

Meeting title:	Public Trust Board	Public Trust Board paper K				
Date of the meeting:	10 th August 2023					
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
<p>The report highlights the delivery and performance of R&I at UHL, progress of important research, engagement activities and newsworthy items.</p> <p>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.</p>

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

August 2023

1. INTRODUCTION

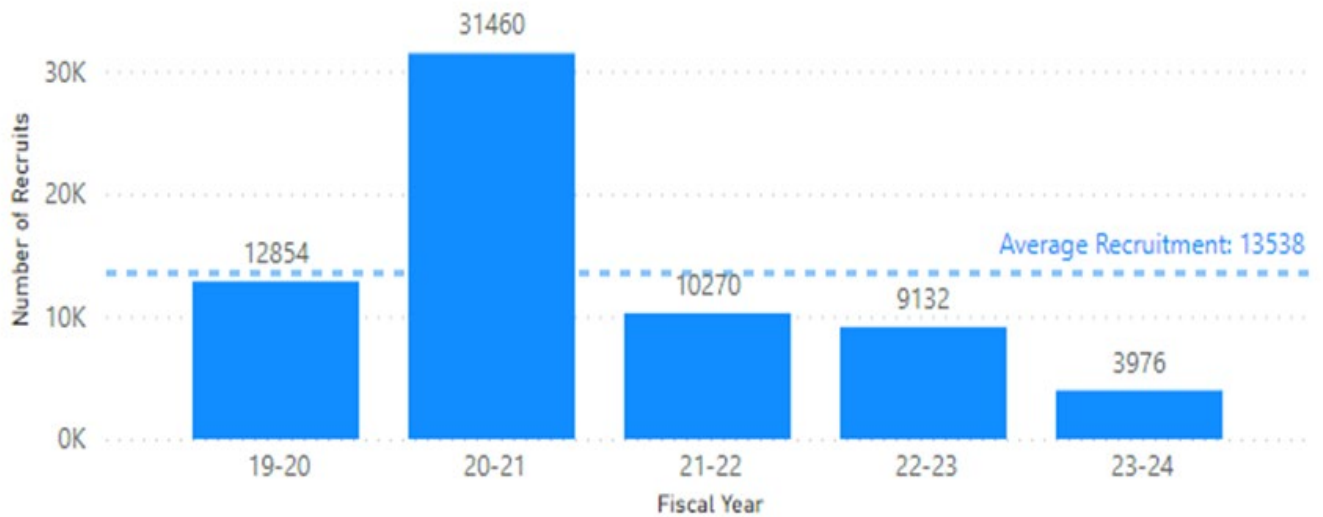
This report describes UHL R&I activities, performance and delivery in the last few months.

2. RESEARCH PERFORMANCE AND DELIVERY

2.1 Recruitment into CRN Portfolio Studies

Since the last R&I report in May 2023 there is some legacy COVID-19 urgent public health research activity with participants in follow-up, but other study activity continues to move back towards business as usual.

	19/20	20/21	21/22	22/23	23/24
New Studies Approved	168	131	207	213	65
Commercial studies approved	51	34	60	62	18



Fiscal Year	Number of Recruits
19-20	12854
20-21	31460
21-22	10270
22-23	9132
23-24	3976

Figure 1: Comparative Annual Portfolio Recruitment for UHL 2019- present (data complete to early July 2023)

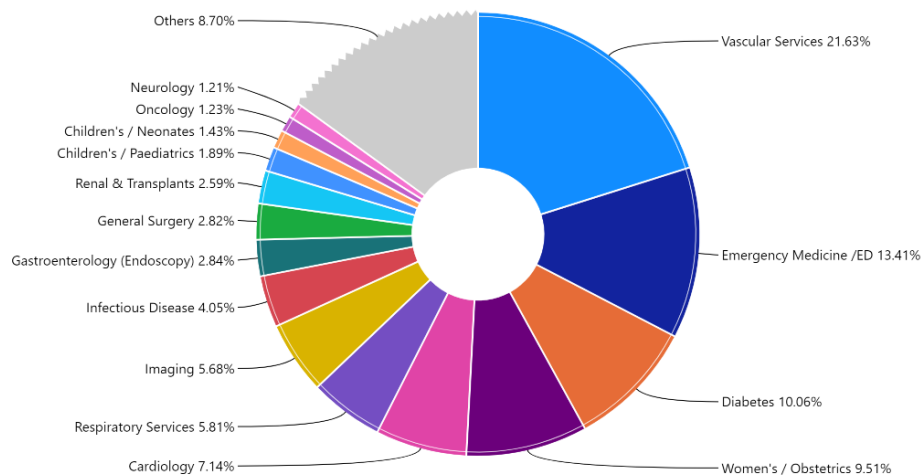


Figure 2. Portfolio Recruitment at UHL 2023-24 by Clinical Speciality (data complete to early July 2023)

2.2 Performance Analysis

Clinical trial recruitment is now picking up and is projected to exceed 2022/23 as a consequence of:

- i. Detailed performance analysis of study performance across specialties at UHL.
- ii. Targeted identification of potentially high recruiting studies.
- iii. Additional targeted support to studies with potential to recruit high numbers of patients

2.3 Final Report on NIHR Leicester Clinical Research Facility

We have received excellent feedback from NIHR on our final NIHR CRF annual report (Appendix 1):

'This CRF has delivered amazing results over the last 12 months providing hundreds of Covid vaccinations to the people of Leicester. The CRF also provided ongoing training programmes for all the CRF staff and PPI contributors which were compulsory and lasted 12 months.'

3.0 ENT STUDIES AT UHL

3.1 ENT studies at UHL encompass malignant and non-malignant ENT diseases and are based largely at LRI. ENT has been identified for support to enable growth and development of their research portfolio.

We will be joined by Mr Oladejo Olaleye, Consultant ENT Surgeon at UHL to discuss his research and plans for growth in ENT research at UHL.

4.0 RESEACH FUNDING AWARDS

4.1 NIHR Capital Award. UHL, together with its partners at the NIHR Clinical Research Network and Nottinghamshire Healthcare NHS Foundation Trust, has been awarded over £6M from the NIHR for capital projects to support high-quality research. The projects put forward include CT and MRI scanners, equipment for exercise laboratories, our type 1 diabetes and technology programme, the foot and tendon suite, and isolators for our proposed aseptic laboratory.

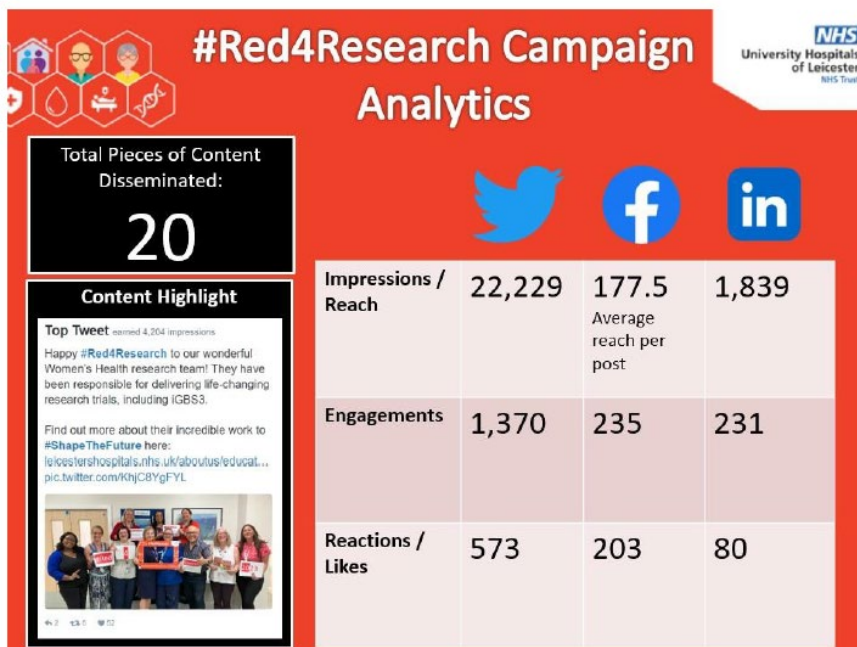
4.2 Research Capability Funding. Delivery of commercial clinical trials in the NHS is a DHSC and NIHR priority as part of the Research Reset process. UHL delivered 91.4% of commercial trials on target for recruitment to time and target against a national target of 80%. The cut-off date was the 21st July 2023. As a result, UHL will receive an additional £75,000 research capability funding.

4.3 National Institute for Health Research HealthTech Research Centres (NIHR HRCs). The UHL bid for an HTC has been shortlisted for a Stage 2 interview. This will take place on 22nd August and a contingent from UHL and University of Leicester will be attending in London.

5.0 RESEARCH AND INNOVATION COMMS AND ENGAGEMENT

5.1 Red4Research 2023

Friday 16th June was national Red4Research day providing an opportunity to recognise clinical research and all the colleagues who make it happen. UHL combined a social media campaign with an in-person event at all three sites. The Victoria Building at LRI was illuminated red for the evening.



5.2 Launch of the UHL 'Inspire' journal

The first issue of Inspire was published in May 2023. Designed to highlight the work of nurses, midwives allied health professionals, health scientists and pharmacists, 'Inspire' will be published three times a year to share knowledge experience and achievements across different professional groups and specialities.



Prof Nigel Brunskill
August 2023

NIHR CLINICAL RESEARCH FACILITY

Feedback on Final Annual Report - 1 April 2021 to 31 August 2022

NIHR Leicester Clinical Research Facility

Summary of Feedback

The NIHR would like to thank all staff for their contribution to delivering the work programme over the year and for the time taken to compile this annual report. We appreciate that the Covid-19 pandemic has continued to create challenges for delivery and reporting.

In this final report, the CRF has reported completion of all their objectives. Thank you for your support on studies that explore the longer-term effect of Covid-19 and the effects on ethnic minority healthcare staff (PHOSP COVID and UK REACH respectively). We note that the findings from PHOSP-COVID led to leveraging of external funds from UKRI and Genentech for two interventional trials. We also note that the CRF has reported a new working relationship with the University Hospitals of Northamptonshire (UHN) NHS Group, which should enable the delivery of early phase trials at UHN in the future. We look forward to hearing about this development in future reports.

Over the extended reporting period, the CRF leveraged just under £10 million from a wide variety of external funding sources, with the majority of the funding obtained from industrial partners. Over the last five months of the CRF contract, a total of 135 studies were reported. Five of these are first-in-human studies; all of which were reported as high-intensity/risk studies.

Thank you for providing the added value examples, which we enjoyed reading. NIHR may be in touch in the future for additional details should the examples be developed further into case studies.

There have been no major changes to the CRF's strategy, the original objectives were met including the mid- and long-term objectives and there were no significant issues reported.

**Centre
Overall (RAG)**



Progress Descriptors

Green = On track. No risks to delivery were identified, and 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 CRF continued to implement its strategic objectives with no significant issues. However, we note that the CRF was still recovering from the effect of the COVID-19 pandemic which impacted study delivery.

The CRF made significant progress along its translational pipeline, in particular leading the PHOSP and COPD-ST2OP studies. The CRF has been a major contributor to the recruitment of the RECOVERY study and related outputs. We also note that the CRF continued to work closely with the Leicester NIHR Patient Recruitment Centre to develop a seamless pipeline for sponsors and investigators facilitating early-phase commercial study delivery through to later phases.

The CRF has reopened several studies in various disease clusters that had been paused due to Covid-19 studies; there has been an increase in the number of open studies for all disease clusters, and most of the non-commercial studies have met or exceeded their recruitment target. The CRF continued to maintain close links with other NIHR Infrastructure, including the BRC and has also been part of the Trust and University of Leicester Strategic and Governance board. The CRF has also been part of the Midlands Health Alliance (a collaboration between Midlands NIHR infrastructure) and the UKCRF Network.

The CRF has offered various training and educational opportunities at all levels including the Chief Nurse Fellow Programme and *in-vivo* gene therapy training. Other training opportunities offered include CRF-supported courses, study days and conferences.

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.

Objectives	Comments on progress against objectives	RAG Status
<p>Short-term objectives:</p> <p>ST1: Implementation of In-Situ Acute Platforms for Experimental Medicine Studies.</p> <p>ST2: Integration of Existing Speciality Clusters into a Single Federal CRF Structure with Unified Management and Strong Governance.</p> <p>ST3: Increase the proportion of experimental studies performed by University Hospitals of Leicester (UHL) CRF existing speciality clusters.</p> <p>ST4: Aligning Patient Recruitment and Industry Liaison.</p>	<p>ST1: Complete 2019</p> <p>ST2: Complete 2019</p> <p>ST3: Complete 2019</p> <p>ST4: Complete 2019</p>	
<p>Medium-term objectives:</p> <p>MT1: Continue to develop emergency medicine research.</p> <p>MT2: Increase research funding.</p> <p>MT3: Increase research outputs.</p> <p>MT4: Develop training and education activities.</p> <p>MT5: Introduction of long-stay and overnight patient facilities.</p> <p>MT6: Plan timely replacement of imaging equipment.</p>	<p>MT1: Complete 2019</p> <p>MT2: Complete 2019</p> <p>MT3: Complete 2019</p> <p>MT4: Complete 2020</p> <p>MT5: Complete 2021</p> <p>MT6: Complete 2020</p>	
<p>Long-term objectives:</p> <p>LT1: Develop new Cancer CRF accommodation at Leicester Royal Infirmary.</p>	<p>LT1: Complete 2021</p>	

LT2: Augment excellence in research scanning.	LT2: Complete 2021	
Overall Objective 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		
<p>We acknowledge that a new CRF manager was appointed in November 2021, and will remain as manager of the CRF during the 2022-2027 funding period. We also note that the CRF director continued to be the director of R&I for UHL NHS Trust and the Clinical Research for the University of Leicester.</p> <p>We commend you on the recent grant awards from CRUK (£7.3 million) and BHF, which include the PhD Studentship Programme and the Chair of Cardiac Surgery.</p>		
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		
<p>General Comments: This CRF has delivered amazing results over the last 12 months providing hundreds of Covid vaccinations to the people of Leicester. The CRF also provided ongoing training programmes for all the CRF staff and PPI contributors which were compulsory and lasted 12 months.</p> <p>Areas which are particularly noteworthy or represent best practice and merit dissemination to other Centres: Setting up the 'Participant Research Engagement Group (PREP) and forming collaborations with the Leicester Centre for Ethnic Health Research (CEHR). The (PREP) Supported the CRF to gain additional funding for a piece of research that will improve drug efficacy. This is clearly an exciting piece of research, and it would have been nice to read about the impact and outcomes. The PREP took an active role in the design of the research project.</p> <p>Areas for improvement: It is really good that efforts to connect with underserved communities are continuous and ongoing. We would like to hear how this is progressing as part of the new award, so please keep us informed.</p>		
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: NOCRI Feedback		
<p>The Leicester CRF has fully participated in the NIHR Recovery, Resilience & Growth programme and the NIHR Leicester CRF Director has participated in several national conversations about this in the national forum and has remained a dominant focus of activities this year with supporting the delivery of the ACCORD Trial ran through the Respiratory TRC.</p> <p>The CRF utilised strong relationships with the local NIHR Infrastructure and organisations based in the Midlands to drive the industry opportunities being delivered and supported by the CRF. The CRF has also</p>		

supported a range of SMEs both UK based and internationally combined with discussions with large pharma (Novartis) to build strategic partnerships.	
Industry (RAG)	<p>Green = On track. No risks to delivery identified.</p> <p>Amber =Satisfactory. Minor issues, no risk to delivery, areas to consider in feedback.</p> <p>Red = Unsatisfactory. At least one major issue identified in feedback.</p>

Feedback of Actions Required or Areas for Consideration

Section	Comment/ Action
Overall Assessment	No action required.
Overview of activities	No action required.
Overview of objectives	Thank you for reporting progress against the CRF's short-, medium-, and long-term objectives. We would however have expected to see greater detail of reporting against your objectives, which were completed within the timeframe of the reporting period, as well as progress on previously highlighted objectives, such as the "Medium-Term Objective - Continue to develop emergency medicine research" .
Governance and Leadership	No action required.
PPIE	It is really good that efforts to connect with underserved communities are continuous and ongoing. We would like to hear how this is progressing as part of the new award.
Industry (NOCRI)	No action required.

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

<p>Dear Professor Brunskill,</p> <p>NIHR would like to thank you and all CRF staff for their contribution to delivering the work programme over the duration of the NIHR CRF contract despite the continued challenges presented by the Covid-19 pandemic. We would also like to thank you for the time taken to complete this final report; we appreciate your, and the CRF team's efforts, in reporting your progress on an annual basis.</p> <p>We have no concerns which require immediate action. Once again thank you for all your endeavours in directing the CRF.</p> <p>Kind regards, NIHR</p>
