University Hospitals of Leicester NHS
NHS Trust

Meeting title:	Public Trust Board	**Public Trust Board paper M**
Date of the meeting:	11th April 2024	
Title:	R&I Quarterly Trust Board Report	
Report presented by:	Prof Nigel Brunskill, Director of R&I	
Report written by:	Prof Nigel Brunskill, Director of R&I	

Action – this paper is for:	Decision/Approval		Assurance	x	Update	X
Where this report has been discussed previously	N/A					

To your knowledge, does the report provide assurance or mitigate any significant risks? If yes, please detail which
No

Impact assessment
The report highlights the delivery and performance of R&I at UHL, progress of important research, engagement activities and newsworthy items. These elements have a largely positive impact on staff and patients and highlight efforts around engagement in research. Good research outcomes have had a positive impact on reputation.

Purpose of the Report

To give assurance around UHL R&I activity and performance

Recommendation

To receive updates and to be assured

UHL R&I QUARTERLY TRUST BOARD REPORT

April 2024

1. INTRODUCTION

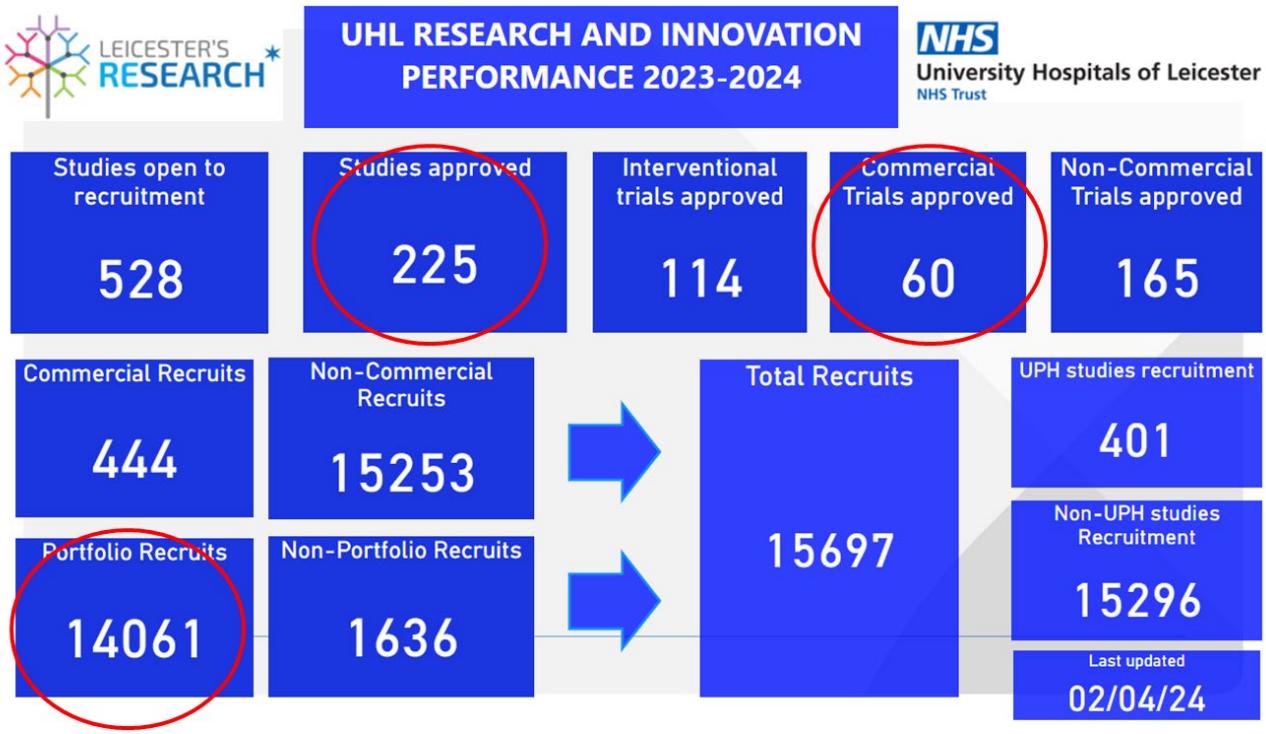
This report describes UHL R&I activities, performance and delivery in the last few months.

2. RESEARCH PERFORMANCE AND DELIVERY

2.1 Recruitment into CRN Portfolio Studies

We are now approaching the deadline of last week in April for uploading annual recruitment numbers onto the national portfolio management system. The 23/24 research activity dashboard is provided below.

Overall recruitment numbers into clinical studies has been really excellent and exceeds those of previous years. Numbers of new studies opening at UHL are also strong.



	19/20	20/21	21/22	22/23	23/24
Total New Studies Approved	168	131	207	213	225
Commercial studies approved	51	34	60	62	60

Figure 1: UHL study recruitment metrics 2023/24

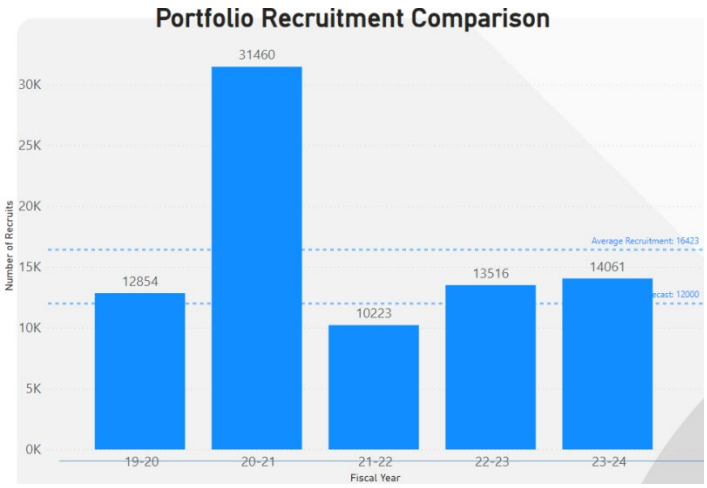


Figure 2: Comparative annual portfolio recruitment for UHL 2019-present (data complete to late March 2024)

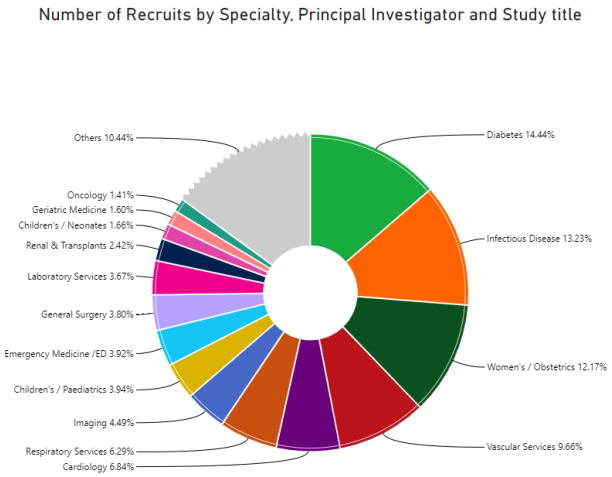


Figure 3: Spread of UHL recruitment activity by clinical speciality 2023024

Project ID	Project Short title	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Total
156442	UK-REACH/ REACH-OUT	12	9		2	1	2	829	160	339	419	1	3	**1777**
136546	iGBS3	31	113	149	180	167	140	132	104	74	116	113	59	**1378**
122478	PHAST-F- Work package 2	540			289					426				**1255**
107298	The Multi-Ethnic Lifestyle Study	54	94	63	99	256	295	68	50	7	45	57	20	**1108**
135992	The MMQ Study			16	27		77	64	215	172	59	25	22	**677**

Table 1 Highest Recruiting studies at UHL 2023-2024

2.2 Examples of High-recruiting Studies at UHL

Recruitment into clinical studies at UHL is broadly spread across all areas. The highest recruiting studies are distributed across various specialities at UHL, see examples below.

UK Reach/Reach-Out Study
A study into if, how and why ethnicity affects COVID-19 clinical outcomes in healthcare workers, and the impact of COVID-19 on the physical and mental health of minority ethnic healthcare workers.
iGBS Study
A study to help develop a vaccine against Group B Streptococcus infection in newborn babies
PHAST-F Study
A feasibility study to evaluate acceptability, uptake and effect of combined peripheral arterial disease, high blood pressure and abdominal aortic aneurysm screening.
Multi-Ethnic Lifestyle Study
This study aims to explore different lifestyle behaviours in people with and without long-term conditions, in a multi-ethnic population, to be able to use this information to inform health care in the UK.
The MMQ Study
The study is a cross-sectional, self-reported participant questionnaire with retrospective data linkage verification. The primary objective for the research is self-reported treatment burden, with secondary objectives around the factors associated with multimorbidity, such as the coronavirus, frailty and polypharmacy, ethnicity, deprivation and NHS utilisation.

2.3 CRN Indicative Budget
UHL has been allocated an indicative budget of £2,219,655 by CRN for the period 1st April 2024 – 30th Sept 2024. This represents a flat budget for the first half of the 2024/25 year. The second 6 month budget period will be under the auspices of the new Research Delivery Network and will be announced in due course.

3.0 NIHR LEICESTER CLINICAL RESEARCH FACILITY

3.1 The Leicester CRF has now completed its first full year since its latest designation. The last annual CRF annual report has been well received by NIHR and all items RAG rated Green (see attached feedback from NIHR, Appendix 1).
The contract period for the current CRF has been extended by NIHR until 2029.

4.0 NIHR LEICESTER BIOMEDICAL RESEARCH CENTRE

4.1 The activities of the Leicester BRC are guided by an External Scientific Advisory Group (ESAG). ESAG have recently released their latest report that accompanies this quarterly R&I Report (Appendix 2).

Dr Aarti Parmar NIHR Leicester Biomedical Research Centre Manager will attend Trust Board to discuss the contents of the ESAG report.

5.0 UHL RESEARCH AND INNOVATION NEWS AND EVENTS

5.1 Investment New South Wales Going Global Program
In April 2024 UHL and Leicestershire Academic Health Partners, along with Health Innovation East Midlands, will host a visit of entrepreneurs and health innovators from NSW Australia. Over a day and a half of structured presentations and meetings

the visitors will receive advice on using the NHS as a test bed for innovation and development of innovative solutions to healthcare problems. The meeting will be held in the Bob Burgess building at the University of Leicester.

5.2 The PHOSP-COVID Team studying long-Covid have been shortlisted as a finalist for the Outstanding Team Impact Award at the MRC's Impact Prize.

5.3 Professors Laura Gray and James Burton have been awarded prestigious new NIHR Senior Investigator Awards. In addition, Martin Tobin, Professor of Genetic Epidemiology and Public Health at the University and a Fellow of the Academy of Medical Sciences has had his award renewed for a second term.

5.4 Working together to tackle TB. Members of UHL's Tuberculosis service marked World TB Day on 21 March 2024 by inviting experts from across Leicestershire to discuss how they can work together to improve case finding, diagnosis and patient centred treatment.

5.5 Leicester BRC welcomes Dame Maggie Aderin-Pocock MBE. In February the Leicester BRC received a visit from the Chancellor of the University of Leicester, Dame Maggie Aderin-Pocock MBE. Dame Maggie met with the BRC Director and heard from researchers within the Lifestyle and Cardiovascular themes and enjoyed a tour of the Leicester Diabetes Centre and the CVS building at Glenfield Hospital.

5.6 Leicester BRC researchers awarded £14 million to expand research into the prevention and management of chronic disease through physical activity. More than £14 million has been awarded to the University of Leicester, which forms part of the NIHR Leicester BRC to expand its research into the prevention and management of chronic disease through physical activity. This transformative work will directly benefit people living in Leicestershire and is among 18 Higher Education projects to receive funding from Research England's Expanding Excellence in England Fund. It is the highest amount awarded to any institute.

5.7 The LLR ICB Health Data Science and Research Conference was held at College Court on 12th March 2024.

Prof Nigel Brunskill
April 2024

NIHR | National Institute for Health and Care Research

NIHR CLINICAL RESEARCH FACILITY

Feedback on Annual Report

From 1 September 2022 to 31 March 2023

NIHR Leicester Clinical Research Facility

Summary of Feedback

The NIHR would like to thank all staff for their contribution to the delivery of your work plan and for preparing this year's annual report.

The Leicester CRF has made good progress across all the agreed objectives, and have made many commendable achievements. We are pleased to hear that the CRF successfully secured Foundation year trainees to gain research experience and will be hosting the UKCRF Network Conference 2024. The Spartan study in IgA nephropathy achieved a milestone, with the first data set to be presented at the American Society of Nephrology meeting.

We were pleased to hear Dr Matt Ahearne, a CRF researcher, has obtained the Career Development Award during this period. In addition, the Leicester ECMC, which plays a key role in delivering studies associated with Leicester CRF, has secured the renewal of the Experimental Cancer Medicine Centre Award of £1.5 million.

Thank you for submitting interesting added value examples. We were very pleased that Leicester CRF is planning to establish a national holistic and integrated clinic and research hub for Fragile X and the RECONNECT Trial has received extremely positive feedback from parents involved in the study. NIHR may be in touch in the future for additional details should the examples be selected to be developed into NIHR case studies.

Centre Overall (RAG)		**Progress Descriptors** **Green** = On track. No risks to delivery identified, minimal feedback. **Amber** =Satisfactory. Minor issues, no risk to delivery; areas to consider highlighted in feedback. **Red** = Unsatisfactory. Issues identified that require action from the Director, or input from CCF. **Black=**Unsatisfactory. At least one major issue identified that requires escalation to DHSC.

Overview of activities

The NIHR thanks the CRF for preparing this report and for providing updates against each of the agreed objectives, and we congratulate you for being on track towards achieving all of your objectives.

No change to the approved CRF strategy was reported. However, challenges persist in terms of workforce shortages and turnover, particularly among research nurses, pharmacists, and imaging staff. Please keep us updated with how these challenges impact CRF activity, as well as how dual registration of university student nurse placements address this issue and support succession planning.

Collaborative efforts across clusters are ongoing to explore various avenues to enhance and sustain staffing levels. Additionally, UHL has secured funding through a recent NIHR capital call to expand research pharmacy capacity. Recognising a gap in PI support, the number of consultant PAs funded for PIs within the CRF has been increased. The newly appointed Commercial Manager will also play a pivotal role in driving early-phase commercial work.

With regards to imaging, the Leicester CRF reported that challenges were encountered with external providers of PET scanning and their approval processes. Additionally, MHRA approvals are currently slow,

although national measures are being implemented to address this issue. Please keep NIhR updated with how these challenges impact activity at the CRF.

The Leicester CRF has successfully collaborated with a number of industry partners, charities and are working on the development of a commercial agreement between UHL and Flatiron to make healthcare data available for cancer research.

Leicester's acute platform studies achieved 100% occupancy. Most studies in the Cancer Cluster were high risk and high intensity and have a generally higher individual occupancy rates compared to other clusters.

Overall Assessment of Activity *(RAG)*		**Green** = On track. No risks to delivery identified. **Amber** =Satisfactory. Minor issues, no risk to delivery, areas to consider in feedback. **Red** = Unsatisfactory. At least one major issue identified in feedback.

Governance & Leadership

No changes to the governance structure was reported.

A Deputy Director, Dr Neil Greening, has been appointed. The CRF manager, Ms Tracy Kumar, has led a management restructure of the Cancer Cluster based in the Hope Facility at Leicester Royal Infirmary. The CRF has successfully appointed a new Training and Development Lead whose role is to support staff delivering early phase and highly complex trials.We look forward to hearing about how this role supports staff development and capacity building at the CRF.

We are pleased to hear that no concerns have been raised from the Executive Board Meetings. Recruitment and study data reporting metrics and dashboards have been highlighted as important areas for development, monitoring and review to ensure a streamlined seamless approach is in place for reporting purposes.

The Leicester CRF is working closely with the newly appointed UHL Head of Quality Assurance and Compliance to further streamline processes and deliver high quality safe early phase complex trials.You are also collaborating with the newly appointed UHL Commercial Manager in the UHL R&I Department to support uptake of early phase commercial trials.

Overall Progress Governance and Strategy		**Green** = On track. No risks to delivery identified. **Amber** =Satisfactory. Minor issues, no risk to delivery, areas to consider in feedback. **Red** = Unsatisfactory. At least one major issue identified in feedback.

Comments on PPIE: NIHR PPIE Team Feedback

General Comments

The CRF has been able to demonstrate how they are promoting the UK Standards for Public Involvement in their centre, their Joint Public Involvement Strategy fully aligns their objectives with the standards. The CRF has engaged and involved underserved communities in the delivery of their PPIE strategy, they have also provided inclusive opportunities for public members, and more importantly have involved public members in governance of their work.

Areas which are particularly noteworthy or represent best practice

In order to support CRF colleagues' engagement with underserved communities in their research

'Cultural Competency' training for CRF staff has been arranged, funded and is underway – this has begun with their senior team will expand to involve all CRF staff- to facilitate better engagement in the 'hard to reach' communities, build trust and ultimately have more involvement in early phase research.

The CRF displays good public involvement practice through extending its successful Patient Partner model into the governance structure of the BRC, and standardising and expanding the role. The CRF Operations Manager has begun work to develop role descriptions for the Patient Partner roles to be embedded in the CRF Board, BRC Board, and Research Theme Operational Groups, in partnership with representatives from the same groups.

It is particularly noteworthy and also represents good practice that all cancer patients are supported to complete the Cancer Patient Experience Survey at UHL which includes questions about research opportunities.

This good public involvement approach extends to remuneration processes. Resources to support reward and recognition to support public members will be sourced and current systems for making legal and ethical payments will be reviewed and aligned. CRF is working jointly with the BRC to ensure that a standardised approach to reward and recognition is agreed (except in our community investment model projects). The CRF Operations Manager is developing a payments policy that supports both legal and ethical payments to ensure our opportunities are inclusive.

PPIE (RAG)		**Green** = On track. Information asked for has been provided in full and no issues identified. **Amber** = Satisfactory. Minor gaps in information provided and/or areas to consider in feedback. **Red** = Unsatisfactory. Large gaps in information provided and/or at least one major issue identified in feedback.

Engagement with Industry: Feedback from NIHRCC Business Development (formerly NOCRI)

Leicester CRF continues to build upon strengthening existing relationships with industry partners. The CRF have displayed a number of successful collaborations that has results in new trials or funding, examples include:

- ACCoRD - Takeda and CRUK
- Glofitamab bispecific trials
- IMMU -132-09 - Commercial trial in breast cancer
- Industry funded by Abbott (£480,00) study on patients with chronic limb threatening ischemia.
- Narsoplimab funded by Omeros (£500K)
- Phase 2A trial of tocilizumab in persistently inflamed patients with long-COVID funded by Roche (no value mentioned)
- Several funded studies of BAF and April inhibitors (Values £750K)

Industry (RAG)		**Green** = On track. No risks to delivery identified. **Amber** =Satisfactory. Minor issues, no risk to delivery, areas to consider in feedback. **Red** = Unsatisfactory. At least one major issue identified in feedback.

Skills and workforce development

The Leicester CRF has appointed a new CRF Training and Development lead to analyse training needs and link CRF staff across UHL. There have clearly been a wide range of opportunities offered to CRF staff to enhance their skills and knowledge, such as attending the RCN education and UKCRF conferences. We are pleased to hear that Research Nurses and associate clinical practitioners were encouraged to take up leadership roles and management of early phase studies.

All staff have access to CRF training resources such as induction, SOPs, resuscitation training and ad hoc emergency scenario training. Complimentary learning from ATTC network and ELfH on advanced therapies, GMOs, immunology and anaphylaxis were available to increase staff expertise in all aspects of early translational and experimental medicine research.

We were pleased to hear that the Clinical Research Practitioners are supported in seeking NHCS registration, and new apprenticeships were allowed for development outside of degree and within working practice. The Leicester CRF also encouraged its workforce to work closely with universities including participating in lectures to inspire the next generation.

Skills and workforce development (RAG)		**Green** = On track. No risks to delivery identified. **Amber** =Satisfactory. Minor issues, no risk to delivery, areas to consider in feedback. **Red** = Unsatisfactory. At least one major issue identified in feedback.

Feedback of Actions Required or Areas for Consideration

Section	Comment/ Action
Overall Assessment	No actions required.
Overview of activities	No actions required.
Overview of objectives	Please refer to the Objectives Tracker spreadsheet for relevant comments on the progress of the objectives.
Governance and Leadership	No actions required.
PPIE	No actions required.
Industry	No actions required.

For the Director: Summary of Progress Made/Immediate Actions Required

Dear Professor Brunskill,

We thank you and the CRF staff for the contribution to delivering the work programme over the past few months of the CRF award and for the time taken to complete the annual report.

We have no concerns which require action at this time, but please review the above sections and the objectives tracker spreadsheet to view additional updates for the next annual report.

Once again thank you for all your endeavours in directing the NIHR Leicester CRF.

Kind regards,

NIHR Infrastructure Team

NIHR | Leicester Biomedical Research Centre

NIHR Leicester Biomedical Research Centre External Scientific Advisory Group meeting

November 2023

Contents

Report on Personalised Cancer Prevention and Treatment Theme

Report Prepared by Professor William Gallagher, Professor of Cancer Biology, School of Biomolecular and Biomedical Science, University College Dublin

Summary

Attendees: Prof William Gallagher (ESAG Member) Prof Jacqui Shaw (Theme Lead), Dr Caroline Cowley, Dr Esther Moss, Prof Karen Brown, Catrin Pritchard

While a new thematic area, considerable progress has been made in terms of embedding the 'Cancer' Theme within and across the BRC. The theme management structure is now in place and working well, with good evidence of EDI in practice. The current team membership is smaller than some of the more established themes but making very significant impacts on the research landscape. Particular areas of strength are in chemoprevention, liquid biopsy, and patient-derived explant (PDE) area, as well as a very strong clinical presence in the mesothelioma space.

There was discussion around the need to recruit a Professor of Medical Oncology/Honorary Consultant that will also act as clinical lead for the Cancer theme to replace Professor Anne Thomas, who recently retired. It was indicated that the specific area of oncology was open-ended, with the key being to find the best person for the post in leadership terms. It will be key to promote the collegiate approach and support package from the College, as well as training support, mentorship and the broader collegiate environment that exists in Leicester. This situation has demonstrated the requirement for pro-active legacy planning when people are approaching retirement and the need for ongoing development of those already in situ. This appointment is critical to the long-term sustainability of a Cancer theme in the next BRC competition.

There was a discussion regarding recruitment of clinical rising stars and general expansion of staff numbers to grow the theme, enable more cross-theme working and bring in emerging themes, such as big data and AI. It was noted that non-clinical staff have a heavy teaching load and there was a critical dependency on certain key investigators. It was indicated that recruitment is complete apart from the clinical lead, with all PhD positions filled in the first round. A discussion was had in respect of training and development needs for emerging and more established researchers. It was suggested that there should be regular highlighting of early career researchers/'rising stars' to the Communications team. Discussions were had in respect of teaching load and grant writing support, along with stepwise expansion of the thematic area.

There was a discussion regarding identifying and highlighting the unique selling points of the cancer theme for the next BRC submission. In addition to the flagship chemoprevention studies under Colo-Prevent, other identified impact case studies included (a) ctDNA guided trials and aiding development of a novel FDA test, (b) MiST/SELECTmeso trials and focus on immuno-oncology responses, and (c) explant-informed clinical studies.

In relation to the PDE work, there is a key opportunity to progress this into a national platform, if appropriate supports are put in place. To scale appropriately, there needs to be consideration given over to recruitment of an additional PI in this arena, as well as additional depth in respect of imaging and spatial profiling expertise.

In respect of the chemoprevention strand, a query was raised in respect of whether lifestyle interventions were also being explored. It was indicated that some initial contact with the Diabetes Centre had taken place to examine this angle. Moreover, a new Lecturer in the Cancer Theme has expertise in this area in preclinical models and is keen to move into human studies. The challenge may be to make such work unique but, if deemed promising, it could be built into an arm of the Colo-Prevent trial. There was a discussion about how the chemoprevention work may impact on policy, with a key focus being on having voices heard. As the Colo-Prevent study is a world first, it would be beneficial for more widespread impact to foster collaborations at a European or broader level.

There was a discussion around whether the Cancer Theme have developed any home-grown therapeutic interventions. It was indicated that, while there are researchers involved with expertise in target discovery and therapeutic innovation, the focus tended towards licensing out rather than grow in-house. It was discussed that linking more with structural biology expertise within the University would be beneficial. It was commented upon that, while drug discovery had been mostly localised to specific (other) sites by CRUK, there is substantial collaboration ongoing particularly in respect to the use of the PDE platform for efficacy studies.

There was a general discussion regarding cross-theme interactions and the need to increase the theme's influence on shaping the national agenda around cancer research. It was commented upon that the current focus of the theme is such that it allows for work across themes and platforms. Joint workshops are being considered for the New Year, with

clear opportunities to work closely with data and population health. Specific areas of development include work relating to sleep/circadian rhythms and the emerging sub-theme – Living with and Beyond Cancer. Regarding wider influence, there was work ongoing to position team members within the broader landscape via the Oncology Translational Research Collaboration (O-TRC) and the Experimental Cancer Medicine Centre (ECMC), albeit the focus would be only on one or two areas given the limited number of people within the team. It was suggested that engagement with the Scientific Council member of the International Agency for Research against Cancer (IARC) would be useful to discuss broader opportunities within the prevention area. It was highlighted that the capacity to build industry partnerships is a risk as the infrastructure is not fully in place. It was suggested that the BRC identify champions for developing ideas towards implementation via industry collaboration.

There was a discussion regarding the original plan of establishing an international basket trial for rare B cell malignancies to enable access to novel targeted therapies (Unmet need objective 4, Appendix 5, p84). It was indicated that this initial objective may be more difficult to achieve than it was thought previously. While this goal is still being pursued, an additional objective was proposed for discussion, namely 'Leverage and maximising investment: Develop partnership with pharmaceutical and biotech companies for the assessment of novel targeted therapies.' This would be a short-term objective over 1-2 year and monitored by securing funding from a variety of industrial partners. Success would be measured by the development of up to 4 new industry or academic collaborations. Full support for this revision of the objective was given. It was also discussed that it would be useful to have a framework for co-designing studies with patients, where possible.

There was a discussion regarding increasing impact on patient care, with a particular focus on fast-track review of ctDNA technologies for implementation in the NHS. It was suggested that there should be greater focus on investigating the health economics of ctDNA monitoring, including the practicalities of delivery. It was also indicated that the Theme should consider capitalising on the work in breast cancer and take this success story into other cancers and clinical challenges.

There was a discussion regarding emerging themes and new objectives. It was indicated that there is an emerging project examining the psycho-oncology aspects of ctNDA monitoring via cross-theme working between Esther Moss and Natalie Darko, with a PhD student project supporting this. There is also an interest in examining the effect of circadian rhythm effects on ctDNA sampling, with a key area of growth being sleep effects on LTCs especially within ageing populations. Overall support for the development of this sub-theme and suggested objectives was provided. It was recommended that the Theme find out about the PPIE induction programme run by Barts, which incorporate dedicated lectures and lab work for patient partners over a 5 day period.

Recommendations

1. With the retirement of co-theme lead Prof. Anne Thomas, recruitment of a senior clinical academic is critical, and the maintenance of medical oncology specialism within theme is preferred.
2. It was suggested to target Wellcome for funding additional PhD positions and consider other sources of funding for clinical trainees (e.g. HOPE Against Cancer).
3. In addition to supporting both early career researchers, consideration should also be given to assisting more established (mid-career) researchers who are excelling in their area but may require additional opportunities for development and support to maintain trajectory.
4. It was recommended that greater (centralised) support be provided in terms of grant writing/development. A particular focus around pursuing funding opportunities at an EU level is encouraged, given the re-entry of the UK into these programmes.
5. There should be regular highlighting of early career researchers/'rising stars' to the Communications team.
6. To scale the PDE platform appropriately, there needs to be consideration given over to recruitment of an additional PI in this arena, as well as additional depth in respect of imaging and spatial profiling expertise.
7. To facilitate even greater impact in respect of chemoprevention studies, it would be beneficial to foster more collaborations at a European or broader level.
8. The BRC should identify champions for developing ideas towards implementation via industry collaboration.
9. The Theme should investigate the PPIE induction programme run by Barts, which incorporate dedicated lectures and lab work for patient partners over a 5 day period.
10. The theme should consider identifying and highlighting the unique selling points of the cancer theme for the next BRC submission, as discussed above.

Report on Cardiovascular Theme

Report Prepared by Dr Andrew Whittaker, Freeline Therapeutics

Summary

Attendees: Dr Andrew Whittaker (ESAG Member), Prof Gerry McCann (Theme Lead), Prof Matthew Bown, Dr Carl Edwards, Michelle Newton

Overall, it is clear that the cardiovascular theme group are performing to a high standard and will have no difficulties in achieving many of their short- and medium-term goals and objectives, especially those relating to project delivery, funding, people development, and publications.

The quality of the science being performed and its relevance to clinical (NHS) practice, public health and potentially to the biopharmaceutical industry is evident. Examples include research into spontaneous coronary artery disease (SCAD), aortic aneurysms, heart failure with preserved ejection fraction (HFpEF), sudden cardiac death risk, and the interaction of CV disease across multimorbidity. There is good evidence that the potential commercial value of projects is recognised, such as with the LifeMap project led by Prof Andre Ng, but there is scope for this to be considered for more projects.

Both the proteomics work led by Prof L Ng and the manganese-enhanced cardiac MRI are two projects that I see as having potential for particular interest to industry. Indeed, it may even be worth considering whether the proteomics work could be further developed into a University spinout company given the novelty of the work versus what is available commercially. For the cardiac MRI, I think the next stage in developing this work to give it added value to industry would be to evaluate the ability to detect an effect of a drug intervention plus back-translation into pre-clinical models if feasible, and how this relates to clinical parameters and outcomes. The team should consider approaching companies (including early-stage biotech) that are working in drug discovery & development for treatments that modulate calcium-handling in the heart (e.g. SERCA2a, Phospholamban, Camk2d).

The conceptual application of the outputs of the research projects is evident across the theme, however a strategy for how these would be implemented in practice is a bit under-developed. For example, the development of polygenic risk scores to enable improved identification of patients at high(est) risk of CV events is supported by good scientific evidence. However, how PRS would ultimately be applied in routine NHS clinical care is less clear. Ideally, this kind of technology needs to be available and easy to use at the level of primary care and non-academic secondary care institutions in order to have the greatest impact. It would be good if the teams can think about a strategy on how this would be done.

When considering multiple long-term conditions (MLTCs), it would be beneficial for the teams involved to think like a Pharma company. For example, from a drug development and regulatory approval perspective how do you structure endpoints in clinical trials that includes a heterogeneous patient population with varying degrees of lung disease, heart disease, metabolic disease etc? Would only hard clinical endpoints be valid (e.g. hospitalisation for exacerbation of “xx” disease or all-cause death) or could surrogate endpoints be developed and validated (e.g. functional outcomes, health resource utilisation, measures of independent living etc). The work on MLTC endpoints could potentially be expanded to influence national and international guidelines; discussions with the MHRA (if possible) may also be useful. The Pharma industry rely on frameworks being generated by academic research by key leaders and in international guidelines.

Recommendations:

1. Following this progress review, to identify any areas that are lagging behind in expected performance in order to rationalise priorities and resources on ensuring key objectives will be met across all projects, and that important projects do not fall so far behind that mitigations cannot ensure successful completion.
2. Consider using existing funds (e.g. BHF Accelerator) to initiate pump priming research in areas of potential future expansion.
3. Consider additional areas of growth and collaboration including:
    a. The effects of vaping on CV (as well as respiratory and metabolic) health. Opportunity to initiate long-term follow-up studies in young adults.
    b. Pulmonary vascular disease in HF, obesity and renal diseases.
        i. Identification of reliable peripheral biomarkers of elevated pulmonary pressure in pulmonary hypertension due to HF, renal failure and obesity.

   ii. Novel targets for new therapeutics in pulmonary hypertension due to HF, renal failure, and obesity.

c. The role of the immune system in CV diseases, especially HFpEF and diabetic cardiomyopathy.

d. Collaboration with renal teams to research into shared pathobiological pathways in the heart, kidneys and pulmonary vasculature that may enable identification of key molecular pathways amenable to therapeutic intervention of benefit to multiple organs.

4. Realisation of the potential commercial value of the proteomics research led by Prof L Ng.
5. Areas of potential high interest to biopharmaceutical industry (both small biotech and large Pharma) can be developed to align with Pharma industry values and ways of working.
6. The team could consider the possibility of establishing a cardiovascular imaging core lab (echo, cardiac MRI, cardiac CT) with capacity and capabilities to provide a service to Industry-sponsored trials as well as academic research studies, although I appreciate this would be a sizeable undertaking requiring significant additional resource.

Report on Respiratory Theme

Prepared by Professor Liam Heaney, Professor of Respiratory Medicine, Queen's University Belfast

Summary

Attendees: Prof Liam Heaney (ESAG Member), Donna Finch (ESAG Member), Prof Chris Brightling (Theme Lead), Dr Pranab Halder, Michelle Bourne

The Leicester BRC Respiratory Theme builds on a strong legacy over many years in translational science and clinical trials in airways disease, particularly asthma and chronic obstructive pulmonary disease (COPD). The theme now incorporates expansion areas of interstitial lung disease and infection (tuberculosis / infection) and long-COVID.

The science is strong particularly in airways disease and particular highlights are (1) leading in the 3TRABC study within the Europe-wide 3TR consortium, which seeks to understand the molecular mechanisms of poor therapeutic responses and exacerbations of inflammatory diseases (2) a new MRC award to study free fatty acid receptors in asthma and (3) plans to incorporate a paediatric programme and to seek EU funding to further explore the role of biomarkers in paediatric asthma diagnosis and management. Given a large part of the COPD clinical problem is damage rather than inflammation, one potential area for development would be to consider work in this area as there did not seem to be any specific plans for work in this area. The Respiratory focus is also well embedded in the other Thematic areas e.g. Lifestyle and Environment Themes with clearly defined cross-thematic projects.

The PHOSP-COVID programme has been world leading in exploring outcomes after acute severe COVID infection and mechanistic work in long-COVID. A particular strength has been the interface with other UK Consortia and datasets to validate and identify control populations for the PHOSP-COVID programme. The work being performed is highly relevant to clinical practice, public health and addresses important unmet needs in respiratory disease.

The ILD programme is smaller and less evolved within the Respiratory theme. The potential for this area was clearly communicated in the discussions and the genetics and functional genomics components of this programme are strong. There is a large clinical cohort available but this is probably underutilised both in terms of Phase 2/3 clinical trials and enabling mechanistic investigations in ILD. The recent appointment of a new NHS Physician (Dr Fasi Khan) has started to expand this capability with participation in 3 – 4 Industry sponsored clinical trials currently. There are a number of specific mechanistic areas under study e.g. gal-3-fibrosome and KCa3.1. Specifically, for the study of KCa3.1 as a target in acute exacerbations of interstitial lung disease, the development of the acute exacerbation service and the current availability of a potential therapeutic e.g. Senicapoc, this would seem ideal for a phase 2 PoC study.

The Infection sub-theme is also at an early phase of development. The focus is predominantly tuberculosis which is facilitated by a large disease prevalence in the local catchment area and specific focus is probably good idea when a new thematic workstream. However, there is also S. Pneumoniae work and during discussion, it was confirmed that the sampling and biomarker work will also cover non-tuberculous mycobacteria, which is also an increasing clinical problem across multiple respiratory diseases. The novel use of PET/CT to better characterise latent / active tuberculous disease is novel and the potential use of phage therapy in TB complex and NTM disease harnesses the strength of the Centre for Phage Research and the University strength of phage therapies in veterinarian medicine. There are ongoing commercial partnerships exploring TB detection and multi-omic biomarkers to develop future precision medicine intervention studies and this is a good example of industry partnership.

The programme is well placed to deliver on its listed objectives, though in some areas of the briefing document, the progress against objectives lacked metrics and difficult to know how this related to “How will you monitor and manage success”.

Recommendations

1. Across the programme, one important development is the development of an ‘acute exacerbation clinic’ which is planned for the next 6 – 12 months and will allow near patient testing and studies in acute infections/exacerbations across all the sub-thematic areas. This area is an important programme for future clinical and therapeutic development for personalised treatments in respiratory disease. The ESAG is very supportive of this initiative and would strongly encourage that any barriers to this plan are dealt with effectively to allow this to happen
2. A great strength of the Leicester Airways Team has been to secure large EU finding for European Consortium and programme grants and the UK Government announcement that UK Institutions can now apply for HORIZON and

Innovative Health Initiative funding as of September 2023 – this work should be encouraged and supported given the strong track record in securing funding and delivering on these programmes.

3. Concern was discussed regarding the new regulatory processes applying to medicines, vaccines and medical devices under the remit of the UK Medicines and Healthcare products Regulatory Agency, which has led to a more challenging process with longer timelines to gain approval – this has hindered recent innovative CTIMP studies in the respiratory theme. Northern Ireland is under different arrangements as EU approvals must also apply e.g. it was recently discovered a medical device being used in all other severe asthma centres in UK could not be used in NI as the relevant EU approvals were not in place – it may be with the passage of time, the MHRA can streamline processes in the post Brexit area, but this is something which will be monitored at future ESAG meetings. This issue is a risk factor to all other themes across the Leicester BRC.
4. A recent UKRI infrastructure bid to deliver a combined cardiorespiratory building was unsuccessful – the respiratory group feel that space to accommodate future plans and appointments has become a limiting factor. As part of the UKRI application process, detailed architectural plans have been developed and the ESAG would strongly encourage that future finding opportunities are actively sought by the BRC Leadership team to advance these plans and try and avoid capacity for future development being inhibited by lack of appropriate infrastructure.
5. The ESAG recognizes the substantial opportunity for the ILD programme and whilst some areas within this programme are strong, there is the potential for missed opportunities in the coming years and the overall impression was of a somewhat fragmented programme. The ESAG would encourage the BRC Leadership team to produce a clear developmental framework to expand the academic team within this theme and to ensure supported engagement of the clinical team with protected research time.
6. In the BRC bid, a number of posts were agreed with Leicester University which required matched supporting funding from the University in addition to the BRC funding. The BRC has been asked to 'delay' appointment of these positions due to funding constraints within the University. The ESAG finds this position unacceptable and would strongly stipulate that funding for these posts is made available by the University so that these posts can be appointed at the outset of the BRC funding period. Delaying these posts is likely to substantially compromise the development of the respiratory and infection programme in the subsequent years. This is a risk across all themes accessing the matched support funding from the University of Leicester.

Report on Lifestyle Theme

Report prepared by Professor Tom Yates, Theme Lead Lifestyle

Summary

Attendees: Prof David Dunstan (ESAG Member), Prof Tom Yates (Co-Theme Lead), Prof David Stensel (Co-Theme Lead), Prof Melanie Davies, Prof Sally Singh, Prof Charlotte Edwardson, Prof Louise Goff, Dr James King, Dr Joe Henson, Dr Luke Back, Dr Jack Sargeant

- Douglas Twenefour (ESAG Member) was unable to join this session, due to confusion about the possibility to dial in remotely. He joined the collective ESAG session in the afternoon.
- After introductions and outlining the purpose and structure of the session, the session took a systematic approach through the theme objectives outlined in the briefing document to guide discussion.
- Discussions were incredibly positive, with Prof Dunstan commending the progress to date across the theme (at Leicester and Loughborough), raising no major concerns.
- Areas of specific notable discussion included:
  - **Key appointments to the team** – Recruitment and appointments into key roles across the theme (at Leicester and Loughborough) were discussed, including internal appointments into NIHR-funded and match-funded posts, as well as senior appointments in Prof Louise Goff, and the imminent start of Prof Claire Meek in December 2023. Prof Goff provides extensive expertise in nutrition and health inequalities, most prominently ethnic health. Prof Meek is an expert in diabetes, pregnancy and antenatal care, and the use of lifestyle interventions in combination with technology.
  - **Physical Space / Capacity** – whilst the growth in the team was commended, queries were raised regarding physical space to locate these staff and support capacity for their research. This was flagged particularly at the Leicester General Hospital (LGH). It was agreed that this is a genuine concern, and an area of strategic importance across the theme and LGH more widely. A recent NIHR Capital Funding award has helped initiate further at Trust and University level regarding expansion of the Leicester Diabetes Centre space (at LGH), but that these discussions are ongoing and timelines (to prevent returning NIHR Capital Funding) remained challenging.
  - **Extending the CODEC study to include gestational diabetes** - An amendment to the CODEC study to include type 1 diabetes was discussed, following the appointment of Professor Pratik Choudhary in 2020. It was raised whether CODEC would be further expanded to include gestational diabetes (GDM) given the appointment of Prof Meek. It was agreed that whilst some participants in CODEC would have had GDM, a more dedicated amendment would be made to include more focused recruitment of this group and the inclusion of appropriate dedicated questionnaires/other assessments.
  - **Statistical approaches for platform trial secondary outcomes** – the lifestyle theme platform trial was discussed, for which the protocol is currently undergoing University of Leicester sponsor review. This is built on a collaboration with methodological experts at Oxford Primary Care CTU. Prof Dunstan highlighted that he is not an expert in these methodologies, but appreciated the rationale for such a platform approach, and commended the work to date. Prof Yates sought perspectives regarding the issues of statistical testing of what will be a large number of secondary outcomes, particularly regarding the use of Treatment Policy (similar to traditional intention to treat) and Trial Product (similar to traditional per protocol) estimands as used in novel trials of pharmacotherapy (something Prof Davies has experience with). An action was agreed for Prof Davies to explore further with Prof Yates. The approach of identifying "key secondary outcomes" which would be tested using both approaches, with others secondary outcomes tested using only one, was suggested as a possible option to limit some analyses.
  - **Health Economics Capacity** – the theme's work in pushing experimental medicine through to early translation was discussed, but queries regarding capacity and expertise for economic evaluations were raised. It was discussed that there is some internal expertise through the data innovation theme in Dr Claire Gillies, and that the group had long standing collaborations with external groups (most prominently University of Sheffield). However it was agreed that greater internal capacity and expertise would be beneficial.
  - **DART TRC** – the Diet and Activity Research Translational Collaboration (DART TRC) was discussed. DART was a previous additional component of infrastructure to support cross-BRC collaboration for themes with an interest in lifestyle, obesity, diet, physical activity and other related areas. Prof Davies was the previous convener of the DART, with Prof Stensel the Leicester Lead, and with the Leicester BRC Lifestyle Theme hosting the DART Collaborations Manager. It was highlighted that despite multiple rounds of discussion and review regarding the

proposed DART strategy for this BRC cycle, the NIHR have not renewed the DART TRC, but have invited a new submission into the upcoming TRC call. It was highlighted that the majority of the themes who were previous members of DART remain enthusiastic to continue a collaboration and are attending an in-person meeting in Leicester in December 2023. The purpose of this meeting will include strategic decisions for moving this collaboration forwards, as well as for individual pieces of future collaborative work.

- **Core outcome set** - time prevented discussion of the Core Outcome Set in detail within this session – but it was agreed that this would be reviewed by Prof Dunstan as a follow-up, using the briefing document and additional documentation to provide written feedback with comments, queries and suggestions. A bespoke follow-up discussion will be arranged if necessary.

Recommendations

1. The issue of Physical Space and Capacity to accommodate the expanding team, particularly at the Leicester General Hospital (LGH) need to be addressed as an area of strategic importance, particularly in LGH more widely.
2. Statistical approaches for platform trial secondary outcomes to be further explored and defined as outlined above.
3. Focus on Health Economics Capacity within the Theme by expanding internal expertise and capacity would be beneficial.
4. The ESAG was supportive of the proposed meeting in December 2023 to advance strategic decisions for maintaining the collaborative programme in the Diet and Activity Research Translational Collaboration (DART TRC).
5. Thematic core outcome dataset to be reviewed by Prof Dunstan as a follow-up to ESAG meeting and addendum written feedback and suggestions with a dedicated follow-up discussion as needed.

Report on Data Ethnic Health MLTC Theme

Report Prepared by Professor Colin McCowan, Professor in Health Data Science, University of St Andrews

Summary

Present:

Prof Liam Heaney (ESAG Chair), Colin McCowan (ESAG Member), Prof Kamlesh Khunti, Prof Laura Gray, Clare Gillies, Martin Tobin, Freya Tyrer, Seema Ragha

BRC has a strong statistics base for this theme but there is a need for greater visibility of AI capabilities. Some new appointments are planned but it will be important to think whether this is enough and are there others across the BRC network who could support AI work for this theme. Current capacity needs to be better described but it may also need to be expanded. Important that statistics team are seen as academic collaborators not providers of a service. This was previously the case but it's now important to maintain the visibility as independent researchers. There was discussion around a Best Practice group. The theme currently have a structure in place and they are writing and publicising analysis plans and protocols for epidemiological studies.

There is a need to articulate evidence of specific projects' work across the theme. Ensure access to local specific data and build regional links TRE. (Nigel Brunskill). Possibility of biobanking spare routine blood but it was unclear exactly what data sources this theme will use from the documentation but this was well described in the discussions. Identify specific areas of expertise and where possible points of difference to other sites.

USPs are:

- Leadership in Ethnicity and MLTC and access to data such as ONS, NHS England and National Diabetes Audit
- Expertise in AI and machine learning is not clear in the briefing documentation. collaborations with Mathematics dept. MSc in Population Health Data Science
- AI posts – just interviewed for a joint lecturer post between mathematics and CLS
- Methodological/epidem/ support MSc
- Link with Loughborough Uni – Data Scientist, DECODE Team
- Local collaborations such as 2 AI PHDs and a Lecturer who will be based in RWEU.

Ensure there is proper collaboration with other themes, rather than statistical support only. There are some good examples but again, not well articulated.

There was a recommendation to increase the theme's industrial collaborations which are based on the USPs rather than just the long-standing relationships with KK/MJD.

- UoL – Global Health links to China and India.
- Links with ORION, Astra Zeneca, Servier, NOVO, Sanofi, Lilly and Unilever. Other collaborations with insurance companies ongoing.

HDRUK – establish links with the Midlands Network group. The theme are already linked with national HDRUK and the HDRUK-BHF Data Science Centre

Think about how analysts working across different projects can learn from each other and share common codes etc. Some good initiatives already but having a standard approach to how to tackle and document data projects and a shared data/ analytics commons could help accelerate this.

There were some key areas of strength across BRC that should be maximised. Lots of work already going forward across themes e.g. COVID/Long COVID but this could be reviewed regularly to identify opportunities.

Public health input in this theme is key and is there but should be better described. Local data would seem key to some of the proposed developments. It is crucial to work with the partner NHS Teaching Hospital Trusts to ensure the new data warehouse can provide access to local patient population Ideally look to develop this to have primary/secondary care

data. EXCEED has done this already so there is an existing use case to build on.

Development of the biobanking/EHR (again existing in EXCEED) would seem a key next step for the BRC.

TRE has three distinct stages – data collation, data preparation and hosting access. The last stage of this can be easily subcontracted to organisations such as SAIL.

Discussed briefly issues EXCEED have had about working with commercial companies despite data all being consented. Important this was resolved.

Recommendations

1. There is an overall need for the theme to improve messaging and communications related to their expertise and specialisms, of which there are many. In particular, the ESAG briefing document needed more detail.
2. Strategic staffing positions to strengthen AI and also use of local routinely collected data.
3. Support for Dr Free in his negotiations to get BRC access to data for research is essential whether from existing staff or new positions.
4. Look to further develop biobanking with linked EHR.
5. Resolve collaboration with industry for data resources such as EXCEED.
6. There is a need to make it clear that the theme has Public Health input.
7. There is a need to be much clearer in the USPs; what data does this theme have access to that others don't? One example being ONS data.
8. It is crucial to work with the partner NHS Teaching Hospital Trusts to ensure the new data warehouse can provide access to local patient population, ideally look to develop this to have primary/secondary care.
9. Develop a standard approach to how to tackle and document data projects and a shared data/analytics commons could help accelerate this.

Report on Environment Theme

Report prepared by Professor Anna Hansell and Hayley King

Summary

Present: Guy Marks (GM)(ESAG Member), Anna Hansell (AH) (Theme Lead), Josh Vande Hey (JVH), Chris Brightling (CB), Bibek Gooptu (BG), Leah Cuthbertson (LC), Julie Morrissey (JM), Hayley King (HK).

Each project was summarised by the project lead(s) and discussed with Guy Marks. The insight and support provided by Guy was greatly valued by the team.

Professor John Gulliver's departure was also discussed and the impact this has on the theme achieving their overall objectives.

Does home indoor air exposure affect symptoms in people with moderate-severe asthma?

Leads: Anna Hansell, Chris Brightling

- Discussion around whether VOCs produced by fungi have a toxic effect themselves. Separation of VOC and fungal effects may be challenging, but could explain how individuals who are not allergic to moulds react to them. It could also be part of the explanation as to why patients clearly identify moulds in the home as an issue but anti-fungal treatment does not work.

What are environmental triggers for interstitial lung disease in different populations?

Lead: Bibek Gooptu

- Discussion focused on whether there is a common environmental trigger to this disease such as shared customs e.g. cooking but also the importance of considering genetic factors.
- GM has a colleague who samples the environment using filters placed in the nose, which can then be immune-stained from the persons own serum to determine immune reactions to the environment – this could be an interesting technique for this project.
- GM suggested that the first step is to identify the antigen then to move on to a case control study with those who also react and don't get the disease to determine the differences.
- Currently case controls avoiding genetic links are being considered to isolate environmental exposures.

Does ambient air pollution exposure impact responses to physical activity in patients with LTCs and MLTCs, including cardiovascular and metabolic diseases?

Leads: Anna Hansell, Andre Ng, Josh Vande Hey

- There was discussion of a similar app in use in Australia created by Faye Johnston. The app provides information about the environment including pollens and air pollution for the area that the user is in. The app also collects information about their symptoms so has dual purpose and is part of its strength.
- It is important that the app provides information over time and space rather than about one static area as people are constantly moving.

Does outdoor air pollution affect microbiome and pathogen behaviour in vitro and clinical course in patients with COPD or COVID-19?

Leads: Julie Morrissey, Chris Brightling

- GM suggested there is opportunity here to look at the questions from a broader perspective that appeals to funders and publishers. There are potentially two frames for the questions:

1. How does air pollution influence the microbiome in the lung, and what are the consequences of that? Are there any effect modifiers (e.g. smoking or pre-existing lung disease) that influence the impacts of air pollution in the microbiome and subsequent outcomes?
2. Are there mitigating factors that can be implemented to offset the effects on the microbiome and its subsequent health effects?
    c. For the foreseeable future there will be areas of the world where pollution is high but where enough cannot be done to significantly lower levels. Are there opportunities for mitigate of health effects?

- There was discussion on the potential for changes in the microbiome being linked to disease onset as well as progression. This gives an opportunity to potentially target changes to the microbiome as an early-stage intervention and can include consideration of whether these changes are part of the mechanism by which people develop respiratory disease such as COPD.
- Discussion on steroids and how these can cause microbiome change. GM suggests that if a steroid-naïve population is required Vietnam could be an appropriate choice.

Do current environmental exposures in clinical settings affect health?

Leads: Josh Vande Hey, Rebecca Cordell, Sarah Johnson

- GM: His colleagues who focus on sleep colleagues are particularly interested in light but also in noise. The effects of sleep impact on cognition, memory and performance. This could be particularly relevant in a hospital setting where an outcome can be delirium in those who are predisposed. Sleep colleagues also perform performance tests (e.g. driving simulator) and psychometric testing to determine the impact of sleep deprivation.
- Potential hypothesis: noise and light cause deteriorating function due to sleep deprivation.
- GM suggests finding someone with an interest in the effect of sleep deprivation on function to work with on this project.

Thunderstorm Asthma:

- There was discussion of a newly developing project on thunderstorm asthma. The causes are different in the UK and Australia, where it is associated with grass pollen. Warning systems have now been built into apps to warn users of weather contributions which may cause a spike in the condition.

Recommendations

1. Interstitial lung disease project to consider nasal filter sampling.
2. Recommended that the air pollution and physical activity look into the Australian app designed by Faye Johnston.
3. Microbiome – to frame the questions in a broader context to appeal to funders and publishers, e.g. include effect modifiers and mitigating factors.
4. Exposure project – suggestion to identify a research expert within the BRC interested in sleep deprivation to collaborate with on this project.
5. There is a further risk with the loss of John Gulliver's senior post within the theme and a significant risk to capacity within this new and relatively small theme if this post is not replaced.

Supporting Platforms

There are a number of overarching Platforms across the BRC, specifically Industry and Commercialisation (no academic lead currently), Informatics Platform (led by Dr Rob Free), Training and Capacity Development Platform (ked by Professor Sally Singh), Inclusion, Involvement and Communication Platform (Dr Natalie Darko).

Industry and Commercialisation

The stipulated BRC ethos is it allows us to set up work that then leverages additional outputs and in terms of business and commercial commercialization, this is a key aspect of the BRC, as such our objectives include:

- To have at least two applications to a major funder each year, with at least 50% of these being cross theme.
- To have a partnership with industry annually, resulting in publications, funding applications or shared research projects.
- Aspiring for at least an 8-fold return on investment, our objectives have a five-fold return but that will rely on leveraging commercial and enterprise funding.

A recent bid for Health Tech Research was shortlisted but ultimately unsuccessful – this bid would have been a pathway to commercialisation particularly around Heath Technology. The main issue identified was the lack of capacity within the commercial team at UoL to deal with the upscaled BRC (over 200 PIs) and the lack of leadership to provide and advocate and champion in this area. There was further discussion on the challenges of the pipeline and the focus on external companies' vs spin-out companies and regional challenges.

The discussion moved to the appointment/recruitment of a commercial lead and the type of individual needed, for example someone from an industry background or mixed background can be quite useful because it brings that culture with them and a lot of places which have a highly fertile ground for innovation that have people who come back and forth between industry and academia. It was noted that some thematic areas have stronger Industrial links e.g., respiratory theme has multiple partnership programmes with Industry whereas in other thematic areas this is lacking. There was some discussion on potential barriers to appointment to this position and on the challenges of commercialisation including the successes with clinical translation pathway where we interact with industry.

Recommendations

1. Given a BRC focus is to leverage additional outputs in terms of business and commercial commercialization, the ESAG felt that it was essential that an academic lead for the Industry and Commercialisation to be prioritised and an appointment made in the early New Year.
2. Given the feedback from the Health Tech Research submission that the commercialisation team was too small, the ESAG would encourage University support in this area e.g., commitment to a BRC resource to focus on business development and would support further discussion with Carl Edwards (Commercial Manager at University of Leicester).

Informatics Platform

Dr Rob Free gave an update on the informatics platform. They have been streamlining processes and making sure themes have equal access to the platform via a request portal. They have designed and implemented bespoke study dashboards. They can also support researchers to use OpenSpecimen and REDCap.

A key discussion area was the requirement for a Trusted Research Environment (TRE) which is not currently available within the BRC. There was reference to an East Midlands TRE hosted at University of Nottingham and one possibility would be to align with this initiative and leverage the governance processes which are already established there. There was additional discussion about the secure data environment (SDE) requirements for early phase clinical trials (phase 1 secure data environments are allowed to build their own infrastructure whereas Phase 2 clinical trials are not – the East Midlands TRE was believed to be a phase 2 environment). It was noted that the East Midlands have engaged with a commercial company (BC Platforms: Your Partner in Advancing Personalized Medicine) to develop the infrastructure for the phase 2 TRE and this is has staff resource from the Nottingham TRE.

The BRC has developed a dashboard to standardise data metrics across the BRC and this data will be used to demonstrate progress made against commitments in the BRC funding commitment. The data metrics the current iteration of the dashboard measures are as follows:

1. Current return on investment
2. Total Income by source
3. Number of Cross Theme Projects Across the BRC
4. Number of Participants Recruited
5. Total BRC publications
6. Percentage of NIHR Acknowledgements
7. Number of BRC staff completed training: Cultural Competency
8. Number of BRC staff completed training: Active Bystander
9. Number of Platform Support Requests
10. Number of NIHR Senior Investigators
11. Number of staff on NIHR funding panels.

Explanation of the different sources of the data used for the BRC Dashboard and the complexities and inconsistencies of some of that data were discussed with the ESAG. There are 16 different sources of information and there have been some issues with data quality including key tracking measures e.g., active bystander training. The additional part of this is to develop ways of standardising EDI data across the BRC which will allow measurement and benchmarking against key metrics. There is further work being carried out on network analysis to capture inter theme working and collaboration. The University has recently changed the systems which they utilise to capture data, which has resulted in a delay in data transfer and accuracy. Some of the data is pulled directly from tools such as Scopus (publications) and other data is currently entered manually. The ESAG was impressed with this initiative and there was some discussion around commercialising this dashboard for use by other BRCs and research networks.

There was also a further suggestion to plug impact assessments into this tool. UoL keeps a record of impact cases that align with commercial cases. Access to real-time applications and award data is an absolute priority for the college, for the BRC and all investigators. There should be recognition that there are many different sources for information and the amount of data cleaning that needs to happen is phenomenal. There is ongoing data cleaning and refining. The dashboard will develop and evolve over time as well as bringing in further metrics that we will be reporting on. The aim is to provide enough accurate information for theme leads to make decisions within their themes. The dashboard has a variety of functions – an external response to NIHR to ensure we are meeting our objectives as well as decision making.

Recommendations

1. The BRC should focus on development of a TRE for access to routine healthcare data and facilitating important linkages with this data across their research platforms
2. There appears to be established infrastructure to support Phase 2 Clinical Trials in Nottingham which is resourced

from the Nottingham TRE – the ESAG suggests that formal links with this infrastructure should be established to leverage their infrastructure and governance processes to support Phase 2 Clinical Trials and linkage to routine healthcare data

3. There are a number of important initiatives in the HDR-UK Driver Programmes and the BRC should try and link in with these to leverage their expertise in establishing TREs and linked data

Post-Report Update

University of Leicester and University of Nottingham have now established a Trusted Research Environment.

Inclusion, Involvement & Communications

In terms of public involvement, the ESAG noted evidence of a clear public communication strategy e.g., extensive media coverage of the long COVID data emerging from PHOSP-COVID programme. There are also important initiatives in Public involvement in Research including active (1) outreach into underrepresented communities and (2) implementation of enhanced data collection and record keeping processes to support annual reporting and strategic development to ensure we continue to work with our diverse communities. There was some discussion on what is being measured and how the BRC can measure the effectiveness of individual initiatives.

The ESAG commented on notable achievements e.g., recent appointment of 22 PhD students from diverse backgrounds, appointment of the new Director of Inclusion to develop a strategy which will keep focus of EDI in all aspects of the BRC programme and plans to collect data in the BRC using the NIHR Diversity Question Set.

There was discussion on the potential implementation of Economic Costing metrics for Ethnicity, Diversity and Inclusion by NIHR. Professor Natalie Darko reported that when NIHR visited the Leicester BRC recently there was an emphasis on changes to NIHR reporting. NIHR have set 2027 diversity professional targets for their funding committees and panels and one thought would be to benchmark currently against these metrics across the BRC programme. A key question is what has the BRC spent on EDI, what is the impact, what is the return on investment? One option discussed was to look at location footprints related to populations using the 2021 census.

The BRC asked how they can best support diverse research teams to deliver public involvement? The ESAG felt embedding Patient and Public involvement early in the discussion and development of all projects is ideal. There can be challenges particularly with patients as often a select group will volunteer whose view is often not broadly reflective of the patient population as a whole. Engagement of a truly representative and diverse group should be proactively sought, including strategies to ensure ethnic diversity and broad inclusion.

Recommendations

1. The ESAG would recommend that the BRC identify plans to capture relevant metrics around their proposed EDI initiatives to try and demonstrate that these have worked effectively. Ideally these should be aligned with the required format for NIHR reporting.
2. Accepting that implementation of Economic Costing metrics for Ethnicity, Diversity and Inclusion will be required by NIHR, processes should be established which will provide information on what the BRC is spending on EDI initiatives and what is the effectiveness and impact on this investment.

Training & Capacity Development

A brief update on the training and capacity development platform was provided by Sally Singh. The ESAG noted important initiatives to increase capacity including an NIHR INSIGHT submission: Inspiring Students into Research scheme and a 'secondment' programme from clinical work to encourage periods in research by clinical staff in the NHS.

A benchmarking survey is currently in the final stages of development across the BRC and will be rolled out across the research landscape at UHL and partner organisations. It is hoped that this survey will provide an insight into the thoughts and feelings of staff about research and also identify researchers that are at the mid-point within their careers. This will also help to show gaps in training and where potential support can be provided to this important and often overlooked research group.

The challenge of how the BRC can increase diversity at senior research levels (e.g., for underrepresented professions/ protected characteristics) was noted and again the appointment of the new Director of Inclusion and a strategy will keep focus on diversity in all aspects of the BRC programme.

In November 2022 Leadership Development Training was delivered and attended by 23 BRC Early Career Researchers to upskill and develop our workforce.

Recommendations

No additional specific recommendations.

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