

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

Trust Board Bulletin – 1 November 2018

The following report is attached to this Bulletin as an item for noting, and is circulated to UHL Trust Board members and recipients of public Trust Board papers accordingly:-

- **Research and Innovation quarterly update** – lead contact point: Mr A Furlong Medical Director (0116 258 3871) – **paper 1**

It is intended that this paper will not be discussed at the formal Trust Board meeting on 1 November 2018, unless members wish to raise specific points on the reports.

This approach was agreed by the Trust Board on 10 June 2004 (point 7 of paper Q). Any queries should be directed to the specified lead contact point in the first instance. In the event of any further outstanding issues, these may be raised at the Trust Board meeting with the prior agreement of the Chairman.

UHL Research and Innovation: Quarterly Trust Board Report Nov 2018

Author: Professor Nigel Brunskill, Director of R&I Sponsor: Medical Director **Trust Board Bulletin paper 1**

Executive Summary

Context

UHL is a Trust active in Research and Innovation (R&I). This report describes current R&I performance against metrics, projects under development, new challenges and potential threats.

Questions

1. Is UHL performing well in the delivery of quality research at expected volume?
2. Are large projects planned with appropriate partners and managed appropriately?
3. Are upcoming challenges understood?

Conclusion

1. UHL performs well in delivering high quality research as judged by NIHR and LCRN data, recruitment remains under continuous scrutiny.
2. A larger number of large projects are in development, some being close to start date. There is a wide range of NHS and Academic partner engagement.
3. A number of challenges are recognised and planning is in place to mitigate risks.

Input Sought

Report is presented for information and assurance.

For Reference

Edit as appropriate:

1. The following objectives were considered when preparing this report:

Safe, high quality, patient centred healthcare	[Yes]
Effective, integrated emergency care	[Yes]
Consistently meeting national access standards	[Not applicable]
Integrated care in partnership with others	[Yes]
Enhanced delivery in research, innovation & ed'	[Yes]
A caring, professional, engaged workforce	[Yes]
Clinically sustainable services with excellent facilities	[Yes]
Financially sustainable NHS organisation	[Yes]
Enabled by excellent IM&T	[Yes]

2. This matter relates to the following governance initiatives:

Organisational Risk Register	[Yes]
Board Assurance Framework	[Yes]

3. Related Patient and Public Involvement actions taken, or to be taken: [Insert here]

4. Results of any Equality Impact Assessment, relating to this matter: n/a

5. Scheduled date for the next paper on this topic: [quarterly]

6. Executive Summaries should not exceed 2 pages. [My paper does comply]

7. Papers should not exceed 7 pages. [My paper does comply]

UHL R&I Quarterly Trust Board Report November 2018

1. Introduction

This report describes current R&I performance against metrics, projects under development, new challenges and potential threats.

2. Research Performance

The activity of UHL in initiating and delivering clinical research is performance monitored by both the NIHR Central Commissioning Facility (NIHR CCF) and the East Midlands Clinical Research Network (EM CRN). In turn the UHL R&I Office reports research CMG level activity and performance to each CMG via the R&I Executive Committee.

2.1 NIHR CCF

UHL is also judged by its performance in initiating and delivering clinical trials to time and target. In Q1 2018/19 this figure has been excellent and represents a sustained performance. In terms of initiating research, UHL is in 18th place (out of 203 Trusts) in League 1 (of 7).

In terms of delivery UHL is in 14th place (also League 1).

2.2. EM CRN

Cumulative recruitment into portfolio clinical trials for 18/19 is approximately in line for that in 17/18 although the number of trials delivered by UHL may be lower this year, although note the numbers in the histogram for 18/19 will rise by the end of year . Working with colleagues from EM Clinical Research Network we have established an action plan to maximise clinical trial recruitment at UHL (please see accompanying paper)

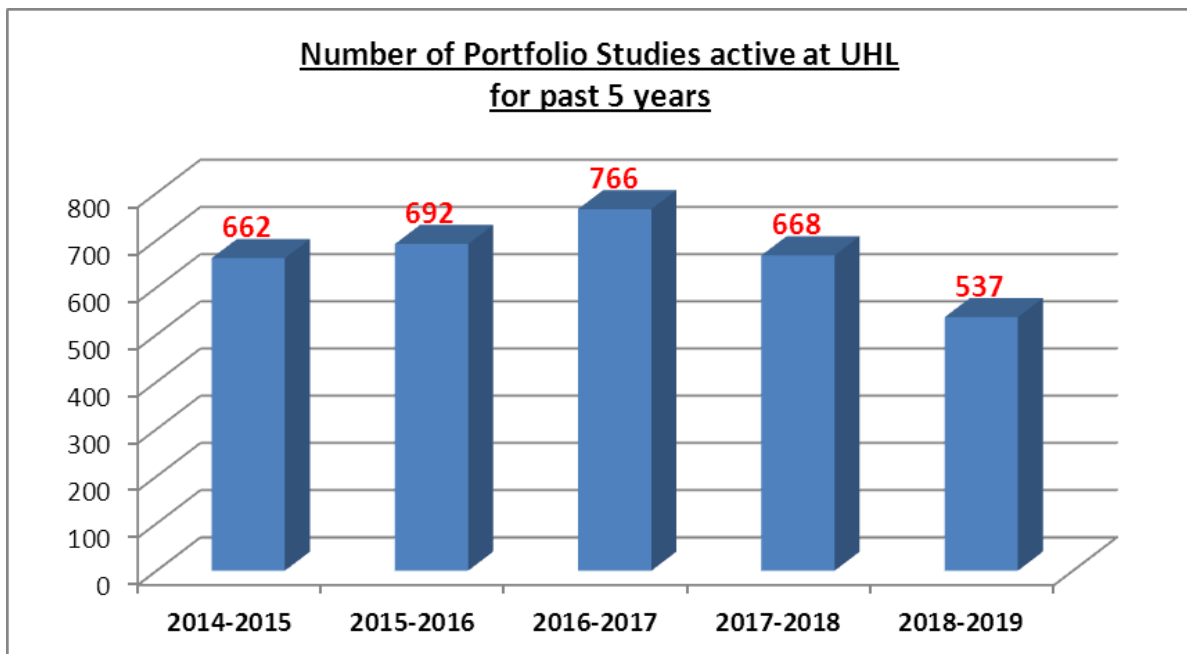
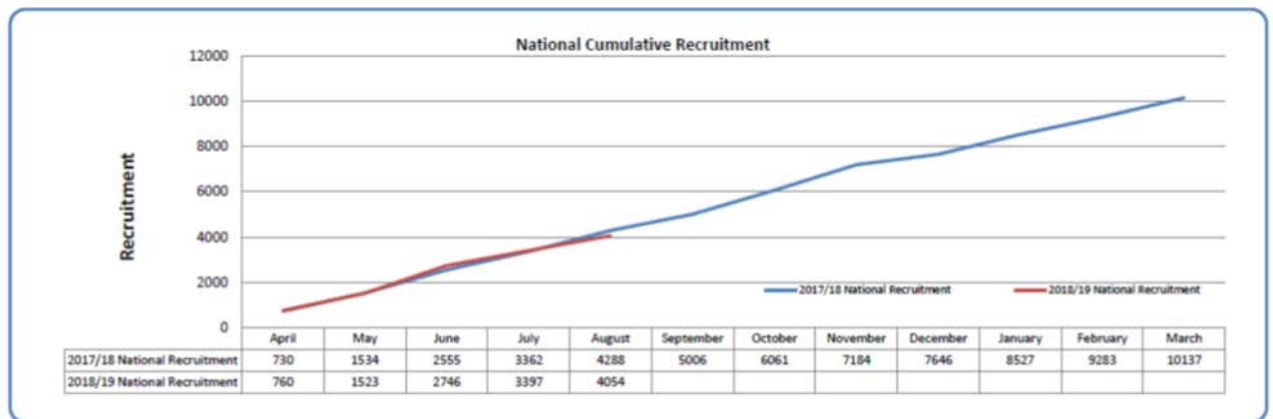


Figure 1. NIHR portfolio studies active at UHL per year



Sources: EDGE and NIHR Open Data Platform
 2018-09-21 University Hospitals of Leicester NHS Trust Partner Report
 Data cut 10-09-2018

Figure 2. Cumulative UHL recruitment into NIHR portfolio studies 2018/19 vs 2017/18.

3.0 The 100,000 Genomes Project

After 3 years of hard work the 100,000 Genomes Project is about to end at UHL. Recruitment of rare diseases completed at the end Sept 2018 and was 14% above of planned trajectory. The Trust has contributed very significantly to the East of England Genomic Medicine Centre. A total of 1147 rare disease participants have been recruited at UHL along with 487 cancer patients (renal, endometrial, ovarian, breast, testis, prostate, upper GI, mesothelioma, haematological oncology).

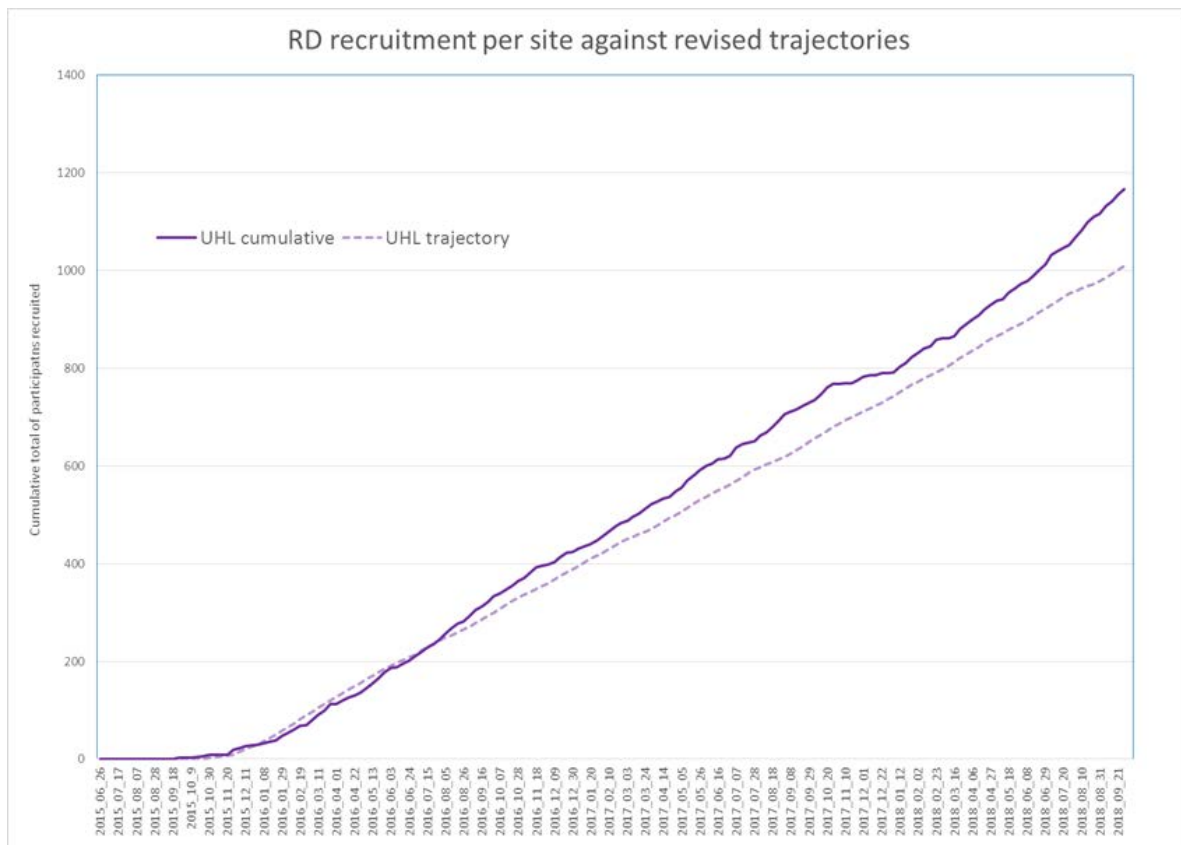


Figure 3. Cumulative rare disease recruitment into 100,000 genomes project at UHL

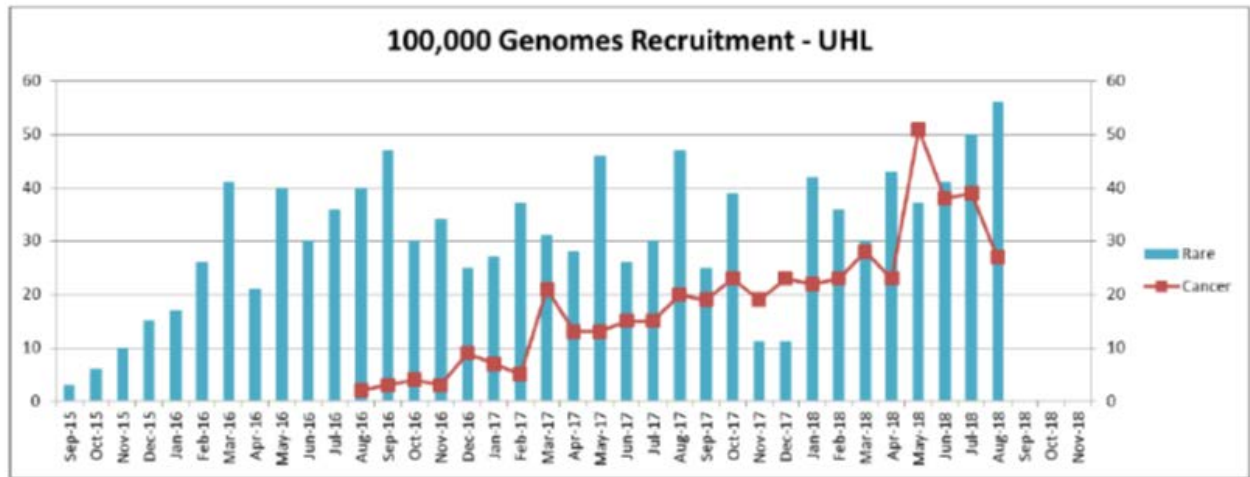


Figure 4. Monthly cancer and rare disease recruitment into 100,000 genomes project at UHL

4.0 Ongoing Projects and Recent Awards

4.1 BRC and CRF

Both these flagship projects are running well and have received favourable comments on their recently submitted annual reports. At the time of initial award the CRF was asked to provide a 2 year report against strategic milestones before NIHR agree to release of the final 3 years of funding. This is in preparation for submission by mid-Feb 2018.

4.2 Grant Awards

Dr Linzy Houchen-Wolloff. SPACE FOR COPD© delivered as a maintenance programme on Pulmonary Rehabilitation discharge: a randomised controlled trial evaluating the long-term effects on exercise tolerance and mental wellbeing. NIHR RfPB £350,928

Prof Elaine Boyle. Multicentre open label, pragmatic randomised controlled trial of early surfactant therapy versus expectant management in late preterm and early term infants with respiratory distress. NIHR HTA, £1,675,930

Prof Christina Faull. Thinking ahead about medical treatments in advanced illness: A qualitative study of barriers and enablers in end-of-life care planning with patients and families from Black, Asian and Minority Ethnic (BAME) backgrounds. NIHR HS&DR, £417,144

5.0 Research and Innovation inclusion in CQC Inspections

In 2018 National Institute for Health Research (NIHR) announced (<https://www.nihr.ac.uk/news/research-to-be-recognised-by-regulators-for-its-role-in-improving-patient-care/7737>) a new partnership between NIHR, the Health Research Authority (HRA), the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Care Quality Commission (CQC), to develop new research indicators for use as part of CQC's monitoring and inspection programme.

The partnership is leading a collaborative project to develop indicators to assess research activity in NHS organisations under the well-led category of CQC inspections. The collaborative project will identify how this can be evidenced by organisations and will run until late Autumn 2018. Research will then be incorporated into CQC inspections from early 2019.

The CQC's focus will be on how well integrated research is within organisations, and will not concentrate on academic credibility, publications and grant income as these impacts are captured elsewhere. One key development is an agreement by CQC to include a question about research opportunities offered to patients in the CQC Annual Survey of Inpatient Experience.

Current information suggests that the following will be inspected by CQC:

5.1 Research Awareness - how does the organisation make research opportunities known to patients, the public and healthcare professionals?

5.2 Research Facilitation - how does the organisation proactively support the delivery of research from board level to the clinical setting(s)?

5.3 Research Equity - how does the organisation support the research programme across the breadth of its services?

Preparations for such inspections are advanced and a detailed plan to address these issues will be going to UHL Executive Strategy Board in November.

Portfolio Trial Recruitment at UHL Analysis and Action Plan

1. Introduction

UHL is very active in the delivery of clinical research studies, but for 2018/19 both numbers of participants recruited to studies, and numbers of active studies (Figure 1) have decreased compared to previous years. This paper outlines the plan for optimising organisational engagement with clinical research and maximising recruitment to studies by actively managing both study pipeline and delivery of active studies.

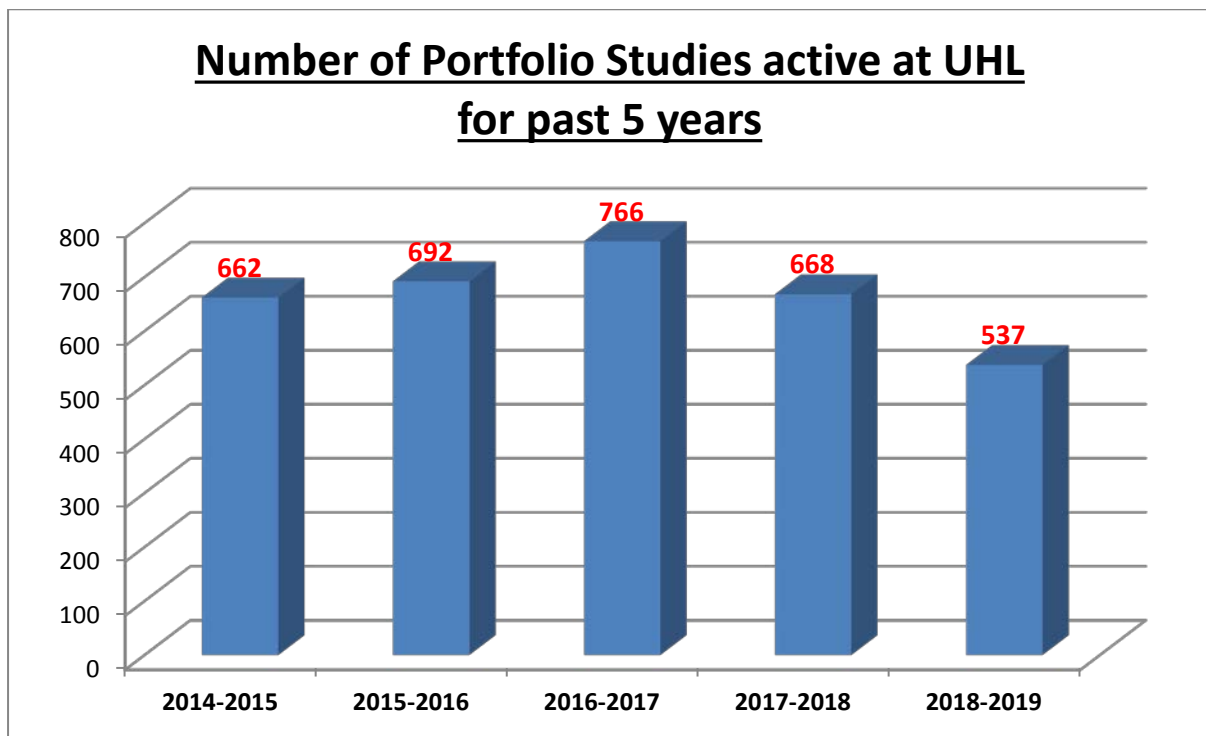


Figure 1. Number of portfolio studies open to recruitment at UHL in each year. For 2018-19 this represents numbers of studies open, up to and including Aug 2018 so is likely to rise by April 2019.

2.0 Organisational Focus

The last few years have seen unprecedented pressures on clinical service delivery at UHL. The following steps will be taken to ensure clinical research and delivery of portfolio studies remain visible areas of priority across UHL.

2.1 A Trust Lead Nurse for Research

A UHL Lead Nurse for Research job description has been written and graded. Some discussion is underway to identify the funding for this 0.5 WTE post to be sited within R&I Department but linked closely to the Corporate Nursing team. This individual will act as focal point for research nurses in the Trust.

2.2 Re-written Job Description for CMG R&I Leads

This has been completed, approved by HR and discussed with the leads themselves. New role description includes greater focus on delivery and performance relating to portfolio study recruitment.

2.3 Contracts for Non-Medical Research Staff to be held in R&I

Previously research staff were employed in R&I, but this changed ~7 years ago and currently most research active staff are employed in CMGs. This poses the following problems:

2.3.1 HR process is complex particularly for embedded organisations, such as the Biomedical Research Centre, that cross CMGs.

2.3.2 There is no consistent approach to appraisal, training and career development.

2.3.3 It is not possible to deploy the research workforce flexibly according to demand and to maximise delivery.

2.4 Trust-Wide Customer Satisfaction Survey of the UHL R&I Department

A survey/questionnaire requesting views on all aspects of R&I function was circulated to all Trust employees and selected University staff. Around 100 responses had been received by the time the survey closed in mid-August 2018. The results are being collated and themes will be picked up and discussed at internal R&I Team meeting prior to the delivery of an action plan to improve the R&I service to customers across the Trust.

2.5 A Refreshed Digital R&I Presence across UHL

Leicester's Research (<http://www.leicestersresearch.nhs.uk/>) is the clinical research website for Leicester's Hospitals. This is in the process of being refreshed and more prominently linked from the UHL home website. In addition R&I will be promoted much more prominently on the UHL website.

2.6 A Trust-Wide Invitation to Consultants to Participate in Clinical Research

The UHL Director of R&I and Clinical Research Network will send regular e-mail invitations to all UHL consultants inviting participation in clinical research offering access to necessary training and a list of available portfolio studies in relevant specialities that could be opened at UHL. An initial email approach in this way has resulted in >20 responses from consultants.

3.0 Research and Innovation Office Process

Increasing participant recruitment is the top priority for the UHL R&I Team. This is led by the UHL R&I Director, but a series of new processes have been established to ensure involvement of the whole UHL R&I Team.

3.1 Monday UHL R&I Team Operations Meeting

Attended by R&I Director, Operations and Feasibility Teams and the Study Support Team. This meeting deals with current operational issues, identifies at the individual study level barriers to delivery and recruitment – including feasibility, set-up and active management of actively recruiting studies - and establishes a weekly plan.

3.2 Wednesday Study Delivery Meetings

The UHL senior R&I Team meet to discuss internal operations and performance data for the previous week focusing on delivery to time and target of active studies. On alternate weeks this meeting takes place at LRI to allow participation of CRN colleagues. Data discrepancies and barriers to delivery are identified, solutions are agreed and cascaded for implementation by the R&I team at the Operations meeting (see 3.1).

4.0 Portfolio Study Pipeline

Trust researchers may be approached about available portfolio study 'Expressions of Interest' (EoI) in several ways:

- by the Clinical Research Network
- by the Trust R&I Department
- independently by academic colleagues in, or outside Leicester

- directly by industry contacts
- by a combination of the above

It is imperative that this process is co-ordinated, that timely responses are provided, and that UHL's potential study Principal Investigators (PIs) recognise that they are responding on behalf of UHL and that responses (or lack thereof) impact on the way the organisation is viewed externally.

This pipeline will be more actively managed as follows:

4.1 Regular direct communication from Director of R&I to all research active staff emphasising importance of taking on new studies.

4.2 Refreshed and expanded contact lists for EoI agreed and harmonised with CRN

This will capture all existing key study contacts and research group leads/managers across UHL. In addition, the following will be included:

- all active/recently active (last 5yrs) PIs in the clinical speciality
- all consultants responding to 2.6 (above)
- relevant CMG R&I Leads

4.3 Three-monthly review and update of contact lists for EoI

4.4 Early follow-up by UHL R&I of all EoI distributed by both CRN and UHL R&I

4.5 Weekly review of distributed EoI and any related responses

4.6 Chasing responses to EoI

If no response after 2 weeks, or study declined, there will be personal follow-up from Director of R&I to offer support and to understand reasons for decline/no response

4.7 Reporting of EoI outcomes as internal performance metric

5.0 Delivery to Time and Target

In addition to the actions above, a T&T campaign will launch at UHL in Autumn 2018 to raise awareness of the importance of this aspect of research performance. There will be a communications campaign to drive this, focusing on the use of Edge and supported by the logo below (Fig 2).



Figure 2. Autumn 2018 UHL T&T campaign logo

6.0 Flexibility to Increase Delivery

Numerous steps have been taken to maximise use of resources

6.1 Agreement between CRF speciality clusters to share facilities with other groups

6.2 Formation of Rapid Recruitment Team (RRT) at LRI

Based in Research Space at LRI, RRT will support flexible delivery of studies across specialities and across sites.