunities to develop post-graduate training in translational medicine alongside joint NHS/private sector scientific and professional development courses; and ix) Increase public engagement and education about biomedical research.

7. Support for public engagement. This will be further extended in UoA1, particularly in view of our hosting of the British Science Festival 2014, and advice will be taken from the UoB Public Engagement Working Group as to how best to develop new approaches.

d. Relationship to case studies

The Case Studies presented reflect and exemplify the use of a range of the approaches included in our strategy for generating impact. Successes in delivering Impact in the four areas defined above have been important in informing the development of the overall strategy moving forward.

Changes to health care policy and regulations impacting on health are represented by the case studies on the use of biocides, antibiotic usage in food producing animals, MRSA screening, and tuberculosis screening, which have individually influenced either international policy or UK regional healthcare protocols. The most significant Impacts, at least in terms of the variety and number of Case Studies, is in the area of **Changes to clinical practice and patient involvement in their own health**. Hence, the case studies focussing on Rheumatoid Arthritis, Lupus, ATM, Rare Diabetes Syndromes, Atrial Fibrillation, severe leg ischaemia (BASIL), Thyroid, Fetal Surgery and Maternal Health, each reflect demonstrable improvements in patient care through improved detection, categorisation or therapy across a broad range of diseases. The performing of **Clinical trials and implementation of the outcomes** underpins or serves as an end point for much of our Clinical Medicine research, already providing Impact, but also likely to produce additional benefit in the future. Key examples from our portfolio of Case Studies include the Bladder Cancer and PulseOx trials. Finally, **Design, commercialisation and implementation of novel diagnostics** is represented by the Serascience and Tetramer Case Studies, and will be an ever-expanding area of Impact generation as we begin to maximise the benefit of our commercialisation infrastructure. All areas encompassing our Impact clearly have **Healthcare Organisations** at their core, including discussion with policy makers (e.g. Biocides and Antibiotic Resistance) and local health authorities (e.g. MRSA and Tuberculosis screening) while **Business** has so far been closely aligned with our diagnostics agenda. The **Wider Public** have been fully embraced in our approach to Impact, including through the media (e.g. interviews relating to the consequences of Biocides) and engagement with patient groups in the development of changes to clinical practice (e.g. Rheumatoid Arthritis). The importance of working with patients and the public is underlined by the PulseOx Case Study, which has successfully linked to public and patient organisations, ATM and thyroid work with the A-T Society and British Thyroid Foundation respectively, as well as the Maternal Health study in which charity work with Ammalife has played a huge part in disseminating the findings to Muslim groups and the general public nationally and internationally.