Institution: University of Southampton

Unit of Assessment: 1 Clinical Medicine

a. Context

The main constituents of UoA 1 (Clinical Medicine) are based within the Faculty of Medicine. The Faculty celebrated its 40th Anniversary in 2012 and, while a relatively new and small medical school, it has made a substantial impact across areas of research strength in basic discovery (cancer, human development, nutrition, respiratory medicine, immunology, stem cells and regenerative medicine, applied neuroscience, and primary care). The vision of the Faculty of Medicine is *to lead innovative learning and discovery for better health across the lifecourse.* To that end we have invested in multidisciplinary research teams, creative educational programmes, translational research programmes, clinical infrastructure and enterprise to deliver on this vision. Main non-academic stakeholders can be considered in 4 groups:

1. Health policy makers, health care commissioners, and health care providers

Our research and personal inputs have impacted directly on government health policy and national and international health guidelines and reports. Work from Human Development and Health has led the creation of both the evidence base for, and development of, clinical and preventive guidelines for the most effective identification, management and treatment of severe malnutrition at different stages in the lifecourse (including intervention at pregnancy): during childhood for WHO (Impact Case Study 5), and for adults, the application of the Malnutrition Universal Screening Tool (MUST, Impact Case Study 8) in all hospitalised patients, and the incorporation of this into guidance for care for NICE. With Nutricia and the Department of Health, we have written guidelines for a national screening tool for COPD patients with evidence of malnutrition (provided to NICE, launched via our UoS portal) that is used nationwide by clinicians. Our research has driven major advances in lymphoma care over the last two decades, leading the development of effective new antibody treatments as well as directing the international clinical trials that have defined standards of care for Hodgkin's and Burkitt's lymphoma in the UK and internationally. This work has underpinned significant survival, quality of life and cost benefits in the care of the 14,000 people affected by lymphoma in the UK each year (Impact Case Study 27).

Our research has also influenced national guidelines and treatment strategies for osteoporosis and osteoarthritis, and specifically the role of Vitamin D supplementation (Impact Case Study 3). This has resulted in substantial health cost saving and is exemplified by our work on osteoporosis informing two NICE technology appraisals, with cost savings for the NHS estimated at £1bn per year. We have created an enterprise unit, NETSCC (NIHR Evaluations, Trials and Studies Co-ordinating Centre), hosted by the Faculty to deliver national research programmes for the Department of Health. Critically, we have created the Southampton Centre for Biomedical Research (SCBR). This is a partnership between University of Southampton and University Hospital Southampton NHS Foundation Trust (UHS) to which we have mapped research activity across both institutions enabling complete alignment of University research and clinical research creating a value-chain from discovery to translation and implementation.

2. Pharma and Industry

Our translational basic science research has impacted on the global pharmaceutical and medical devices industry. Pharma and industry are critical for the country's economic success and a partnership between industry, academia, and the NHS with a focus on translating basic discoveries into clinical practice is a central impact of our work. Examples include:

- *answering unmet medical needs, new employment and wealth creation through formation of spinouts* We have created seven spin-outs in the last decade, for example: Karus Therapeutics – novel histone kinase inhibitors with applications in oncology and inflammation; Synairgen – novel antiviral therapies for patients with respiratory disease (Impact Case Study 18); iQur – focus on liver disease and related diagnostics; Epigen – an international industry – academic consortium using epigenetic biomarkers to determine whole life health outcomes relating to early life nutrition: Impact Case Study 5).
- *licensing and partnering with Pharma*. Our research engagement pushes the boundaries of current practice to foster a culture of innovation and enterprise with Pharma and industry. For example our partnership with Genmab to bring therapeutic monoclonal antibodies to the

cancer clinic (Impact Case Study 20).

3. Next generation of biomedical scientists and clinicians

We are a research-led Faculty with our education delivered in a research-rich environment, providing and informing student teaching, both undergraduate and postgraduate by internationally leading researchers. Our translational research impact includes improved clinical care and training, with new approaches to health provision through the Southampton Centre for Biomedical Research (vaccine delivery, respiratory care, antibiotic provision, musculoskeletal and cancer treatment).

4. Patients and Public

Our research impacts directly on patients through the implementation of new knowledge, interventions, practices through the NHS and global healthcare providers, and through the SCBR as indicated above for examples of improved patient treatment and outcomes for older people with malnutrition in hospital and prevention of osteoporotic fractures. Our paradigm shift on the importance early development on Non Communicable Disease is impacting on public health by highlighting importance of pre conceptual maternal and child health for preventing future adult disease. Our research here has impact and reach from school children (healthy choices and lifestyles) evidenced by our LifeLab programme from our Human Development and Health research. Similarly, work on lymphoma treatment with the development of professional policy and practice facilitated public and patient awareness of developments in lymphoma care and contributed to patient information for the Lymphoma Association and Macmillan Cancer Support (Impact Case Study 27).

b. Approach to impact

Within UoA 1 we have adopted a multi-faceted strategy to deliver our vision that is flexible, responsive and multidisciplinary in approach to achieving impact of our research programmes to non-academic users and beneficiaries. Our strategy has been built around the contribution and impact of our translational biomedical research to improving the quality of life of all in the widest context and has involved close interactions with health policy makers and health care providers, associated stakeholders, industry, patients and the public.

Health policy makers, health care commissioners, and health care providers

Our academics continue to shape science policy in health, medical practice and translational research. Specific examples include the development of nutrition guidelines in malnutrition and COPD (Wilkinson) and the MUST programme (Impact Case Study 8), as well as our work on the importance of vitamin D in bone development and osteoporosis (Cooper). The framework outlined in the 'MUST' report formed a framework for the NICE guideline document on nutritional support in adults in all care settings, as well as other guidelines, including e-guidelines for primary care (Elia and Jackson), chronic kidney disease (Roderick), alcohol policy (Sheron), and nutrition workforce (Jackson, Margetts) supporting our outreach impact strategy.

Our leading academics (Holgate, Davies, Cooper, Elliott, Djukanovic, Little (UoA2), Jackson, Hanson, Oreffo, Johnson, Cameron, Glennie) hold strong relationships and advise and closely interact with a variety of charities (e.g. Wellcome Trust, CRUK), research boards (Research Councils, NIHR), learned societies and relevant stakeholders providing a platform and opportunity to influence the research agenda and translation of research into policy guidance.

The University hosts the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) as a business unit, which manages research programmes and activities for the NIHR within which The Southampton Health Technology Assessments Centre (SHTAC), an NIHR centre of excellence for health technology assessment, produces independent, reliable and rigorous research on the benefits, harms and costs of health technologies. Research outputs have directly informed national policy (e.g. NICE, National Clinical Directors, Advisory Group on National Specialist Services) on the management of over 20 health conditions between 2008-2013, including cancers, hepatitis, heart disease, mental health conditions and psoriasis and it has influenced international policy e.g. on Alzheimer's dementia and morbid obesity for groups within New Zealand and Canada. We are a key partner of the newly established Wessex Academic Health Science Network (AHSN) and a member of the Wessex CLAHRC, both of which which will foster implementation of evidence-based care.

Pharma and Industry

The University of Southampton is a leading entrepreneurial university, with an impressive track

record as a partner to business and the public sector as a source of invention and innovation. 40% of our research programmes have commercial partners. Since 2010 significant contracts have been agreed by the Faculty of Medicine with both pharmaceutical and nutrition companies with projected earnings (for Southampton) between 2011 and 2015 exceeding £15 million. Recent agreements in the area of cancer vaccine development are worth in excess of £5 million with potential royalty earnings of £100 million. Academics in UoA1 work closely with the University's Research & Innovation Services (R&IS) and the Faculty Research and Enterprise Teams to maximise exposure, reach and impact of all research as it develops. Specifically, R&IS, the University's 60-strong technology transfer service, provides support on deal negotiation, contract drafting, business development and support, spin-out creation, incubation and intellectual property management. We have also established the following mechanisms to enhance our research impact and to aid academics deliver impact:

1. **Enterprise advisory board**: Senior academics (Professors Cameron, Oreffo and Dr Wilkinson) and entrepreneurs (Professor Peter Johnson, CEO of Scintellix, LLC, USA; Pharmaceutical Sector Advisor Dr Nick Camp - Group Leader, Eli Lilly, UK; Dr Ross Garrett, Director, Zimmer Orthobiologics, USA; Don Spalinger, Director of Research & Innovation Services University of Southampton, UK; Dr Jill Fabricant - President and CEO of Cell Viable Corporation, USA and Ian Clarke, CEO Genentech, USA), supporting the development of the enterprise and innovation agenda and providing guidance on best practice.

2. **Faculty International and Enterprise Group (FINE) and the Health & Pharma University Industry Sector Team (UIST)**: These two groups play a significant role in developing the impact of the Faculty of Medicine. Our research-led reputation has enabled teaching and research exchanges (for example the University of Auckland, New Zealand and the National University of Singapore in our epigenetics programme) and collaborations with companies (for example Genentech, USA, GSK Bio in Belgium, Abbott Nutrition in the USA and Singapore, Danone in France, Roche and Nestlé in Switzerland) – Impact Case Study 5). The UIST specifically targets corporate outreach and partnering opportunities both in research collaboration and employer engagement following a Higher Education Innovation Funding allocation of £200,000 in 2012.

3. **Enterprise Fellows** – We have developed, over the last 6 years, a cohort of five Enterprise Fellows within the Faculty of Medicine. Originally supported by the London Technology Network (LTN) the University took over this activity, through the creation of the Health-Pharma UIST. The primary goal of the Enterprise Fellows is to make business aware of the research activities and expertise present within the Faculty. The work includes: i) Technology mapping of research activities undertaken by staff; ii) Targeted promotion and advertising of research activities of interest to the business community through UIST-organised events; iii) Establishment of introductory meetings between Faculty staff with members of the business community. Specifically, the fellows have mapped Faculty research activity against declared pipeline needs of the top-ten pharmaceutical companies the Faculty interacts with as well as local SMEs.

Our Enterprise Fellows have participated in over 100 meetings with different companies, displaying more than 150 technologies at LTN events attended by over 1000 industry delegates. These events included: i) Technology Strategy Board: Fighting infection through detection; ii) Biomarkers and iii) Bottlenecks in Drug Discovery. At BioTrinity (a leading UK life science event) our Enterprise Fellows in collaboration with R&IS showcased medical research innovation from the Faculty of Medicine, reaching out to potential business partners with more than 50 meetings resulting in 16 collaborations. One of these has led to the creation of a National Centre for Translational Vaccinology, linking capabilities in Southampton and Porton Down. Through such meetings research deals were reached with a number of companies, including Abcam, Abbott, Amgen, Biocompatibles, GE Healthcare, Merck, Phillips, Sigma and Wyeth. The impact of this Enterprise Fellows activity is evidenced by an increase in external funding to the Faculty over the past six years totalling over £2.5M.

4. **Patent Panel** – In 2009, the Faculty of Medicine established a Patent Panel that responds within 48 hours to meet the needs of academics to evaluate and provide options for commercialisation of research. This is evidenced, for example, by patenting of early work from the Southampton Epigen consortium (see Impact Case Study 5). Faculty investment in intellectual property on recommendation of the panel is linked to a high probability of support for licensing. For example i) our meningitis vaccine patent licensed to GSK, 2010-11; ii) spin-out Karus is built on a patent

portfolio established by Medicine and Chemistry and iii) significant external research income (The EpiGen Consortium has licensed both patents and confidential know-how to Nestlé Research Centre to investigate ways of improving maternal and child health during pregnancy Nestlé See http://www.southampton.ac.uk/mediacentre/news/2011/nov/11_117.shtml - and other nutrition companies). The panel also emphasises that not all intellectual property is manifest as patents; trademarks, copyright and confidential know-how can be examined by the panel.

5. **Workshops & conferences** – Research is disseminated within a raft of Faculty-sponsored workshops and conferences such as the Wessex Immunology Group Spring Meeting 2013 on Translational Immunology, open to both academia and industry.

6. **Knowledge Transfer Partnerships** – In 2010 alone we held over 50 contractually based business collaboration agreements, and during the period Dec 2008 to Dec 2010 achieved a 100% success rate with KTP applications between our medicine academics and business. The University of Southampton currently has a portfolio of fifteen live KTP projects, ranging across five Faculties worth over £2m. The University has particular strength in its biomedical bioengineering KTPs, with special highlights including the award-winning project with Finsbury Orthopaedics on hip joint replacement technology (selected as the Best Knowledge Transfer Partnership for the South East region by the Technology Strategy Board), as well as two projects with Aurora Medical (dental implants) and Arterius Ltd (stent technology*).*

7. **Reward** - The Faculty of Medicine actively supports and, critically, will promote research and education-led academics who incorporate an innovation and enterprise component in their academic portfolio – evidenced by the first enterprise focused chair in 2009 (Paul Townsend, co-founder of Karus Therapeutics).

Impact on next generation of biomedical scientists and clinicians - Our scientists and clinicians are actively supported to showcase their work nationally and internationally through faculty bursaries as well as our annual postgraduate clinical/basic science conferences specifically for research students, clinical fellows and postdoctoral fellows (see 5 above).

Impact *with* patients and public - Our translational and applied research always has patient and public involvement; which has helped in all stages of the research process, from developing the question, providing guidance on study materials, and shaping final research reports and critically dissemination of findings. We actively seek to involve the public in the design of research as exemplified by the appointment in 2012 the UK's first clinical research facility public and patient involvement (PPI) officer to the NIHR Wellcome Trust Clinical Research Facility.

We have a strong multifaceted outreach programme to showcase the impact of our research and education for students, teachers, school students and the general public. In 2010 alone, our outreach initiatives providing interaction between the general public and Medicine and enterprise, reached more than 37,500 individuals through our LifeLab, National Science week, NHS patient day and cancer research activities (CR UK Breast Cancer activities). For example, through our Research Engagement Manager, Hannah Fox, within Cancer Sciences and CR UK, in 2012 we have reached over 32,222 individuals in Open Day, Race for Life and Trust activities, hosted 945 visitors to our CR UK centre and held 60 separate events. Through LifeLab, over the last five years we have developed a programme engaging school children and schools across Hampshire with “hands on” research to encourage life-long health that maps across to our osteoporosis and nutrition case studies. Since we launched the pilot scheme of LifeLab in 2008, over 1000 children have taken part from schools across Hampshire and in 2013 LifeLab has moved into purpose built facilities allowing for significant expansion of the programme.

In another approach, Pauline Pratt, an artist-in-residence in Cancer Sciences Unit since 2006 has delivered numerous interactive exhibitions throughout the region. For example “Faith’ involved 901 individual contributors to the art installations and had a total of 6247 gallery visitors. Artist in residence Professor Kathleen Rogers exhibited a stem cell programme of work in 2013.

c. Strategy and plans

The University of Southampton is one of the world's leading entrepreneurial universities, with an impressive track record as a partner to business and the public sector, and as a source of invention and innovation. 40% of our research programmes have commercial partners. In the period 2008-2013, the Faculty of Medicine worked with many of the major Pharmaceutical

companies and NIHR securing total revenues in excess of £25M with funding of £9.7M for NETSCC, over £2.5M catalysed by Enterprise Fellows and the remainder directly from Pharma and Industry. In the 2008 Library House report, Southampton was ranked No 3 in the world for spin out activity after Stanford (USA) and Cambridge. The Faculty of Medicine research programme and impact strategy is integral to maintenance of Southampton as a topflight research-led university.

Our aim is to secure our reputation as an internationally recognised Medical School. To enable this we continue to build on three distinctive features: i) our strong partnership with the local NHS to deliver translational research and equip the next generation of doctors to work in a rapidly-changing environment; ii) collaborations at the interface between physical and life sciences with engineering, mathematics, computing, chemistry and nanotechnology; and iii) exploitation of the enterprise agenda to maximise the impact of our research and education.

Specifically, we will deliver excellent and innovative education, focusing our research on high quality basic science in distinctive areas of strength, with an emphasis on common diseases (e.g. asthma, osteoporosis, obesity) and clinical translation across the lifecourse. Our goals and plans are directed at maximising impact from our current and future research *and* education, through a coordinated and focused strategy that includes:

- Expansion of our current research, innovation and enterprise platform to inform and facilitate our world-leading, distinctive research activities in cancer, human development, nutrition, respiratory medicine, immunology, stem cells and regenerative medicine, and applied neuroscience (and primary care in UoA2).
- Strengthening links with national and international partners in industry, NHS and academia to allow impact demonstration.
- Establishment of a successful SCBR base that has seized these opportunities, resulting in the award of two Biomedical Research Units (renewed in 2011 and one upgraded to BRC status), the Cancer Research UK/NIHR Experimental Cancer Medicine Centre, and the Wellcome Trust Clinical Research Facility. Our next step will be to expand our SCBR base to include translational Immunology incorporating Porton Down and the regional genetics service hosted by Salisbury Healthcare Trust that will be facilitated by the recent opening of ew £1.6M Wessex Investigational Sciences Hub laboratory (WISH) as part of the SCBR.
- Continuing to harness our privileged relationship with University Hospital Southampton NHS Foundation Trust (UHS), we have established the Health-Pharma UIST Team to showcase our activities and facilitate interaction with industry/corporate partners. We will continue to provide coordinated clinical services, patient access and translational research capacity enabling greater impact of our translational biomedical research. For example, our unique technology platforms GCLP Immunometry, molecular microbiology, genetic stratification within appropriate business frameworks to aid our engagement with industry and, critically, our development of new template agreements for cooperative research and development (CRADA) to aid this process.
- Enabling and providing the appropriate infrastructure to deliver impact from our research. Specifically, the Faculty of Medicine will continue to:
  - expand and fund the International Advisory Groups for Research, Enterprise; the Patent Panel; and Enterprise Fellows to support the creation, translation and delivery (wealth creation) of impact.
  - exploit our intellectual property through licensing, especially in the development of long term research partnerships, taking action to raise awareness of the management and exploitation of intellectual property in the Faculty.
  - strengthen our relationship with the NHS, and the partnership with UHS and other local NHS partners, to ensure we are regarded as a nationally important, and internationally recognized centre for translational medical research.
  - engage with pharma and industry through our Health-Pharma UIST using sector-specific strategic plans and consulting with industry members of the UIST Advisory Board.
- Continuing to enhance collaboration between primary care and public health. We have recently established a University Strategic Research Group jointly directed from Faculties of Medicine (Roderick, Cooper) and Human and Social Sciences, to harness our

multidisciplinary research strengths to address important population health issues both in UK and globally, and to engage practitioners and other stakeholders. We will continue to enhance collaboration between primary care and public health and both secondary care-based researchers and basic scientists, to focus on the spectrum of disease, care pathways and to better translate our findings. For example, our new Chair of Primary Care (Thomas) is integrating research into primary care, community and public health aspects of respiratory disease (asthma, COPD) with our existing excellence in basic and early translational respiratory research (Djukanovic, Wilkinson).

- Enabling development across all our education programmes of additional portfolio activities such as international BM programmes, Masters and tailored course units, and bespoke training to develop maximum impact. Specifically we will build on our international BM EU programme with Kassel and tailor specific MSc programmes in translational medicine for students in Middle-East and Far East markets.

d. Relationship to case studies

The Faculty of Medicine delivers impact through national and international engagement with policy makers/government, healthcare organisations, Pharma and industry, charities and patients and users of health services through our actively managed enterprise agenda and environment. This is exemplified by:

Impact Case Study 03: The Role of Vitamin D in Reducing Osteoporotic Fractures - Work in our MRC Lifecourse Epidemiology Unit has contributed via NICE guidance, to £1billion annual savings to the NHS in its healthcare provision for osteoporotic fractures in older adults and has helped shape national/international guidance on vitamin D supplementation during pregnancy and in older age.

Impact Case Study 05: Nutrition, developmental epigenetics and lifelong health - Southampton's "developmental origins" lifecourse cohort studies, including the Southampton Women's Survey and our studies in India and other developing countries, have led to a paradigm shift in the current approach to non-communicable diseases. Thus, our cohort studies have informed NICE public health guidance, Nutrition policy (UK-Foresight, Tackling Obesities: Future Choices report (2007) and United Nations Policy (High Level Summit 2011).

Impact Case Study 06: Omega-3 Fats - The findings of a novel mechanism of action by which omega-3 reduces cardiovascular events and mortality have contributed to UK government guidelines on nutrition. The research has informed European atherosclerosis guidelines and enhanced wealth creation through patent and license activity in several countries.

Impact Case Study 08: MUST - A new tool for combating malnutrition in the UK - The 'Malnutrition Universal Screening Tool' (MUST) for detecting and managing malnutrition is currently rolled out to over 80% of hospitals and care homes in England and 98% in Scotland. Approved by NICE, this tool is an integral part of the UK's health policy framework (providing an annual cost saving of £71,800 per 100,000 population) as well as informing teaching programmes on managing malnutrition. MUST is the third highest cost saving figure of all NICE implemented guidelines.

Impact Case Study 18: Breathing New Life into the Treatment of Respiratory Illnesses - We have generated a spin-out company, Synairgen that has enabled the discovery and development of new therapeutics for asthma. Synairgen has an established patent portfolio and major Pharma collaborations that has enabled clinical development of inhaled IFN-β1a in asthma and chronic obstructive pulmonary disease.

Impact Case Study 20: Treatment of cancer with monoclonal antibodies - Our work has been pivotal in bringing two types of anti-cancer monoclonal antibodies, from lab to market/clinic to treat resistant leukaemia. The work has resulted in patent, licence activity and the development of a new class of anti-cancer antibodies. Critically, we have been key in the development of a multi-million dollar drug, launched in 26 countries and under evaluation in 19 on-going clinical trials worldwide for diseases ranging from lymphoma to rheumatoid arthritis and multiple sclerosis and thus enhancing the UK economy.

Impact Case Study 27: Setting the standard in lymphoma therapy - Development of effective new antibody treatments that have defined standards of care for Hodgkin and Burkitt lymphoma in the UK and internationally. The research has underpinned significant survival, quality of life and cost benefits in the care of the 14,000 people affected by lymphoma in the UK each year.