

<p>Institution: University of Leicester</p>
<p>Unit of Assessment: Clinical Medicine</p>
<p>a. Context</p> <p>One of the key drivers for establishing a Medical School in Leicester in 1975 was to have a direct impact on the health and wellbeing of people living in the East Midlands. Over the past 38 years the Unit has evolved to deliver internationally recognised medical research which has been acknowledged with the award of three NIHR Biomedical Research Units in the past five years, emphasising the Unit's research strengths in diabetes, cardiovascular and respiratory disease. Beneficiaries of the research, described in detail in the submitted Impact Case Studies, include:</p> <p><u>The individual.</u> The research has improved the quality of care delivered to patients and carers across the UK and internationally through development of:</p> <ul style="list-style-type: none"> • Education and empowerment programmes for patients with diabetes. • New devices and IT solutions to improve the detection of cardiovascular disease. • New drugs to treat respiratory diseases including asthma. • Design and delivery of national and international clinical trials, the results of which have informed clinical guidelines and improved the way common diseases such as diabetes, stroke, asthma, heart attacks and high blood pressure are diagnosed and treated across the world. <p><u>The National Health Service.</u> Research and research leaders have driven the development of:</p> <ul style="list-style-type: none"> • New NHS services, including the first national diagnostic service for patients with the respiratory disease Primary Ciliary Dyskinesia. • The NHS Health Checks Programme designed to prevent heart disease, stroke, kidney disease and diabetes. • NICE policy and guidelines (Prof D Barnett, First Chair, NICE Appraisal Committee 1999-2009). <p><u>UK Government & International policy.</u> The research has informed policy makers in:</p> <ul style="list-style-type: none"> • The Food Standards Agency, European Union (Caffeine exposure in pregnancy). • The Ministry of Defence, US Department of Defense (Tranexamic acid in trauma). • The Home Office, International Red Cross, Interpol (Post-mortem computer tomography). • The Department of Health (all Impact Studies). • The Ministry of Justice (Prof Peter Furness, First National Medical Examiner 2012-present). <p><u>The Biotechnology and Pharmaceutical sector.</u> The Unit's research has led to:</p> <ul style="list-style-type: none"> • Development of close industrial collaborations (drug and device development in cardiovascular and respiratory disease). • Development of University spin-out companies (Haemostatix, which is developing first-in-class products to treat bleeding in surgery, trauma and in leukaemic patients). • Design and delivery of clinical trials of new therapies: in the last five years the Unit has supported the recruitment of 2,655 participants into ~150 commercial studies for over 100 different life-sciences companies; many trials were designed and led by members of the Unit. • Leadership of regulatory authorities: MHRA (Prof Sir Kent Woods, Chief Executive 2004-2011), European Medicines Agency (Prof. Sir Kent Woods, Chair Management Board 2011-present).
<p>b. Approach to impact</p> <p><u>Coordinated College Support for Impact and Enterprise.</u> The College of Medicine, Biological Sciences and Psychology (CMBSP) developed a strategy for research-related impact and enterprise in 2011, following assessment, reorganisation and focusing of research activities into internationally competitive research themes. Impact and enterprise activities are now coordinated and developed through a College Enterprise Committee which contains an impact and enterprise champion from each research theme, with responsibility for disseminating ideas, raising awareness of potential opportunities and increasing the active involvement of research groups. Recognising the importance of the Unit's NHS partners in generation of impact, the Director of Research and Development for University Hospitals of Leicester NHS Trust, representatives from the NIHR BRUs and CLAHRC are seen as key members of this committee. This structure, together with increased support from the central Enterprise and Business Development (EBD) office of the University, has provided Unit staff with an effective system to support the assessment of the impact potential of</p>

research and to access expert advice on possible translation pathways. Coordination of impact and enterprise activities has encouraged the research themes to organise impact-focused events, such as Prof. Peter Goodfellow's presentation on how to set up a business, catalysing renewed interest in spin-out companies with several poised for launch in 2013/14. The University has provided targeted financial support for promising translational projects to provide proof of principle data, to protect intellectual property (IP) and to engage with potential partners. Staff are supported to realise the impact potential of research with appropriate relief from duties such as teaching, which facilitates productive interactions with beneficiaries including secondment to industrial partners.

CMBS now houses an embedded enterprise and business development centre known as the Biobator, with five staff from the EBD office providing support for translational opportunities arising from primarily biological and medical research. This central support has been strengthened by the appointment of two business development managers, which for the first time provides strong support for the development of collaborations and partnerships with NHS organisations, companies, translational charities and other potential beneficiaries, such as the Technology Strategy Board. This is particularly valuable for those academic staff with no prior experience of assessing the potential impact of research and translational activities, who can be guided through the process, advised on potential partner organisations and assisted in meetings with potential collaborators or funding bodies. The Biobator has two experienced technology transfer and IP managers, providing support and advice for this aspect of impact delivery, including the licensing of successful translational programmes to deliver economic, social and healthcare benefits.

In 2011 the University created a Centre for Translational Therapeutics (CTT) aimed at addressing the decreased activity in pre-clinical and pre-competitive drug discovery in the pharmaceutical sector by offering an infrastructure that co-ordinates the world-leading basic research programmes at the University with outstanding clinical practice conducted within the Unit. Overall, the recently implemented strategy to support translational work and impact delivery aims to encourage a very positive environment, in which these activities are strongly supported, highly valued and become a normal outcome of innovative research.

Partnership with the NHS. In tandem with these internal initiatives the Unit has strengthened its links with NHS partners and the NIHR over the period of assessment to facilitate delivery of impact. The focus of this partnership has been to drive early translation of the research into the day to day delivery of healthcare. Partnership between research themes in the Unit and NHS organisations has been formalised in six key areas:

1. NIHR Biomedical Research Units (BRUs)

Following a highly competitive bidding process the University was awarded three (out of a national eighteen) BRUs in 2012, in part because of the clinical impact already achieved from the research generated by this Unit (see submitted impact studies). These BRUs focus on Cardiovascular Disease (awarded 2008, renewed 2012); Respiratory Disease (awarded 2012); and Nutrition, Diet, Lifestyle and Physical Activity (awarded 2012). Each BRU undertakes translational clinical research and is designed to enable basic scientists, health researchers and clinicians in the Unit to work together to develop new treatments for the benefit of patients. The approaches used by the BRUs to deliver impact for the Unit include:

- Working with patients and carers to ensure the research reflects their needs and priorities.
- Working with the healthcare and bioscience business sector to facilitate the early introduction of novel technologies developed by the Unit to enhance patient care such as HealthSTATS' wrist sensor for measurement of central aortic pressure (Times Higher Education Award for Innovation and Technology, 2011) and the LifeMap™ System for early detection of Sudden Cardiac Death (Medical Futures Innovation Award, 2011).
- Working in partnership with the pharmaceutical sector to translate basic scientific observations into new treatments and testing these in clinical trials (designing and delivering trials of the AstraZeneca drug mepolizumab in eosinophilic asthma).

2. LNR Collaborations for Leadership in Applied Health Research and Care (CLAHRC)

The Leicester, Northamptonshire and Rutland (LNR) CLAHRC, hosted at the University, was established in 2008 to support the translation of research evidence into practice in the NHS. It has

Impact template (REF3a)

been one of the principal avenues for embedding the Unit's main research themes into clinical practice and has achieved considerable local, national and international clinical impact through:

- Developing and disseminating resources to empower patients to manage their own illnesses.
- Developing systems in Primary Care for early identification and structured early intervention in common chronic conditions such as mental illness, diabetes, cardiovascular, respiratory and kidney disease to reduce long term complications.

3. NIHR Comprehensive Local Research Networks (CLRNs) & Clinical Research Networks (CRNs)

Members of the Unit have developed and managed the NIHR CLRNs and CRNs in LNR since their inception in 2008. These networks have facilitated translation of the Unit's research themes into tangible impact both nationally and internationally by:

- Working with patients to ensure they are at the very centre of the Unit's research activity.
- Providing the infrastructure to support the Unit's translational clinical research strategy, eg. the Stroke and Diabetes CRNs facilitated the national clinical trials that form the basis of two of the submitted Impact Studies.
- Supporting partnerships with the life-sciences industry to deliver their research programmes.

4. The Diagnostics Development Unit (DDU)

The DDU was established to bring together expertise in the Unit, Atmospheric Chemistry, Physics and Astronomy, Space Research Centre, and IT to explore innovative ways to diagnose disease in the emergency setting with the ultimate aim of developing bespoke 'Point of Care' devices. The DDU, in the Emergency Department of University Hospitals of Leicester NHS Trust, has been designed to enable emergency care for the patient with state-of-the-art analytical instrumentation sited in an adjacent instrument room. The DDU is working with a number of bioscience companies to evaluate the early introduction of new technologies into clinical practice.

5. The Experimental Cancer Medicine Centre (ECMC)

Established in 2007, the ECMC brings together basic scientists, clinical researchers, clinicians, the biosciences sector, patients and carers to facilitate the introduction of new treatments for cancer. The Unit's principal focus is the discovery and development of novel phytochemicals as potential chemopreventive agents and/or as potential adjuncts to chemotherapy.

6. East Midlands Health Innovation and Education Cluster (EM HIEC)

The EM HIEC, hosted by the University, was established in 2010 and consolidates the Unit's impact strategy by bringing together researchers across the Unit, the NIHR BRUs, CLAHRC, industry, charities, public sector and the public with the goal of delivering high-quality patient care and services by embracing and disseminating innovative research produced by the Unit. Examples of successful collaborations include development and introduction of a scoring system to evaluate sick children (Da Vinci Health Technology Award, 2012) and development of education and empowerment programmes for patients with chronic diseases, in particular chronic respiratory disease, which have reduced hospital admission and readmission rates.

c. Strategy and plans

Coordinated University Strategy for Impact and Enterprise. The University continues to implement a very ambitious and positive impact and enterprise strategy. This commitment to translational activities and delivery of impact through active engagement with NHS partners and potential beneficiaries has resulted in substantially increased EBD support for the Unit, including the appointment of two new business development managers based in the Biobator. To catalyse delivery of the impact and enterprise strategies the University has appointed a very experienced Director of EBD, who has led the development of a detailed, user-focused business plan in consultation with impact and enterprise leads for the various Colleges. This includes:

- i) Restructuring and expansion of the central EBD office to produce teams appropriate to the support of impact and enterprise priorities in the individual Colleges, such as CMBSP.
- ii) Strengthened leadership and management within EBD to assist in setting ambitious but realistic targets, and to provide appropriate and timely support to academic staff.
- iii) Enhanced and targeted support for early stage enterprise and translational projects through Proof of Concept and Prospect Funds.

In concert with the development of an overall impact and enterprise strategy for the University, the College (CMBSP), including this Unit, has taken a lead in developing a strategy to capitalise on the

translational and impact potential of its research. This initiative is coordinated through the College Enterprise Committee, which will lead in the development, implementation and support of research-led impact activities in concert with NHS partners. This committee acts as a key coordinator with the central EBD support services and, together with the Director of EBD, strongly influences the priorities of staff within the Biobator. This restructuring, along with the formation of a joint University-University Hospitals of Leicester NHS Trust Research and Development Support Office, has strengthened the successful partnership between the Unit and the NHS.

Partnership with the NHS: going forward. The Unit's strategy for successful translation of research and impact delivery will continue to be based upon strong partnership with NHS organisations and the NIHR Biomedical Research Units and Clinical Research Network.

Each BRU has a research strategy that focuses on translating the Unit's research themes into clinical practice, including the development of new diagnostic tests (improving the NHS Health Checks Programme for vascular disease by adding genetic information) and the testing of new interventions (the role of physical activity in the prevention and management of chronic disease). The Unit and the BRUs are leading multinational clinical research collaboratives which will generate major impacts into the management of chronic diseases over the next decade (AirPROM, 'Airway Disease PRedicting Outcomes through Patient Specific Computational Modelling', a €16M FP7 EU-funded project to improve the diagnosis and treatment of patients with airways disease).

The East Midlands-wide CLARHC will provide another opportunity to deliver significant impact by facilitating translation of the Unit's research into clinical practice and embedding it in routine clinical care through five key themes: Preventing chronic disease; Managing chronic disease; Caring for older people and stroke survivors; Enhancing mental health; and Implementing evidence and improvement. A number of these themes mirror priority areas for the Unit's BRUs and are synergistic with the key research objectives (physical activity in disease prevention; exercise in chronic disease) of the newly established National Centre for Sport and Exercise Medicine-East Midlands (NCSEM-EM) co-hosted by the University, placing the Unit in an unrivalled position to make a significant impact in the care of patients with chronic illness across the UK and beyond. Opportunities to deliver impact have been further enhanced with the establishment in 2013 of the East Midlands Academic Health Science Network (AHSN) which will work with BRUs, CLARHC, EM HIEC and NHS partners to further facilitate translation of the Unit's research into practice. In addition to the ECMC, it is likely the Unit will gain Cancer Research UK centre status (application submitted May 2013) which will increase the ability to impact on the care of patients with cancer through the discovery of new treatments and testing of chemotherapies in clinical trials.

d. Relationship to case studies

By definition, the genesis of some of the impacts reported in the case studies pre-dates the formal support structures and approaches described in the previous sections. However, the Unit's early recognition of the importance of a strategic partnership with the NHS and NIHR, and in particular, its success in securing the stroke and diabetes CRNs and the award of the LNR CLARHC and Cardiovascular BRU in 2008 consolidated the Unit's early impact strategy and directly contributed to the successes described in four of the eight case studies (management of patients with diabetes, hypertension, coronary artery disease and stroke). The Stroke and Diabetes CRNs, led by members of the Unit, facilitated the delivery of large multicentre clinical trials and dissemination of results to the clinical community and patients. The LNR CLARHC enabled rapid translation of the Unit's research into clinical impact, particularly in the management of patients with diabetes. The Nutrition, Diet, Lifestyle and Physical Activity BRU and the new CLARHC will ensure continuation of the significant impacts generated from the research in diabetes. The Cardiovascular BRU supported the underpinning research and translation into clinical impact of the case studies in hypertension and coronary artery disease and continues to support these areas through its Novel Cardiovascular Therapeutic Interventions research theme. The impact of the asthma research programme will inevitably increase with the award of a Respiratory BRU and airways disease themes within the CLARHC and NCSEM-EM.

The breadth of impact-generating research within the Unit has never been greater and the experience and knowledge gained from the submitted cases is already benefiting a number of exciting new programmes.