

**Institution:** University of Leicester

**Unit of Assessment:** UoA1 Clinical Medicine

## Section 1. Unit context and structure, research and impact strategy

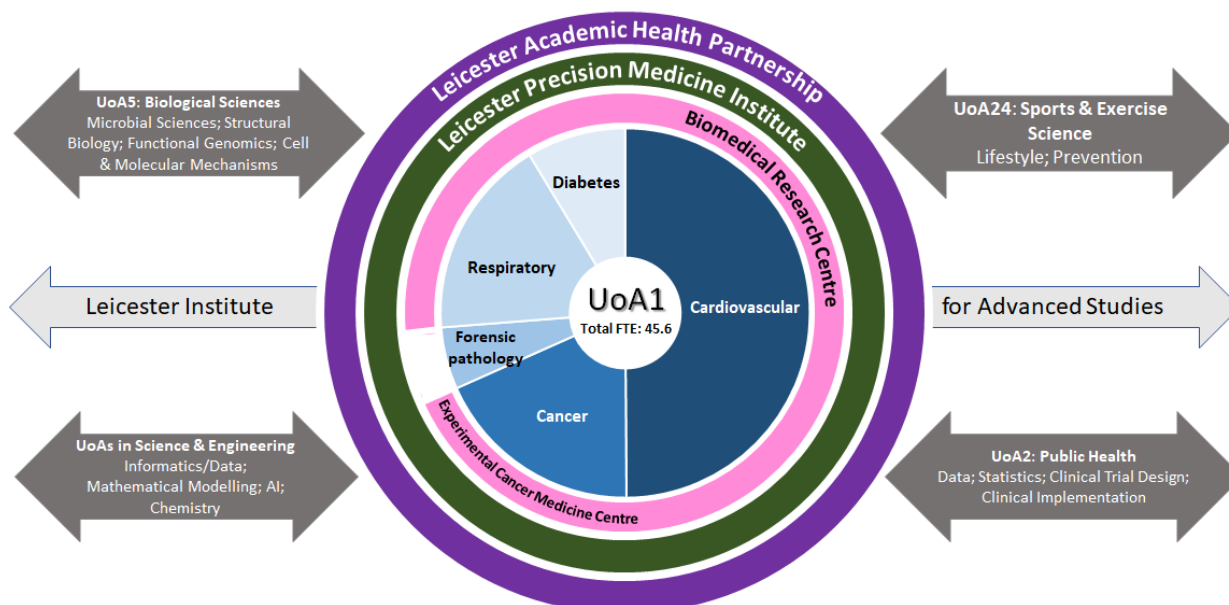
### 1.1. OVERVIEW

This UoA1 return emphasises our multi-disciplinary research, centred on the health challenges of common diseases affecting the UK population. With 86% (39.6FTE) of our return comprising clinical academics, the philosophy of our clinically-led research is to deliver transformative outcomes for patients, underpinned by first-rate research across the bench-to-bedside spectrum integrated with high quality training, a strong commitment to equality and diversity, and engagement of NHS and commercial partners, national bodies, patient groups and regional/local stakeholders.

Top level achievements are:

- Leadership of **international genomics consortia** discovering novel pathways, early detection strategies and risk stratification in cardiovascular, respiratory diseases and lung cancer;
- Our drug discovery pipelines taken forward with UoA5 researchers to early and late phase clinical trials leading to the **implementation of the first new treatment for asthma** in decades;
- Leadership of **global clinical trials transforming patient outcomes and international guidelines** in cardiovascular disease, stroke, cancer, diabetes and respiratory disease;
- **One of three top performing universities in the UK for COVID-19 research** with award of £8.2M government funding. We have been widely acknowledged for our agility to respond to the urgent research needs of the pandemic, integrating with our local NHS Trust to deliver high patient recruitment to clinical trials (e.g., RECOVERY trial). We have also set up and staffed national test centres, advised on the setup of Nightingale hospitals, delivered research in COVID drug delivery, infection prevention and protection, and provided leadership of **the national CMO-prioritised PHOSP-COVID clinical trial** ([www.phosp.org](http://www.phosp.org)).

Since the REF2014 submission, following the appointment of a new Head of College of Life Sciences (CLS) and external review, a new organisational structure re-integrated research themes within departments to further align laboratory, translational and clinical themes. This strategy has allowed consolidation of the UoA1 submission from 78FTE in REF2014 to 45.55FTE with a greater focus on clinical implementation of curiosity-driven research. Our researchers align with four themes of excellence: **Cardiovascular (including Stroke and Renal), Respiratory, Diabetes, and Cancer (including Forensic Pathology)**. Our research is underpinned by rich clinical infrastructure that includes the **Leicester National Institute of Health Research Biomedical Research Centre (NIHR-BRC)** and **NIHR/Cancer Research UK (CRUK) Experimental Cancer Medicine Centre (ECMC)** and fosters close working relationships with staff returned in UoA2 (novel trial design/technology assessment), UoA5 (discovery pipeline), UoA24 (sports science/lifestyle), as well as Units within the College of Science and Engineering (Figure 1).



**Figure 1.** Leicester UoA1 submission highlighting key themes, infrastructure and multi-disciplinary interactions

Our strategy has created a step change in research profile since 2014 resulting in:

- **Top 20 world ranking for Clinical Medicine** in the Shanghai Academic ranking of world universities 2020 and 5<sup>th</sup> in the UK ([www.shanghairanking.com/shanghairanking-subject-rankings/clinical-medicine.html](http://www.shanghairanking.com/shanghairanking-subject-rankings/clinical-medicine.html));
- The award of the **NIHR-BRC** in 2016 (Institutional Environment Statement [IES], section 4.3), building on our Cardiovascular, Respiratory and Diabetes/Lifestyle Biomedical Research Units from 2012, and renewal of the **ECMC** in 2017, directed by our leading female academics **Davies** and **Thomas/Brown**, respectively;
- 2535 original scientific outputs (~56/FTE) attracting 77,000 citations (~30 citations/output) with an average FWCI of 3.7;
- **>£100M funding income (>£2.2M/FTE)**, more than double our REF2014 reported income (~£1.1M/FTE), despite the 1.7-fold reduction in FTE, and higher than the ~£1.5M/FTE reported by Russell Group Universities for UoA1 in REF2014;
- **198 PGR students** completing doctoral awards (~4.4/FTE), an increase from 3.1/FTE in REF2014 and double the 2.2/FTE reported by Russell Group Universities in UoA1 in REF2014;
- Increase in the proportion of Early Career Researchers (ECRs) returned from 17% in REF2014 to 27%.

Our strategy is underpinned by research networks and strong patient engagement, with a key element being our close partnership with the **University Hospitals of Leicester (UHL) NHS Trust** (Leicester Royal, Leicester General, Glenfield Hospitals) and the **Leicestershire Partnership NHS Trust**, reinforced through development of the **Leicestershire Academic Health Partners (LAHP; Figure 1)**. The LAHP is further strengthened by the **Leicester Precision Medicine Institute (LPMI; Figure 1)**, one of five

new research institutes across the University to support research excellence (IES, 2.2). This has provided a forum for the LAHP through active investment in new posts and facilities, cross-board memberships, joint strategic meetings, and an increase in honorary appointments of NHS staff. Joint investment with the NHS Trust is reflected in the **NIHR Clinical Research Facility** award (2016); **NIHR Collaboration for Leadership in Applied Research and Care (CLAHRC)** renewal (2014) and **NIHR Applied Research Centre (ARC)** award (2019); **NIHR-accredited Clinical Trials Unit (CTU)** award (2013, re-accredited 2017); hosting of the **NIHR Clinical Research Network East Midlands (CRN)** in 2014; award of one of only five national **NIHR Patient Recruitment Centres** (2020) leading commercial vaccine trials; and **significant industrial partnership** e.g. with Nipon Telegraph and Telephone (NTT DATA) to support our **Clinical Data Science Initiative**.

We have promoted an **open research environment** by encouraging the uptake of FigShare as a repository where users can make their research outputs available in a way that is discoverable, citable, and shareable, adhering to FAIR principles. During the assessment period, 76% of our outputs were published open access, compared to the Russell Group average of 63% (SciVal). **Research integrity** is central to our philosophy and commensurate with the Concordat for Research Integrity to which we are a signatory, and we regularly disseminate training on Research Integrity and Ethics to all staff and students. We became a public signatory of the Declaration on Research Assessment (DORA) in 2018, affirming our **commitment to the responsible and fair use of research metrics**.

## 1.2. RESEARCH THEMES

Our research is themed by clinical specialty with precision medicine forming a common thread, and an emphasis on the design of innovative clinical studies.

### 1.2.1. CARDIOVASCULAR SCIENCES (21FTE)

The overarching research strategy is based on two key principles: (a) to integrate high quality basic, translational, and clinical science research, and (b) to focus on common cardiovascular diseases and questions of direct clinical impact and relevance.

**1.2.1.1. Precision and Stratified Medicine.** Working with the NIHR-BRC and the LPMI, our research focuses on biomarkers, genomics, and imaging predictors of cardiovascular disease in both the primary and secondary prevention arenas. **Biomarker research (L Ng, Squire, Suzuki** with D Jones [UoA5]) is undertaken in the van Geest Multi-Omics Facility with £10M investment from philanthropy, charity, industry, and the University. International collaborations, especially in the EU-funded Biostat-CHF study, have improved understanding of therapeutic response in heart failure (**L Ng: Eur Heart J** 2017;FWC112.9), and identified gut-microbiome-derived metabolites as a molecular link between dietary 'red meat' and heart disease with scientific and societal impact (featured on BBC1 'The Truth About Meat'). Industrial partner collaborations, e.g., with NTT, have enabled the harmonisation of clinical 'big data' to facilitate AI-driven data mining. Our **genomics researchers (Samani, Bown, Saratzis** with Nelson [UoA2], Codd and Ye [UoA5]) have led international large-scale genomic studies of aortic aneurysm, coronary artery disease and cardiovascular ageing. Their contribution is evidenced by the recent Genome Aggregation Database (gnomAD) in Nature, Nature Medicine and Nature Communications and involvement in other major databases (GENVASC, BRICCS and the NIHR Biobank). These

have identified >160 chromosome loci and underlying disease mechanisms that influence coronary artery disease risk (**Samani**:*Nat Genet* 2015;FWCI32.6; *NEJM* 2015;FWCI18.6; *NEJM* 2016;FW CI38.5). In aortic aneurysmal research, we lead the British Heart Foundation (BHF)-funded UK Aneurysm Growth Study and the population screening research (**Bown**:*Lancet* 2018;FWCI6.1) that has informed NICE guidelines (GID-CGWAVE0769) and National Screening Committee policy. Our **cardiovascular imaging group (McCann, Arnold, Singh)** led by NIHR Research Professor **McCann** in close collaboration with **Davies (Diabetes)** and **Burton** and **Graham-Brown (Renal)**, undertakes clinical studies ranging from imaging biomarkers to large-scale clinical trials. Key achievements include FDA approval for cardiac use of the MRI contrast agent 'Gadovist', and the MR-INFORM (**McCann**:*NEJM* 2019;FWCI41.7), CEMARC-2 (**McCann**:*JAMA* 2016;FWCI16.3) and CvLPRIT trials (**McCann**:*JACC* 2015;FWCI28.2); the latter changing international guidelines in patients with multi-vessel coronary artery disease (**Impact Case Study (ICS) 2, Gershlick**).

**1.2.1.2. Clinical Trials.** Our research covers the discovery and development of drug and device interventions for cardiovascular disease, with translation from preclinical models into Phase II and III clinical trials. The impact is on patient outcomes and international guidelines, as evidenced in three of our **ICs (Coats, Gershlick, Robinson)**. Our research focused on **Arrhythmias and Cardiac Electrophysiology**, comprising pre-clinical work that has been translated into two patents for a novel clinical method of sudden death risk stratification, recognised with the European Heart Rhythm Association Inventors' Award in 2016. We have led trials in **Interventional Cardiology**, including rare coronary phenotypes, that have informed acute patient management with drug-eluting stents (**Gershlick**:*NEJM* 2016;FWCI78.9), thrombolysis (**Gershlick**:*JAMA* 2019;FWCI20.9) and thrombectomy (**Gershlick**:*NEJM* 2015;FWCI51.6), and secondary prevention with combination anti-platelet therapy (**Gershlick**:*JAMA* 2016;FWCI69.7). We identified the first common genetic variant associated with Spontaneous Coronary Artery Dissection (SCAD) (**Adlam**:*JACC* 2019;FWCI9.9) leading to publication of the first European Position Statement on this condition, and supporting the US Consensus documents for SCAD and Fibromuscular dysplasia. We have two patented devices currently in development: the lithocatheter, an angioplasty device designed to tackle calcified, tortuous, and chronically occluded arteries (MRC-funded), and the PAL-VAD device, an extracardiac left ventricular assist device (BHF-funded).

Our cardiovascular data group integrates nationally and internationally available data to answer questions relevant to patient care, for example: the VICORI programme for the first time linked national cancer and cardiovascular audits with other datasets to support the understanding of the interaction between cancer and heart disease in UK patients. Our research on **Stroke** has focussed on hypertension; a common clinical management problem following acute stroke. This has led to revisions of UK, European and US guidelines for the management of hypertension following intracerebral haemorrhage (**ICS3, Robinson**) and peri-thrombolysis for ischaemic stroke (**Robinson**:*Lancet* 2019;FWCI28.9). The ENCHANTED trial of low-dose intravenous thrombolysis has supported individual patient decision-making and management (**Robinson**:*NEJM* 2016;FWCI31.4), as reflected in the latest UK guidelines (Intercollegiate Stroke Working Party, Royal College of Physicians, 2016).

In **Emergency medicine**, our research focuses on two key areas: trauma, particularly the use of tranexamic acid (**ICS1, Coats**); and sepsis, a growing worldwide problem with UK

(**Coats:NEJM** 2015;FWCI130.1) and international collaborative research (**Coats:NEJM** 2017;FWCI34.6), changing international sepsis management guidelines away from goal-directed approaches. We host a **BHF Chair in Cardiac Surgery (Murphy)** undertaking clinical trials to reduce renal complications of cardiac surgery and their modification by diabetes and diet, as well as the adverse impacts of blood transfusion (**Murphy:NEJM** 2015;FWCI59.7). Finally, research in **Renal Sciences (Barratt, Burton, Graham-Brown with Brunskill and Major [UoA2], Didangelos [UoA5] and Smith [UoA24])** includes leadership of global Phase II and III clinical trials of new therapies for IgA nephropathy (**Barratt:Lancet** 2017;FWCI14.3), a programme of NIHR-funded research into lifestyle and exercise on dialysis that culminated in the CYCLE-HD trial as the world's first randomised trial of in-centre nocturnal haemodialysis, and the use of big data to report on risk factors for progression and outcomes in chronic kidney disease (see Brunskill [UoA2]).

### 1.2.2. RESPIRATORY MEDICINE (9FTE)

Leicester is a global leader in **respiratory research** with researchers investigating asthma, COPD, lung infections (especially TB and pneumonia), rehabilitation science, and pulmonary fibrosis. Our innovative research spans fundamental discovery science through to clinical implementation. In an independent worldwide assessment, Leicester had the third highest number of publications amongst the top 100 cited papers in asthma between 1960 and 2017 (doi:j.rmed.2018.03.014). We host the Leicester **Institute for Lung Health**, the **MRC/EPSRC National Breathomics Centre**, the **Centre for Environmental Health and Sustainability**, and the **Leicester Microbial Sciences and Infectious Diseases Centre**. The key components of our research are based around three areas:

**1.2.2.1. Discovery.** We lead several international consortia in the genetics of lung function in health and disease. These have led to the identification of numerous novel risk loci for lung function (**Tobin:Nat Genetics** 2014;FWCI3.35; *Lancet Resp Med* 2016;FWCI12.8), COPD (**Tobin:Nat Genetics** 2017;FWCI8.56; *Nat Genetics* 2019;FWCI10.95), asthma and interstitial lung disease. We examine the expression and function of the molecular targets identified in these studies to determine their therapeutic potential (e.g., IL33/ST2 [**Cousins:AJRCCM** 2014;FWCI13.53]). We are now undertaking a single-centre academic led clinical trial of anti-ST2 in COPD (COPD-ST2OP). We were first to identify an important interplay between T2 and T17-mediated immunity in asthma (**Bradding:Sci Trans Med** 2015;FWCI27.74). A novel potential therapy developed at Genentech targeting both IL-13 and IL-17 is now in early phase development. We were the first to demonstrate a role for prostaglandin D2 type 2 receptor (DP2) antagonists in decreasing airway smooth muscle mass in asthma (**Siddiqui:Sci Trans Med** 2019FWCI5.31) and its effects on airway inflammation in a phase 2 single centre study (**Siddiqui:Lancet Resp Med** 2016;FWCI13.18). Based on these findings, several DP2 antagonists are now in late phase development for asthma.

**1.2.2.2 Biomarkers and Phenotypes.** Our ground-breaking phenotyping research in asthma and COPD led to the development of blood and sputum eosinophilia as biomarkers of severe asthma and the first novel class of therapeutics for over 15 years (Wardlaw ICS UoA5; **Brightling:Lancet Resp Med** 2014;FWCI10.74). This has transformed the treatment of severe asthma and is part of international guidelines. We coordinate the national **MRC/EPSRC Breathomics centre 'EMBER'** through which we are developing novel biomarkers for diagnosis of different causes of breathlessness, response to biologics, and microbial infection (**Haldar:Nat Comm** 2018;FWCI4.01). These signatures are being patented as part of our commercialisation plan. We are working with Mologic Ltd on urinary

signatures to predict exacerbations of airways disease (MailOnline) and are validating a neural network algorithm and home testing kit, which will be published once patents are secured. In addition, we have developed a novel face mask test to rapidly detect early active tuberculosis (**Barer**; *Lancet Infect Dis* 2020;FWCI2.19), which is being adapted for COVID19 testing.

**1.2.2.3. Clinical Interventions.** We have led anti-IL5 receptor trials for COPD (**Brightling**; *Lancet Resp Med* 2014;FWCI10.74), as well as anti-IL13 late phase programmes (**Brightling**; *Lancet Resp Med* 2018;FWCI14.22) and aligned mechanistic trials (**Brightling**; *Lancet Resp Med* 2019;FWCI8.77). An anti-IL4R $\alpha$  biologic, targeting the IL4 and IL13 receptor, is now a newly licensed therapy for severe asthma. We are currently leading mechanistic trials of anti-thymic stromal lymphoietin (CASCADE) and anti-IL5R for asthma (CHINOOK) and anti-ST2 for COPD (COPD-ST2OP), as well as an anti-IL5 study in the acute setting for COPD (COPD-HELP). We have led the early and late phase trials for anti-DP2 in asthma (**Siddiqui**; *Lancet Resp Med* 2016;FWCI13.18). The latest phase 3 trials did not meet their primary endpoint but other DP2 antagonists remain in late phase trials.

### 1.2.3. DIABETES (4FTE)

The multi-disciplinary Diabetes Research Centre (DRC; **Davies** with Khunti [UoA2] and Edwardson, Evans, Harrington, Rowlands and Yates [UoA24]), established in 2012, is the only UK centre of its type recognised by the International Diabetes Federation, and one of only seven in Europe that can push new innovations/interventions from experimental investigations of mechanism and efficacy in diabetes prevention and management, to developing services that are commissioned within routine primary care and directly improve patient outcomes. Together with the **Centre for Black and Minority Ethnic Health**, a unique aspect of our DRC is the ability to focus on the increasing prevalence of Type 2 Diabetes (T2DM) in an ethnic minority population. **Davies** leads major programmes assessing new therapies in T2DM, including the first study of a Glucagon Like Peptide 1 Receptor Agonists (GLP-1 RA) therapy for obesity in T2DM (**Davies**; *JAMA* 2015;FWCI41.3) and the largest phase 3 trial of an oral GLP-1 RA (**Davies**; *JAMA* 2019;FWCI43.6). Our academic obstetrics group (**Baker, Stewart, Tan**) dovetails with the DRC by bringing together biomarker and cardiometabolic expertise. Diabetes is associated with adverse outcomes in pregnancy, including pre-eclampsia and fetal growth restriction and our research aims to improve outcomes in this area by conducting trials that explore underlying mechanisms, improve glucose control (**Stewart**; *Lancet* 2017;FWCI25.3; *NEJM* 2016;FWCI14.7) and re-purpose drugs (**Baker**; *Lancet Child Adoles Health* 2018;FWCI16.1).

### 1.2.4. CANCER & PATHOLOGY RESEARCH (10FTE)

Although small in number, we are a leading cancer centre with global reach, committed to improving survival from cancer in an ageing population. Key contributions are in four areas:

**1.2.4.1. Clinical Interventions.** We deliver novel adaptive early phase clinical trials to establish new treatment paradigms through the Leicester ECMC, underpinned by our unique, state-of-the Art Hope Against Cancer Clinical Trials Facility (CTF), purpose-built to deliver early phase haemato-oncology trials (£12.4M external funding since 2012). This is exemplified by our leadership of the British Lung Foundation-funded MiST study, the world's first molecular stratified umbrella trial aimed at accelerating effective therapy for mesothelioma. We led on the global first-in-man trial of the BTK inhibitor ONO/GS-4059 in relapsed/chemotherapy refractory B-cell malignancies that demonstrated a practice-changing improvement of median survival and durable remission (**Walter**; *Blood*

2016;FWCI9.47) and identified the anti-EGFR therapy Panitumumab is as effective as cetuximab in the treatment of <sup>WT</sup>KRAS colorectal cancer (CRC) (**Thomas**:*Lancet Oncology* 2014;FWCI12.13), with these results leading to **FDA approval** of panitumumab in 2017.

**1.2.4.2. Therapeutic Prevention.** A strong emphasis is on the development of agents that can delay or prevent cancer, recognised by the recent award of £5.8M by CRUK for a 1500 patient platform trial. We have used mouse models and human window trials to define optimal dosing and surrogate biomarkers of potential efficacy, with our studies demonstrating a nonlinear dose response for the protective effects of the dietary agent resveratrol, establishing the new paradigm 'more is not better' in therapeutic prevention (**Brown**:*Science Translational Medicine* 2015;FWCI12.18).

**1.2.4.3. Biomarkers: Shaw** is internationally recognized as a leader in the liquid biopsy field. Her work concurrently profiling mutations and gene amplification in circulating tumour (ct) DNA and circulating tumour cells (CTCs) has driven new innovations in personalised medicine and early detection. In breast cancer, we showed that personalised ctDNA assays detected molecular relapse up to two years ahead of clinical relapse in all patients, providing a critical window of opportunity for additional therapeutic intervention (**Shaw**:*Clinical Can Res* 2019;FWCI3.78). This research with Natera Inc supported the FDA 'Breakthrough Device' designation (10 May 2019) for their Signatera™ ctDNA test. We are ctDNA and pathology leads for the national £13M CRUK TRACERx phylogenetic lung cancer trial, which provided the first evidence that ctDNA profiling can identify sub-clonal dynamics and chemotherapy resistance before CT scanning (**Shaw**:*Nature* 2017;FWCI28.94), whilst unravelling the extent of intratumoural heterogeneity and its impact on increased risk of death (Le Quesne;*NEJM* 2017;FWCI120.57).

**1.2.4.4. Discovery:** We use mouse and human preclinical models to generate mechanistic insights and identify novel therapeutic targets. Mouse model studies have identified mTORC1 as a therapeutic target controlling translational elongation in CRC (Willis:*Nature* 2014;FWCI5.67), and novel mechanisms underpinning mesothelioma (Willis:*Current Biology* 2017;FWCI4.15) and lung adenocarcinoma (**Pritchard**:*Cell Reports* 2020) development. Preclinical models that can predict patient responses to novel therapeutics including immunotherapies are much sought after and hence investment in an innovative patient-derived explant platform, regarded as a 'bright beacon' by leaders in the 3D modelling field (**Pritchard**:*Cancer Research* 2017;FWCI1.82).

**1.2.4.5. Forensic Pathology** is aligned to our clinical medicine programmes with our Unit being the only academic unit of its type in the UK. A major advance is the demonstration of the diagnostic accuracy of post-mortem CT (PMCT) enhanced with targeted coronary angiography (**Morgan**:*Lancet* 2017;FWCI9.23). Implementation of PMCT as a first line technique to avoid invasive autopsy in disaster zones such as Grenfell Tower and the religious/cultural benefits to Muslim communities is highlighted in **ICS4 (Rutty)**. PMCT studies were also instrumental in the diagnosis of perimortem trauma and scoliosis in the skeletal remains of Richard III (**Rutty**:*Lancet* 2015;FWCI4.34).

## 1.2 FUTURE STRATEGY

As part of the University's 'Reshaping for Excellence' process, we will consolidate and extend our translational and clinical strengths in Cardiovascular, Diabetes and Lifestyle, Respiratory, Cancer, and Clinical Data Science towards renewal of our NIHR-BRC and ECMC. In collaboration with our main NHS partners, this will include targeted investment in ECRs, provision of support for innovation and collaboration among established

investigators and enable us to undertake improvements in equipment and infrastructure. Our renewed strategy will increase 'bench-to-bedside' translation by bringing together core facilities and new research platforms, allowing them to be pivot points around which fundamental, clinical and applied scientists can interact and generate interdisciplinary collaborations. In turn, this will lead to greater research and enterprise success.

## Section 2. People

### 2.1. OVERVIEW

Our research progress and innovations during this REF period were made possible by the outstanding **endeavour and commitment of our staff and students**. Critical to enhancing performance, has been our strategy of embedding high quality **personal development support** at all levels and in all professional groups, the delivery of a rigorous **EDI agenda** combined with **targeted and strategically-aligned recruitment and retention** of high-quality staff. Enhancement of the wellbeing of our staff is a common thread and has resulted in **high levels of staff satisfaction** with opportunities for promotion, leadership and career development (>80% in all categories; CLS staff survey 2019), and high rates of **overall satisfaction** (>80%) among our PGRs.

### 2.2. STAFFING STRATEGY AND STAFF DEVELOPMENT

Leicester takes great pride in its ability to **support the careers of its staff**, with strong commitments **to career progression, EDI and ECR development**. In 2020, the University retained its **HR Excellence in Research Award** following an 8-year review, which recognises implementation of the principles of the Concordat to support the Career development of researchers, demonstrating our **long-term commitment** to these principles. A key element to this has been introduction of the flagship **Leicester Academic Career Map (LACM)**, which identifies and reviews developmental objectives within the key domains of research, teaching, enterprise, leadership, and citizenship. Formal personal development discussions (PDDs) are undertaken annually to support promotion and career progression and have resulted in the appointment of six Leicester-based ECRs to permanent contracts and the promotion of five staff from Associate Professor to Professor within this UoA; thus **21% of returned staff were promoted during this REF period**.

#### 2.2.1. Clinical Academic Career Development

86% of staff (39.6FTE) are clinical academics and **29% (12FTE) are clinical academic ECRs**; **8** the product of Leicester's clinical academic career development pathway. A key factor in supporting progression has been the establishment of an integrated approach for managing clinical academic careers from trainee level to senior leadership. This has been achieved by linking various elements of the career path with **strong mentorship and alignment with external funding bodies, particularly NIHR**. This is enhanced by national representation of our staff on several clinical academic training panels including NIHR (**Davies, Bown, McCann**), Kidney Research UK (**Barratt, Burton**), MRC (**Tobin**), National Pre-hospital Emergency Medicine (**Rutty**) and National Integrated Academic Training Advisory Committee (**Bown, Barratt (Chair)**).

At undergraduate level, we have revised our intercalated BSc offer and introduced an intercalated MSc, allowing medical students to undertake a dedicated 9-month research period. Thereafter, our clinical academic trainees are encouraged to enter the **Academic Foundation programme**, which links with our established **NIHR Integrated Academic**



**Training pathway.** Leicester has a strong track-record of supporting NIHR Academic Clinical Fellows (61 during this REF period, an improvement from 49 in REF2014) who undertake a MRes in Clinical Sciences, comprising taught modules in qualitative and quantitative research methods, and a dissertation. Following ACF training, significant support for PhD/MD fellowship applications is provided. During this REF period, **54 clinical PhD/MD students** were supported to completion; 19 of these were externally funded (NIHR/UKRI/Association for Medical Research Charities (AMRC) or other).

Following their PhD/MD, trainee clinical academics are encouraged to continue on an academic track by pursuing either a **Clinical Lectureship (CL)** and/or by securing **external intermediate-level fellowships**. Since 2014, 12 of our trainees have progressed to CL positions, 7 of whom are returned in this submission, and we currently host **10 NIHR/AMRC Clinician Scientist Fellows**. Since 2014 our CLS/fellows have obtained >£600k in project grant funding as PIs and contributed to awards >£3.3M as CIs. CL/fellows are extensively mentored through the next transition to a full clinical academic post. Examples of successful transition are: **Walter** progressing from AMRC-funded PhD fellow through to CRUK clinical fellow and now to an Associate Professor post; **Burton** was a Leicester trainee who progressed to full Professor and is now a NIHR clinician scientist.

### 2.2.2. Non-clinical Academic Career Development

This UoA1 includes submission of 7 non-clinical researchers (6.0FTE) who have a **strong translational profile** supporting clinical implementation of discovery research. Most non-clinical academics are returned in UoAs 2, 5 and 24, and therefore non-clinical academic career development is considered more broadly. As with the clinical academic career pathway, we have improved **support for non-clinical academics and ECRs** through active career management in the form of shadowing initiatives, leadership programmes, coaching and mentorship. This is underpinned by the national training roles of some of our staff including CRUK New Investigator Committee member (**Pritchard**) and ECMC Junior Investigator Group Lead (**Brown**). Our investment in career development has generated positive outcomes with the support of 53 non-clinical staff to Associate Professor and 29 to Professor across CLS. Retaining key staff is also vital for a sustainable research culture and we have had some noticeable successes as reflected in the award of Wolfson-Royal Society merit awards to **Cooper** and **Pritchard**.

### 2.2.3. Retention and recruitment

Strategic recruitment of established and potential future leaders has been directed to priority areas. We recruited: **Phil Baker** from the New Zealand Gravidia Centre as Pro-Vice-Chancellor and Dean of Medicine, and to strengthen our links between cardiometabolic disease to obstetrics, **Andrea Cooper** from the Trudeau Institute USA and **David Cousins** from Kings College London to strengthen immunology research in Respiratory Sciences, **John Le Quesne** from the CRUK Cambridge Institute to fill a gap in cancer pathology, **Toru Suzuki** from the University of Tokyo to lead our metabolomics and clinical data science initiatives and interests in aortic aneurysm, **David Adlam** from Oxford University for his interests in SCAD and development of coronary intervention devices, and **Bee Tan** from Warwick University to integrate diabetes research with obstetrics.

A further significant step has been the **appointment of NHS staff to honorary positions**, facilitated by the LAHP and LPMI, through an annual round. Applications are assessed

against the LACM, resulting in 24 appointed to Honorary Chair and 45 to Honorary Associate Professor. Titles are awarded in an annual ceremony with a high profile invited guest lecture to celebrate links between the organisations. The production of many joint publications and grants testify to the success of this approach, as has the transition of key NHS staff to joint UoL contracts (**Gershlick, McCann, Moss, Burton**).

### 2.3 POSTGRADUATE (PGR) STUDENTS

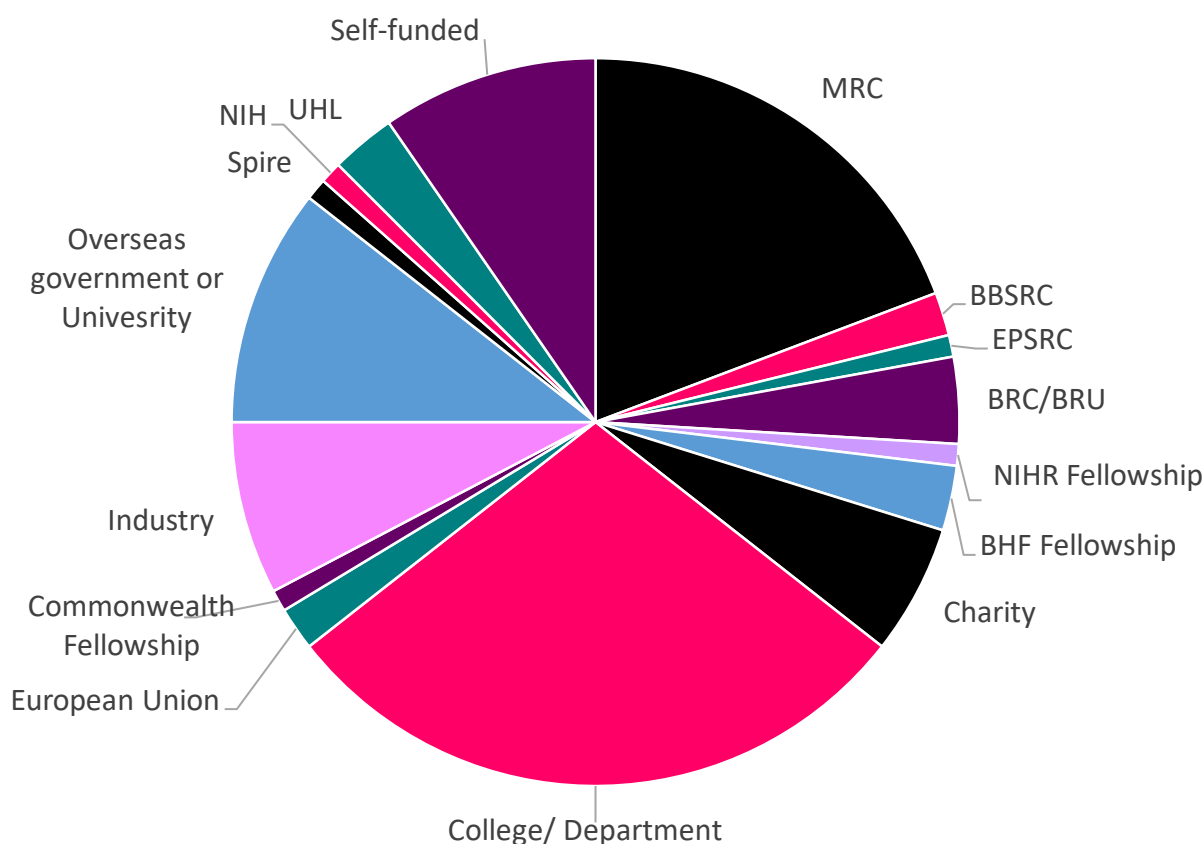
PGRs are an essential part of our research community, and we are committed to ensuring they receive excellent support and training. The University's Doctoral College (DC) was launched in 2017 to replace the previous Graduate School, with a wider remit extending across the early-stage career journey to promote seamless transition. Through our high-quality training programmes, first rate supervision and provision of many opportunities for career progression, we aim to develop **rigorous and intrepid researchers**, both clinical and non-clinical, with world-class capabilities in the leadership, execution, and communication of research, prepared for both academic and non-academic careers across the globe. Evidence of our success is reflected in **consistently higher levels of student satisfaction compared to the sector average** (see below).

#### 2.3.1. Recruitment

198 PGRs across UoA1 disciplines graduated in this REF period, of whom 28% were clinically qualified. The rate of completion was 100%, increasing from 82% in REF2014. We are proud of the diversity of our UoA1 PGR cohort (41% female and 35% BAME), encompassing 32 nationalities: 57% from outside of the UK. In addition to the opportunities for clinical trainees mentioned previously, students within UoA1 are supported by four doctoral training programmes (DTPs):

- **MRC IMPACT** DTP that supports 14 students/annum between the Universities of Birmingham, Nottingham, and Leicester (**total £3.5M** with matched contribution from each institution). Research projects focus on the theme of Complex Disease.
- **BBSRC MIBTP** DTP delivers innovative research across the Life Sciences economy that includes Integrated Understanding of Health. Initially running from 2015-19, the programme was renewed in 2020 and includes the Universities of Warwick, Birmingham, Leicester, Aston, and Harper Adams (**total £20M**), supporting ~60 students/annum and 9 iCASE students/annum.
- **Wellcome Trust** DTP in Genetic Epidemiology and Public Health Genomics (**PI:Tobin, £5.15M**) supports 8 students/annum and focusses on better understanding of the role of genetic factors in health and disease, with a particular focus on inclusivity of under-represented groups.
- **BHF** 4-year PhD programme in interdisciplinary cardiovascular research linked with UHL (**£1.64M**) supporting 3 students/annum with matched CLS funding for 2 students/annum.

Many other PGRs are supported by external funders including industry, NIHR, UKRI, AMRC, EU, NHS, or by internal funding allocated through the BRC, LPMI and College. Overseas government sponsored and self-funded students comprise an additional cohort, representing ~15% of students.



**Figure 2: Source of PGR funding**

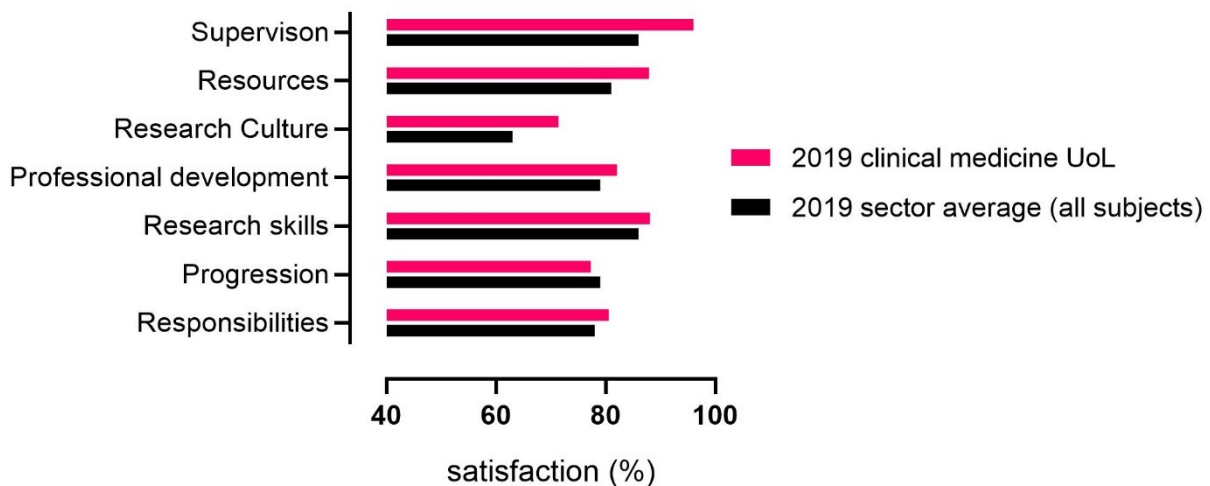
In recognition of the **disruption to PGR training caused by the COVID-19 pandemic**, Leicester provided additional support of **£272k** in the form of funded extensions, fee waivers and emergency hardship funds. This was sector-leading and was incredibly well received by our PGR community. A future ambition over the next REF cycle is to grow our PGR community by securing additional externally funded DTPs, and to re-build our international PGR community post-pandemic.

### 2.3.2. Support, Training and Satisfaction

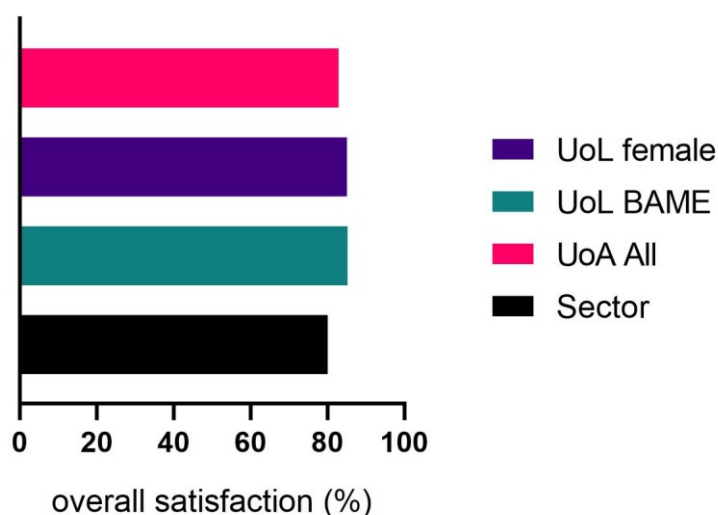
The PGR training programme is based on the skills and experience that UKRI expects PGRs to develop, informed by **Vitae's Researcher Development Framework**. There are **>160 training opportunities** including: research ethics and integrity, research effectiveness (including advanced literature searching, working with big data, visualising data, using bibliographic software and FigShare), academic writing, quantitative methods (including R and SPSS), designing and measuring impact, and media skills. Students benefit from training with industrial sponsors, and our students always enter the national BBSRC Biotechnology Young Entrepreneurs' Scheme (YES), winning in both 2014 and

2018. The DC provides excellent opportunities for PGRs to showcase their research and network. These include: Pint of Science and PubhD; Cafe Research; Three-minute thesis presentations; Doctoral inaugural lectures; Images of Research exhibition; and the Festival of Postgraduate Research, where some of the University’s best students, selected competitively, present their cutting-edge research to academics, employers, and the public. The Career Development Service provides advice for students on career planning, preparing job applications and CVs, as well as hosting career events focused on subject areas in and outside academia. Inspirational career talks by leading female and male academics are key components of this PGR experience. PGRs have an increased offering for their health and wellbeing, including access to both student and staff provisions, a range of 24-hour counselling and supporting services (SilverCloud, Validium) and a series of proactive sessions (Mental Health First Aid Training, Stress Management, Resilience).

The Postgraduate Research Experience Survey (PRES) 2019/2020 results indicate consistently high PGR satisfaction rates across many themes compared to the sector average across all subjects (Figure 3). Overall rates of PGR satisfaction were consistently high for our PGRs, with female and BAME PGRs reported similar levels of overall satisfaction to all (Figure 4).



**Figure 3:** PRES data showing sector comparisons across areas



**Figure 4:** PRES data for overall satisfaction for Clinical Medicine PGR Students

### 2.3.3. PGR integration in the research community, outputs, and awards

PGR students are fully embedded in our research culture, with opportunities to give presentations, co-author papers and attend conferences. Each PGR student is aligned to a research group and participates in group meetings and journal clubs. They are expected to attend Departmental, College and University seminars, and give talks/posters at PGR research days, which PIs, post-docs and fellows also attend.

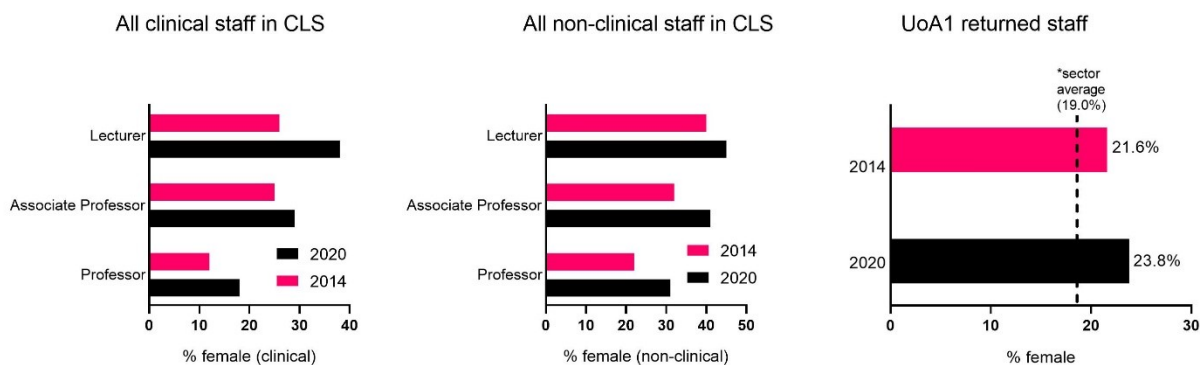
The quality of our PGR cohort is reflected in the large proportion of our submitted outputs that include PhD students as co-authors (34%). Notable examples include: a first authorship for **Walter**, now an Associate Professor, documenting early phase studies of BTK inhibitors in mature B-cell malignancies, which has transformed the treatment of CLL patients (**Walter;Blood** 2016;FWCI9.47); first authorship for **Singh**, now NIHR Fellow, showing that women tolerate pressure overload with greater symptoms in aortic stenosis (**Singh;JACC** 2019;FWC10.65). PhD student Nuzhat Ashra was an invited contributor to an E-life sciences blog and diversity workshop, convened by the MRC, to identify barriers that BAME students face in their careers. All PhD students are expected to present data at a major international conference and the success of our students is reflected in a high number of national/international awards including: Mensa International Scholarship award 2017; FindaPhD PhD Student of the year 2019; Frank Ellis medal in radiology 2020; Four students selected for the Roche Continents' programme celebrating 100 top-talented students across Europe.

## 2.4. EQUALITY AND DIVERSITY

We are a diverse University embedded within a multi-cultural city. EDI is embedded in the University's Strategic Plan and is central to the vision of our new Vice-Chancellor, Nishan Canagarajah (appointed 2019) who has taken on the EDI lead role for the University. A University-wide culture of inclusion is outlined in the institutional environment statement (section 3.1) and encompasses all aspects of our activity. Of relevance to UoA1 is our increased ethnicity-focussed research including the **Centre for BME Health**, which is underpinned by our **leadership of the NIHR-ARC for ethnicity, diversity, and**

**inclusivity.**

We have had particular success in **promoting the careers of female academics**: the proportion of female clinical academics has **increased across all grades** in CLS for both clinical and non-clinical staff and we have improved **female representation in UoA1 compared to REF2014 and national benchmarks** (Figure 5). This has provided an exciting new cohort of female role models at all levels. CLS obtained an Athena SWAN Silver award in 2019.



**Figure 5:** Changes in the proportion of female academic staff in CLS between 2014 and 2020. (\*Medical Schools Council data 2018).

We have supported successful external schemes to promote the return of women to academia, including five Daphne Jackson Fellows since 2013 (two progressing to new positions in CLS and Oxford University). In addition, we are **delighted to have supported the appointment of more staff reporting as BAME** across CLS and report **significant enhancement in BAME representation in UoA1** (28%) compared to REF2014 (19%) and national benchmarks (16%).

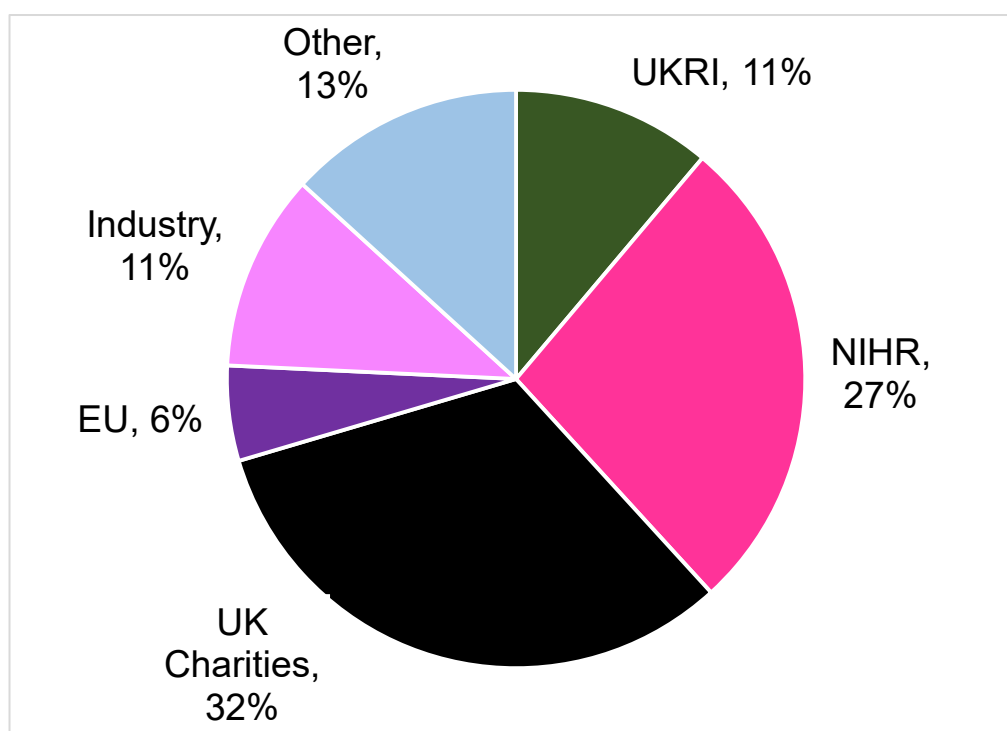
Key to this success has been the introduction of several new practices and procedures. Since 2015, we have ensured fairness and transparency in recruitment and funding decisions by: explicitly stating that applications from under-represented groups are encouraged, engaging search consultants to target specific groups, mandating shortlists that comprise both men and women; and including female, male and BAME informal contacts for job adverts. We include our EDI credentials, logos and a clear statement of inclusivity on job adverts, and our webpages feature our diverse staff and student body. We advertise for part-time, flexible and job-share working options wherever possible and hold all interviews in core hours. We have ensured gender and BAME representation on all shortlist/interview teams and all staff conducting interviews have mandatory Recruitment and Selection, EDI and unconscious bias training. Reasonable adjustments are made for circumstances impacting on a candidate's contribution, e.g., disability, maternity/caring leave, part-time working, and workload models are adjusted to take account of fractional contracts. There are Diversity Champions in every department. Leadership Training has been a strategic area of development, with training increasing in both the number of places and career stage. For example, 10 members of our Unit (3 female) took part in our Future Leaders Programme.

Departments have funded Aurora Training places and three of our Aurora alumni ran a popular 'Women in Leadership' event series for CLS in 2016. We have initiated, enhanced, and embedded strategies to recruit, support, promote and retain women and BAME colleagues through a 'Pathway to Progression' strategy, developed via a Head of Department Project, which comprises a range of interventions for research/academic staff, to ensure women and BAME colleagues receive support at critical points. We have stepped up mentorship using a 'Mentor Connect Scheme' such that ~30% of staff now have a mentor and have doubled our pool of mentors to 95 across CLS. The staff BAME forum is working with the VC to improve the visibility of BAME staff across all grades and areas. This includes actively recruiting BAME staff to senior positions, actively promoting existing BAME staff by a combination of training and job, and by being both outward-facing and inward-looking in tackling Race inequality. Our EDI Action Plan and REF 5-year strategy will continue to invest in and develop these plans as we recognise we have more work to do to achieve 50% female staff at all grades and higher BAME representation to mirror the student body and national demographic.

### Section 3. Income, infrastructure and facilities

#### 3.1. INCOME

Our income portfolio is extensive and diverse. Over the REF2021 period, we have been awarded a total of £110M with an income of £100M, representing an increase of 25.5% compared to REF2014. We have also doubled our income per FTE (£2.2M/FTE). We have substantial funding from NIHR, MRC, BHF, CRUK, Wellcome Trust, industry, and other organisations to support research, infrastructure, facilities, and externally-funded centres (Figure 6), excluding substantial philanthropic donations of £16M.



**Figure 6:** Proportion of income by funding source

One of our key strategic goals has been to deliver transformative outcomes for patients, and this has been underpinned by significant funding for investigator-led clinical trials. These are extensive, and co-terminus with the NIHR-accredited Leicester CTU, activities in the NHS Trust and industrial partnerships. Significant levels of investment in this area are: £5.8M CRUK clinical trial award to identify and implement novel cancer prevention strategies (**Brown/Thomas**), £5.2M NIHR funding for the national PHOSP-COVID clinical trial (**Brightling**), £4M British Lung Foundation investment in mesothelioma clinical trials (**Fennell/Thomas**), £2.5M clinical study funded by GSK to examine Mepolizimab efficacy in COPD (**Brightling**), £2.3M NIHR programme grant to study multicomponent cardiovascular screening (**Bown**), £1.7M study funded by Novo Nordisk in obesity to investigate GLP-1 RA Larglutide (**Davies**), and awards in cardiovascular disease totalling £4.72M to examine the efficacy of novel interventional agents (**Murphy**). Leicester is also regarded as an international centre for dialysis research as reflected by the award of a recent £2.1M NIHR HTA grant (**Burton**).

Other research awards cover basic and translational research endeavours funded by government and charity with highlights including CRUK programme awards totalling £7.2M (**Brown, Pritchard, Shaw**); £2.04M BHF award (**Samani**); £2.2M MRC Pathology Node award (**Brightling**); and £1.3M Wellcome Trust award (**Tobin**). In cardiovascular disease, research priorities are funded by numerous programme grants in arrhythmia (£865K; BHF **Ng GA**), cardiac surgery (£1.4M; BHF **Murphy**), genomics (£2M; MRC **Samani**), stroke (£1.6M; BHF/TSA **Robinson**), and vascular surgery (£882k; BHF **Bown**). Other key awards include: a £1.8M MRC/NIHR Beat Severe Asthma (**Siddiqui**), a £1M MRC programme award for tuberculosis research (**Cooper**), multiple NIHR projects including (NHS/UK Space Agency Award – P-STEP, £2M **Ng A**), EXTEND (diabetes self-management, £594k **Davies**), and BREATHE-health data research hub for Respiratory Health (Chief Scientific Officer: **Tobin**).

Our support for career development (Section 2) has translated into significant successes in supporting individuals through NIHR, MRC, Wellcome Trust and BHF fellowships and personal awards, including BHF-funded personal chair awards to **Samani** (£1.75M, until he stepped down to take on the role of BHF Medical Director) and **Murphy** (£1.8M), NIHR Research Professor to **McCann**, NIHR senior investigator awards to **Brightling, Davies, Robinson** and **Samani**, an MRC Senior Clinical fellowship to **Tobin** (£1M). An NIHR Fellowship to **Singh**, and Wellcome Trust awards to **Haldar** (£1.2M) and **Tobin** (£1.3M). The senior fellowship awards to **Tobin** have allowed him to develop large-scale genomic epidemiology approaches to study the natural history of lung function and COPD, which form a key strategic priority of this UoA. The George Davies Foundation (£5.2M) provided support for a Chair in Vascular Surgery (Sayers [UoA2]) and associated research programmes in multi-morbidity in a frail older population with peripheral vascular disease and at risk of amputation, while the Mayer Foundation (£3.4M) supports the Mayer Chair in Nephrology (**PI: Barratt**) and associated research programmes in IgA Nephropathy, as well as further philanthropic donation of £2M from the Stoneygate Foundation to support our wider renal research.

### 3.2. INFRASTRUCTURE AND FACILITIES

A major aim of the strategic objectives in REF2014 was to establish an NIHR BRC, and this was successfully achieved in 2016 (Director: **Davies**, £11.6M) incorporating Cardiovascular,



Respiratory and Lifestyle themes (formerly, BRUs). Investigators working within the Cardiovascular and Respiratory research themes of the BRC are co-located on the refurbished Glenfield Hospital site, which has been ranked 29<sup>th</sup> in the World (3<sup>rd</sup> in the UK behind the Wellcome Trust Sanger Institute and the Wellcome Trust) in the 2018 Times Higher Education League Table, based on Field Weighted Citation Impact (3.33) and Number of Publications (823).

The **Cardiovascular** Department benefited from a significant infrastructure investment of £12.3M comprising a BHF award of £3M, by £7.6M from UoL and £2M philanthropic donations, to establish the Cardiovascular Research Centre (**Samani**), supplemented by key philanthropic donations including £7M from the Van Geest Foundation to establish the Van Geest Multi-Omics Facility (**Ng L, Suzuki** and Jones [UoA5]), which has leveraged an additional £2M industrial income, and £2M of additional institutional support. The cardiovascular imaging research group (**McCann, Arnold, Singh**) has accumulated significant external infrastructure awards including £2.2M from the NIHR and £1M from the BHF. Other infrastructure awards include: £1M BHF Research Accelerator Award (**Murphy**); £150k MRC award as part of the UK consortium Metabolic Phenotyping (**Suzuki**).

In Respiratory Disease, there is a 2500m<sup>2</sup> dedicated respiratory research facility with immunohistology, cytology and cell culture laboratories. During this REF period, advanced flow cytometry and cell sorting capabilities have been established, funded by a Wellcome Trust Multi-user equipment award (£300k plus £150k University Funds; **Cousins** and Cowley [UoA5]). We have an advanced microscopy facility (IES, 4.2) and run the largest airway inflammatory service in the world analysing >2000 sputum slides per year and hosting the national £2.2M MRC/EPSRC Breathomics Centre (EMBER). The laboratories are ISO9001-accredited and have acted as a central laboratory for over 30 clinical studies. This facility is co-located with the clinical respiratory service, based at Glenfield Hospital, which serves a local population of 1 million, and a tertiary respiratory population of 3 million, and provides the largest bed-base with the greatest number of acute respiratory admissions to a single UK site. There is also an aerobiology laboratory, studying the role of fungi in respiratory disease, which is well connected to core facilities on the main University campus. These facilities and capabilities were funded by NIHR, Wellcome and EDRF with University and NHS matched support totalling ~£8M.

The Diabetes Research Centre is located at the Leicester General Hospital in 4500m<sup>2</sup> refurbished research space (£2M) housed directly above the busy diabetes outpatients service with a dedicated metabolic and physical activity laboratory (also returned to UoA24). The DRC hosts core and associated research infrastructure, including ~150 staff: the NIHR Leicester BRC Lifestyle theme, the East Midlands ARC, the Centre for BME Health, and the Real World Evidence Unit.

The £42M George Davies Centre (IES, 4.2), completed in 2016, and the UK's largest non-residential Passivhaus building, has provided a new hub for the Medical School and non-laboratory-based clinical and non-clinical researchers. Investment in bioinformatics and biostatistics has been key to support our transformative research and it is delivered through the Bioinformatics and Biostatistics Support hub (BBASH), now part of a higher-level alliance BINERI (Biomedical Informatics Network for Education, Research, and Industry) which unifies training, big data analysis, biobanking, ethics, governance, and information

technology. Leicester became the Midlands Substantive Site for the Health Data Research UK institute and access to high-performance computing remains free for all staff and students.

In cancer, UHL delivers all cancer care centrally providing speciality services to a population of 3 million. Through partnership with UHL, we have generated and sustained a critical mass of infrastructure providing the capability to perform all phases of studies including first-in-human, delivered through the Hope Against Cancer-sponsored CTF (**Thomas**). Since 2012, this facility has accounted for ~44% of commercial income to UHL; translating to £12.4M in commercial income and £4.7M in cost savings to the NHS in the last 5 years. We have an exceptional track record of delivering clinical trials as exemplified by the number of companies that use us as a preferred partner (e.g., Novartis), and working with 64 companies in 46 disease areas over the last 5 years. A strategic priority from REF2014 was to grow the facility, which was achieved through additional £1.5M investment from the local Hope Against Cancer charity, allowing the CTF to be extended in 2020. We are a member of a network of 17 national CRUK-NIHR ECMCs (£1.3M, **Thomas, Brown**) and host the Ernest and Helen Scott Haematological Research Institute (**Dyer**), established with £950k in philanthropic donations from the Scott Waudby Trust. The Leicester Molecular Diagnostics Facility (**Shaw**) has secured >£500k investment combined with ISO15189 accreditation, a critical step in the delivery of clinically relevant molecular tests including cfDNA profiling, for the NHS, private healthcare and pharma. Since 2016, the Patient-Derived Explant (PDE) Facility has attracted >£2M from LifeArc, CRUK, Breast Cancer Now and commercial partners (Pfizer, Pierre Fabre) for drug development projects (**Pritchard**). Ongoing therapeutic programmes are facilitated by a £1.6M CRUK network accelerator award, exploiting the structure-guided expertise of UoA5 researchers (**Pritchard** with Carr [UoA5]).

### 3.3. INTERFACE WITH NHS

A major strategic goal from REF2014 was to strengthen the partnership with local NHS organisations, which has been successfully achieved through establishing the LAHP. The LAHP is chaired in rotation by the UoL President/Vice-Chancellor, and Chairs of UHL, and LPT. The LAHP Board includes the LAHP Director (**Brunskill**; also, the UoL/UHL Dean of Clinical Research), the Head of College, Associate Dean for Clinical Affairs, the UoL PVC for Research and Enterprise, the Trusts' Chief Executives, Medical Directors and Directors of Strategy, and the Chief Executive of the East Midlands Academic Health Science Network. The LAHP ensures appropriate deployment of financial, estate and human resource to implement the agreed joint strategic objectives in relation to research and enterprise, and education and training.

There are many other examples of significant collaboration with the NHS, including key NIHR infrastructure projects such as the BRC, ARC (previously CLAHRC), CRF, CRN, ECMC and most recently the hosting one of five UK NIHR patient recruitment centres, plus the honorary appointments process. The success of our partnership is further demonstrated by UHL consistently ranking in the top 15 Trusts recruiting patients and conducting trials (OPD data).

The Head of College and the Associate Dean for Clinical Affairs sit as Non-Executive Directors on the UHL and LPT NHS Trust Boards, respectively. Finally, the University has a close relationship with its Associate Teaching Hospitals, where medical students undertake placements, including Northampton General Hospital NHS Trust (Deputy Head of College is Non-Executive Director) and Kettering General Hospital NHS Foundation

Trust. Apart from the leveraging of externally-funded infrastructure mentioned above, this integration has enabled us to host an NIHR-CRF (Director: Brunskill); the NIHR-CRN: East Midlands (Director: Rowbotham); the NIHR Research Design Service (Director: Williams).

### 3.4. INTERFACE WITH INDUSTRY

Interaction with industry is critical for successful translation of research and has been a particular feature of this REF cycle with strong support from the University. Increased Higher Education Innovation Funding (HEIF) funding over the REF period has supported a range of knowledge exchange activities, and pump-priming of specific areas with the highest impact potential. The University HEIF-funded Proof of Concept scheme for technology maturation and commercialisation routes for intellectual property has provided £195k to UoA1 researchers and provided opportunities for increasing our IP portfolio as exemplified by the Lithocatheter and PAL-VAD devices (see section 1.2.1.2). The Leicester Innovation Hub (IES, 2.5) is a £5.1M programme supported by HEIF funding, the University and the European Regional Development Fund (ERDF). This Hub is the 'front door' to launching great ideas and it provides a dedicated incubation and innovation space, making it easier for companies to utilise innovation support, expertise, and facilities. The Leicester Life Sciences Accelerator (LLSA) (academic lead, **Suzuki**) is funded by a £750k ERDF grant (with equal match from UoL) and delivered in partnership with the Midlands Engine, designed to drive Life Science SME growth within the Leicestershire region. It delivers unique innovation support to SMEs, linking them with the clinical/academic environment at the University of Leicester and the BRC to accelerate product development. A recent example is the development of the self-screening kiosks to detect COVID19 in the workplace in collaboration with Elephant Kiosks Ltd.

In this REF cycle, >£6M pump-priming investment from the University and MRC, administered through the LPMI, has progressed 56 translational research projects towards the clinic. The MRC funded Proximity to Discovery (P2D; £133k) scheme enables visits and initial interactions between academic and industrial partners for knowledge exchange and development of collaborative projects. The MRC Confidence in Concept (CiC; annual awards totalling £1.9M) scheme has been used to initiate academic and industry collaborative projects, and to support translational research development and product development. For example, **McCann** received an award to develop an industrial partnership with Resonance Health Ltd, which led to collaborative industrial research (including in-kind funding from the industry partner), a £1.9M NIHR Research Professorship award, and two BHF Clinical Training fellowships. **Cousins** received an award to develop flow cytometric biomarkers of Type 2 inflammation, which has resulted in collaborative industrial projects with AnaptysBio (£325k) and Genentech (£1.3M). Overall, the return on investment of MRC CiC funding to date has been 11:1. Further evidence of our success in supporting commercialisation of our research is reflected in the success of our spinout companies, with a major highlight being Haemostatix Ltd which was established in 2003 and sold in 2016 to Ergomed PLC following a successful phase 1 clinical trial of its lead product, a topical haemostat to prevent post-surgical bleeding.

We have taken active steps to encourage investigators to work with industry and to attract industrial partners. Key to this has been:

- Creation of the Research and Enterprise Division, and appointment of personnel to support and develop industrial links including a dedicated commercialisation team.

- Appointment of six Business development managers specific to the College of Life Sciences who provide advice on all aspects of opportunities.
- All staff are offered training in commercialisation. Examples include IP and Commercialisation Workshops, and PhD student residential training courses both organised by LPMI using P2D funding.

Our commitment to increased working with industry is reflected in the securing of substantial industry-linked income of £65M during this REF cycle, a near 20-fold increase on REF2014 and 20 patents have been filed by our researchers - a 5-fold increase since 2014. This UoA works with a wide range of industrial partners with notable examples including:

- The **Respiratory Genomic Collaboration** led by **Tobin** undertakes Genome Wide Association Studies (GWAS) to discover novel loci affecting lung function and Chronic Obstructive Pulmonary Disorder (COPD) and separate novel loci for smoking behaviour (smoking initiation, amount smoked and smoking cessation). Ongoing studies include collaborations totalling ~£2M with pharmaceutical companies (GSK, Pfizer, Regeneron, Biogen).
- A **GSK Discovery Partnership with Academia** totalling £9M awarded to haematology researchers **Dyer, Walter**, and emeritus professor Simon Wagner, aimed at developing and testing BCL6 inhibitors for Diffuse Large B-cell Lymphoma.
- A collaboration with **AstraZeneca** on the CHINOOK study totalling £1.8M to evaluate the effect of Benralizumab on airway structure and lung function (**Brightling**).
- Many other industrial collaborations to deliver clinical studies in respiratory disease including £3M investment from GSK (**Brightling**) and £2M investment from Genentech (**Brightling, Cousins**).
- A £1.7M investment from Novo Nordisk (**Davies** with Khunti [UoA2]) for the Cities Changing Diabetes programme to innovate innovative approaches in the prevention and management of T2D.

## Section 4. Collaboration and contribution to the research base, economy and society

### 4.1. COLLABORATION, NETWORKS AND PARTNERSHIPS

UoA1 PIs make a substantial contribution to national and international research through their leadership and membership of academic collaborations, partnerships, and networks. In addition, our PIs have a strong commitment to industrial collaboration and partnerships, and we have benefited from industrial investment of £65M during this REF cycle (see Section 3.4).

### 4.2. CONTRIBUTION TO RESEARCH

The breadth of our collaborative success is evidenced by the fact that the majority of UoA1 senior PIs (24/35) lead and participate in at least 60 national and international networks and consortia. Our academic staff lead and contribute to national and international panels, including of clinical guidelines resulting in patient, societal and economic benefit (see Section 4.2.1) and through our leadership of implementation research with the successive award of an NIHR-CLAHRC, and an NIHR-ARC. Our staff also contribute to the advancement of clinical sciences at the highest level by participation in international and national funding panels (see Section 4.2.1), through journal Editorial Board Chair and membership positions (see Section 4.2.2), and the leadership and organisation of international and national conferences (see Section 4.2.3). Importantly, our research is focused on the delivery of transformative patient outcomes, and

therefore we have exemplars of patient, carer and public participation and collaborative leadership in our research agenda (see Section 4.2.4).

The impact of our contributions has been recognized through a number of prestigious awards and fellowships. These include a Knighthood for Services to Medicine and Medical Research (**Samani** 2015), a CBE for services to Diabetes Research (**Davies** 2016) and MBE for contributions to Forensic Pathology (**Rutty** 2012). We host five Fellows of the Academy of Medical Sciences (**Baker, Brightling, Davies, Samani, Tobin**), four NIHR Senior Investigators (**Brightling, Davies, Robinson, Samani**), an NIHR Research Professor (**McCann**) and two BHF Chairs (**Murphy, Samani**).

We encourage a culture of success in our ECRs, and this is evidenced by our Fellowship successes (see Sections 2.1.1 and 2.1.2). Additionally, we have a track record of ECR recognition through conference awards, and for the importance and relevance of their research to patients and society. For example, **Roman** won a European Society of Organ Transplant Travel Grant for Outstanding Quality of Abstract (2014); **Singh** was awarded a Young Investigator Award by the British Heart Valve Society (2015) and an Early Career Clinical Award by the Society for Cardiovascular Magnetic Resonance (2016); **Moss** secured the Jeremy Wright best oral presentation prize at British and Irish Association of Robotic Gynaecological Surgeons (2015); **Walter** won the Royal College of Physicians and NIHR Trainee Award for contribution to research (2017); **Minhas** was awarded the Royal College of Physicians Quincentennial Lecturer Award (2018); and **Graham-Brown** was the keynote speaker at the Royal College of Physicians Trainees Symposium (2019) and winner of the Raine Award at the UK Renal Association (2020).

#### 4.2.1. Membership of International and National Panels

Our staff contribute to the advancement of clinical sciences at the highest level by participation in advisory boards, committees, and influential policy committees both UK-based and abroad. An exemplar contribution from each of our major research themes is provided:

- In cardiovascular sciences, **Professor Sir Nilesh Samani** is the BHF Medical Director, and Vice-Chair of Main Panel A for REF2021. He is a Fellow of the Academy of Medical Sciences and Emeritus NIHR Senior Investigator. He is recipient of numerous prestigious accolades and awards including most recently the MacKenzie Medal of the British Cardiovascular Society 2020. He co-chaired the Genetics section of the 2019 Topol Review 'Preparing the healthcare workforce to deliver the Digital Future'. He is named in the Top 40 of the GG2 101 most influential Asians (2020).
- In Respiratory Sciences, **Professor Chris Brightling** is a Fellow of the Academy of Medical Sciences and NIHR Senior Investigator. He is Coordinator for several national and international research consortia. He was founding Director of the European Respiratory Society Clinical Research Collaborations and is the current European Respiratory Society Science Council Chair. He is a member of the American College of Chest Physicians' Cough Guidelines, the British Thoracic Society, American Thoracic Society/European Respiratory Society Severe Asthma Guidelines and is on the scientific committee for the Global Initiative for Asthma - GINA. He has been invited as a visiting chair and to receive awards from the Universities of British Columbia and McMaster (Canada), University of California San Francisco and Harvard (USA).
- In Cancer Research, **Professor Anne Thomas** is a Clinical Specialist member of

NICE, member of the NCRI Upper GI and colorectal Clinical Study Groups of the NCRI, member of the MRC Trials Unit Steering Committee and member of the CRUK New Agents Committee. She is Chief Investigator on national studies including CRUK (CTACC) Astra Zeneca/NCRI Collaboration Initiative and leads major clinical trials in cancer prevention, as reflected by the award from CRUK of the £5.9M multi-centre COLOPREVENT study.

- In Diabetes and Lifestyle, **Professor Melanie Davies, CBE**, is a Fellow of the Academy of Medical Sciences and Emeritus NIHR Senior Investigator. She was Chair of the NIHR-BRC Directors' Forum (2017 to 2018) and has multiple influential roles including Scientific advisor to NICE and Chair of the EASD Writing Group, which provides EASD guidelines on the management of hyperglycaemia in type 2 diabetes. **Davies** has had a global impact on the management of diabetes recognised by being ranked 1<sup>st</sup> in the Expertscape list of global diabetes experts (based on publications since 2010) and chairing international guidelines for T2DM management (Diabetes Care and Diabetologia 2018 and 2019).

Several of our staff sit on international and national guideline panels and advisory boards. These include acting as Chair of: the Vascular Society Aortic Special Interest Group (**Bown**), the Chinese International Trauma Rescue & Treatment Association (**Coats**), the ESC-ACCA Spontaneous Coronary Artery Dissection Study Group and ESC-EORP SCAD Registry (**Adlam**), the UK National Post Mortem Radiology Imaging Board (**Rutty**), the Scientific Advisory Board of the Ludwig Boltzmann Institute for Clinical Forensic Imaging (**Rutty**), the Academic and Research Committee Society for Cardiothoracic Surgery (**Murphy**), the NIHR/NOCRI National Strategy Group for Asthma (**Siddiqui**), the Exercise and Lifestyle Clinical Strategy Group for the UK Kidney Research Consortium and the UK Renal Association Chronic Kidney Disease-Mineral Bone Disease (CKD-MBD) Guideline Group (both **Burton**). Many of our researchers are also advisers for NICE, playing a major role in developing new guidelines including: Scientific advisor for NICE Single Technology Appraisal for Sotagliflozin (**Davies**), Clinical Specialist to NICE on behalf of RCP/NCRI/RCP/ACP/JCCO on three Single Technology Appraisals and scientific input on three further projects in Gastric Adenocarcinoma (**Thomas**), and Vice-Chair of a Technology Appraisal Committee (**Squire**).

Our clinical trainees and ECRs are also encouraged to secure external national and international leadership positions, with prominent roles including: **Saratzis** participation on the NIHR HTA Clinical Evaluation and Trials Board and National Lead for Vascular and Endovascular Research Network); Gonem (NIHR HTA Reviewer Development Scheme); Gokani (President Association of Surgeons in Training); **Walter** (Chair of the Junior Investigators Network for the ECMCs); Russell (American College of Chest Physicians Expert Cough Panel).

#### 4.2.2. Peer Review and Journal Editorships

Staff contribute to the advancement of clinical sciences at the highest level by participation in funding panels, both UK-based and abroad. In addition to **Samani's** role as BHF Medical Director, three UoA1 researchers are Panel Chairs for NIHR Senior Investigator (**Davies**), MRC (**Cooper**) and European Respiratory Society (**Brightling**) awards. During this REF period, UoA1 researchers have been members of 44 funding panels including 6 for NIHR, 4 for BHF, 6 for CRUK, 3 for the MRC, 2 for Kidney Research UK, 2 for Breast Cancer Now, 1 for BLF/Asthma UK, and 9 international panels (including NIH and CIHR). We also participated in 10 quinquennial reviews. 85% of our returned staff participated in peer review for international funding bodies and all are involved in peer review for journals. Staff returned under this UoA

comprise 5 international journal editors/deputy editors, 14 associate editors, and 23 editorial board members.

#### 4.2.3. Conferences and Meetings.

Our researchers organised 13 international conferences, 39 one-day meetings and 7 workshops. High profile international conferences include: the 7<sup>th</sup> International Mast Cell and Basophil Meeting (2015, co-organised by **Bradding**), the International Mesothelioma Interest Group biennial meeting (2016, chaired by IMIG President **Fennell**), the British Society for Immunology Summer school (2017, hosted and organised by **Cousins**), the 15<sup>th</sup> International Symposium on IgA nephropathy (2018, co-organised by **Barrett**), the Society for Cardiothoracic Surgery National Research meeting (2019, organised by **Murphy**), and the British Gynaecological Cancer Society meeting on endometrial cancer follow-up (2020, organised by **Moss**).

#### 4.2.4. Patient, Carer, and Public Involvement and Engagement

Patient, carer and public involvement and engagement (PCPIE) has been fundamental to our ability to deliver first class research in clinical medicine, to ensure our research is relevant to patients, carers and public, and results in improvement in health outcomes This links also to our expertise in implementation of healthcare delivery with UoA2 colleagues and exemplified by our significant contribution to the NIHR-CRN. During the current REF period, our Principal Investigators have led 139 CRN portfolio trials and recruited nearly 75,000 patients to the NIHR CRN portfolio studies. This success was instrumental in the award of our NIHR-CRF (in 2016) and most recently in the award in 2020 of one of only five NIHR Patient Recruitment Centres.

Leicester is one of the most ethnically diverse cities in the UK and is uniquely placed to conduct research on issues affecting the health and wellbeing of ethnic and migrant communities. The Centre for BME Health works with patients, the public, community and voluntary sectors, researchers, and health and social organisations to address the health inequalities in health care access and health outcomes. The Centre has a number of community-based research staff who engage with seldom heard communities and inspire community-led research. We design and deliver resources and alternative methodologies that are informed and led by communities who are hard to reach by some clinicians and researchers. This allows us to produce and promote culturally-sensitive resources and raise awareness of the importance of community engagement and collaboration across research and healthcare delivery. We also deliver research with BME groups, host a BME Community Partners' Panels, provide BME Engagement and competency training and collaborate with researchers, universities, and organisations, including NIHR where we have partnered to support the response to covid-19

(<https://bepartofresearch.nihr.ac.uk/COVID-19-Research/COVID-19-for-BAME-communities/>).

Other examples of our engagement include: hosting of the James Lind Alliance Priority Setting Partnership that has allowed clinicians, patients and carers to work together to identify and prioritise uncertainties in Aortic Disease (**Murphy**); our 'Cities Changing Diabetes initiative' has involved Faith Centres, Schools and the Council with the first Global City Sporting Pledge signed by the City Mayor all 4 Elite sports clubs (Leicester City Football, Leicester Tigers, Leicester Riders and the County Cricket Club) and the Diabetes Centre to work together across the city of Leicester to reduce diabetes; and our local Hope Against Cancer charity facilitates access to local communities, organisations and businesses, allowing researchers and patients tell their stories, and to stimulate local corporate social responsibility.

**Unit-level environment template (REF5b)**

Overall, our multi-disciplinary research centred on the health challenges of common diseases affecting the UK population has helped deliver transformative outcomes for patients. This is exemplified in our bench (see UoA5), clinical (this UoA), and public health implementation (see UoA2) research streams. Importantly, this is underpinned by integrated high quality training, and a strong commitment to equality and diversity that reflects the multi-cultural diversity of our patient groups and local stakeholders.