Trust Board Paper V

To:	Trust Board
From:	Medical Director
Date:	25 July 2013
CQC regulation:	

Title:	R&D in UHL: Quarterly report

Author/Responsible Director: Director of R&D/Medical Director

Purpose of the Report: To inform the board of current activity and challenges in R&D

The Report is provided to the Board for:

Decision		**Discussion**	
Assurance		Endorsement	

Summary / Key Points:

UHL has an extensive R&D portfolio and is recognised nationally and internationally for excellence in many of its areas. This report is a high level summary of R&D activities in UHL and considers current challenges.

Recommendations:

The Board is invited to consider this summary and recommend contents and format of future reports.

Previously considered at another corporate UHL Committee?

No

Board Assurance Framework:	**Performance KPIs year to date:**

Resource Implications (eg Financial, HR):
Assurance Implications:
Patient and Public Involvement (PPI) Implications:
Stakeholder Engagement Implications:
Equality Impact:
Information exempt from Disclosure:
Requirement for further review? Quarterly

1. Introduction

1.1 Previously, UHL's Board was informed with respect to research and development (R&D) by minutes of the UHL R&D Committee which was a subcommittee of the Board. The R&D Committee is now an executive committee and the Board will receive formal quarterly R&D reports.

1.2 This is the first report under the new arrangements; therefore, we have prepared a summary of the current situation and present challenges.

2. Major strengths

2.1 *Significant output of high-class clinical research activity*. In financial year 2012-13, UHL: (i) was responsible for 915 clinical trials, including 545 National Institute for Health Research (NIHR) portfolio trials (356 in recruitment phase) and 241 commercial studies; (ii) recruited 9,429 patients to clinical trials, including 7,982 to NIHR portfolio studies; and received a total of £20.1M external research income.

2.2 *Excellent R&D approvals systems*. Study approval times continue to be amongst the best in the UK; in 2012-13, the median number of calendar days for Trust approval was 8.5 days (national target 30 days), from a median of 10 days for 2011-12. UHL was invited to be a facilitator at all 3 national workshops (Leeds, Birmingham, London) as part of the "Faster, Easier Clinical Research" initiative sponsored by the Academy of Medical Sciences, NIHR and NHS Confederation. This is aimed at improving the speed and quality of study approval in NHS R&D departments, including effective working and partnership with NIHR research networks. Our research management team are frequently asked to share best practice with other Trusts and hosted a visit from the Department of Health's Research and Development Directorate who are interested in our approach. We are participating in the NIHR Performance in Initiating and Delivering Clinical Research exercise; this is a pilot which, when finalised, will be rolled out nationally and data made widely available. The most recent data (Q4 2012/13) show that we one of the best trusts for recruiting patients to time and target.

2.3. *Most of our leading research is of direct relevance to patient care, outcomes and service delivery*. It addresses detection, prevention and management of common long-term conditions: (i) cardiovascular disease e.g. genetics, hypertension, novel interventions, arrhythmias, stroke, vascular surgery; (ii) respiratory disease e.g. asthma, chronic obstructive pulmonary disease, pulmonary rehabilitation; (iii) diabetes e.g. prevention, early detection, management; (iv) cancer e.g. early phase trials, biomarkers, prevention, novel treatments; (v) influence of nutrition, exercise and lifestyle on long-term conditions.

2.4. *Other services participate in clinical research (including multicentre NIHR portfolio studies)*. These include: neonatal medicine and outcomes; renal disease; infectious disease; child health; care of the elderly; intensive care medicine; medical genetics, gastroenterology; dermatology; ophthalmology; medical genetics; emergency medicine; health services research; endocrinology, orthopaedics, musculoskeletal medicine; pain medicine.

2.5. *The Trust hosts several NIHR institutions*:

2.5.1 *Three Biomedical Research Units (BRU): (i)* Cardiovascular BRU (with University of Leicester); (ii) Respiratory Disease (with University of Leicester);

(iii) Nutrition, Diet and Lifestyle (with Loughborough University & University of Leicester). Consequently, UHL hosts more BRUs than any other Trust out with London, Oxford and Cambridge.

2.5.2 *Collaborations for Leadership in Applied Health Research and Care (CLAHRC).* In 2009, UHL and partners were successful in bidding to lead the NIHR Leicestershire, Northamptonshire & Rutland CLAHRC. Considered by external reviewers and the NIHR to be a highly successful, its work made a substantial contribution to the current application for an East Midlands CLAHRC.

2.5.3 *Experimental Cancer Medicine Centre.* This centre which develops novel therapeutic strategies to treat cancer, including haematological malignancies, received further funding from the NIHR in April 2012.

2.5.4 *NIHR Research Networks.* These provide financial and managerial support for the delivery of NIHR funded or approved clinical trials ("portfolio trials"). UHL hosts 5 networks i.e. Leicestershire, Northamptonshire & Rutland Comprehensive Local Research Network (CLRN) and topic specific networks in cancer, stroke, diabetes and primary care.

2.5.5 NIHR Clinical Trials Unit – hosted by University of Leicester but very significant for UHL R&D. Currently holding provisional status, UHL R&D is actively supporting the University CTU application for full accreditation with the NIHR.

2.5.6. *Recent establishment of new Clinical Research Facilities (CRF).* These include: Cardiovascular BRU CRF (Glenfield); oncology CRF (Hope Unit, LRI); CRF and diabetes centre (LGH); respiratory CRF (Glenfield).

2.6 *Effective patient and public involvement (PPI) in research*. We receive frequent positive feedback from external sources on our PPI policy and achievements. However, we are constantly seeking to extend and improve this further.

3. Current challenges

3.1 We need to support the BRUs in achieving their stated objectives. Also, we must ensure that they develop in a way that enables a credible application for NIHR Biomedical Research Centre status in the next round.

3.2 We have been major partners in the East Midlands Academic Health Sciences Cluster group which has led directly to the successful East Midlands Academic Health Sciences Network (AHSN) application and licence to operate (June 2013). It is important that we continue to play a major role in the development of the AHSN.

3.3 Historically, we have had an over-reliance on a small number of academic and industry partners. This has improved significantly e.g. collaborations with Loughborough University. These must be maintained and developed further. Our relationship with the University of Leicester is excellent; however, both parties agree that there is still room for significant improvement.

3.4 The NIHR research networks are undergoing a major transition presently. This means that there will be only one research network in the East Midlands area. On behalf of UHL and our partners in the East Midlands, we have applied to host the

new network (formal interview July 23, 2013). NIHR will announce the outcome of the application process in September, 2013.

3.5. The numbers of patients recruited to NIHR portfolio clinical trials is a high profile target. Since its inception, UHL has always met or over performed on this target. However, it is becoming a considerable challenge to continue this record and we did not achieve our target. There are many factors influencing recruitment rate and we have been working with the network to improve this. Early data for this financial year are encouraging but we have more work to do to give UHL the best chance of achieving the target this year (see CLRN report).

3.6. Challenging timelines and quality standards for R&D are being set by national and commercial bodies. Historically, we have scored well on the metrics e.g. study approval times. However, the new metrics (e.g. time from application to first patient recruited) are more challenging. Much of our time is now dedicated to delivering on these..

3.7. We must concentrate on our major research programmes described above. However, it is essential that we foster and support an R&D culture in all our services, as it is recognised that this improves quality, staff recruitment/retention and leadership. A true R&D culture is not yet embedded in all clinical and managerial areas within UHL; however, we are making significant progress.

3.8. Presently, there are some support services within UHL which may limit our ability to deliver UHL's R&D potential. We are working constructively with colleagues on this but more work is needed.

4. Report from the Leicestershire, Northamptonshire and Rutland CLRN

4.1 The CLRN provides quarterly reports to partner trusts on NIHR portfolio clinical trials performance. The latest report is included with this paper. This report has been considered by the R&D Committee since its inception; it will now be presented with our quarterly reports to the Board (a requirement in order to qualify for NIHR funding) .

5. Conclusion

4.1 This report is a high level summary of the present situation. We welcome suggestions from the Board on the content and format of future R&D reports.

Leicestershire, Northamptonshire and Rutland
Comprehensive Local Research Network

NHS
National Institute for Health Research

University Hospitals of Leicester NHS Trust

Monthly Activity Report

Report Date: **12 July 2013**
Data Sourced: 1 July 2013

Welcome to the monthly NIHR portfolio activity report for your trust. This report contains information on 2013/14 recruitment and performance measures.

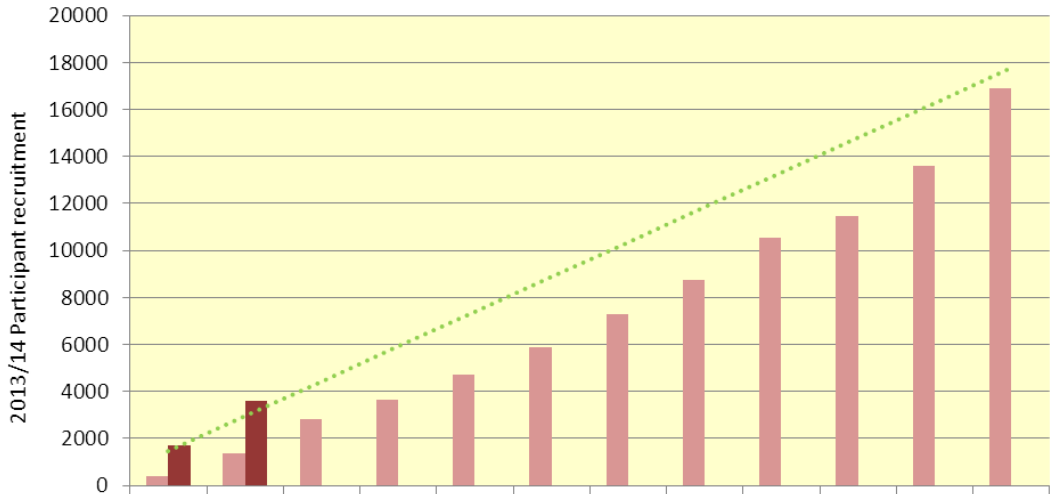
The table below is a snapshot of LNR CLRN member trusts and stakeholder organisations, progress measured against National and Local Performance Measures (N/LPMs). The table also states the corresponding chart within the report. This contains network-wide information, as well as individual information for your organisation.

Recruitment Criteria						
13/14 YTD RAG %	Trust	YTD Recruitment	Annual Target	NPM/LPM	Description	Chart
100.14%	**UHL**	**1,614**	**8,381**	**NPM 1a.1**	**Progress towards 13/14 recruitment target**	**1.2 2.1**
59.51%	KGH	126	1,101	NPM 1a.2	Progress towards 13/14 recruitment target	1.2
97.13%	LPT	99	530	NPM 1a.4	Progress towards 13/14 recruitment target	1.2
67.67%	NGH	165	1,268	NPM 1a.3	Progress towards 13/14 recruitment target	1.2
49.33%	NHfT	45	540	NPM 1a.5	Progress towards 13/14 recruitment target	1.2
159.37%	LRPC	1,214	3,819	NPM 1a.6a	Progress towards 13/14 recruitment target	1.2
85.57%	NPC	326	2,122	NPM 1a.6b	Progress towards 13/14 recruitment target	1.2
105.08%	LNR CLRN	3,589	17,761	NPM 1a	5% increase in recruitment (2012/13 to 2013/14)	1.1
Time and Target Criteria - Network-wide						
46%	LNR	N/A	80%	NPM 2b	% of Non-Commercial Studies (Closed) recruiting to Time and Target in LNR	1.3
87%	LNR	N/A	80%	NPM 2a.1	% of Commercial Studies (CCRN-Closed) recruiting to Time and Target in LNR	1.3
47%	LNR	N/A	80%	NPM 2a.2	% of Commercial Studies (CCRN-Open) recruiting to Time and Target in LNR	1.3
61%	LNR	N/A	80%	LPM 8.3	% of Non-Commercial Studies (Open) recruiting to Time and Target in LNR	1.3
First Patient First Visit (FPFV) - Network-wide						
13/14 YTD RAG %	Area	2013/14 National Target	NPM/LPM	Description		Table
15%	LNR	80%	NPM 4c	NHS Permission to first patient recruited in a trial (<=30 days) in median calendar days for >=80% for all studies		1.4
21%				NHS Permission to first patient recruited in a trial (<=30 days) in median calendar days for >=80% for CCRN led studies		
Research Management and Governance Criteria - Network-wide						
Percent	Area	2013/14 National Target	NPM	Description		Chart
83%	LNR	80%	NPM 4a	Study-wide checks completed within 30 calendar days		1.5
100%	LNR	80%	NPM 4b	Local checks completed within 30 calendar days		1.5

Section 1—Research Network Overview

1.1 LNR CLRN recruitment against recruitment target (NPM 1a)

Figure 1.1 provides a monthly breakdown of reported participant recruitment in portfolio studies by financial year. This includes data from 2012/13 and 2013/14 year to date (YTD). The chart also shows how well LNR CLRN is recruiting towards the overall 2013/14 recruitment target of 17,761 participants.



	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR
2012/13 Recruitment	408	1382	2809	3670	4699	5891	7306	8740	10563	11453	13577	16915
2013/14 Recruitment	1710	3589										
2013/14 Target	1480	2960	4440	5920	7400	8881	10361	11841	13321	14801	16281	17761

Figure 1.1: LNR CLRN recruitment by month and financial year (2012/13 and 2013/14)

1.2 LNR CLRN progress towards recruitment target by member organisation (NPM 1a.1-6b and 5a)

Figure 1.2 illustrates how well LNR CLRN and member organisations are recruiting towards their 2013/14 YTD recruitment targets.

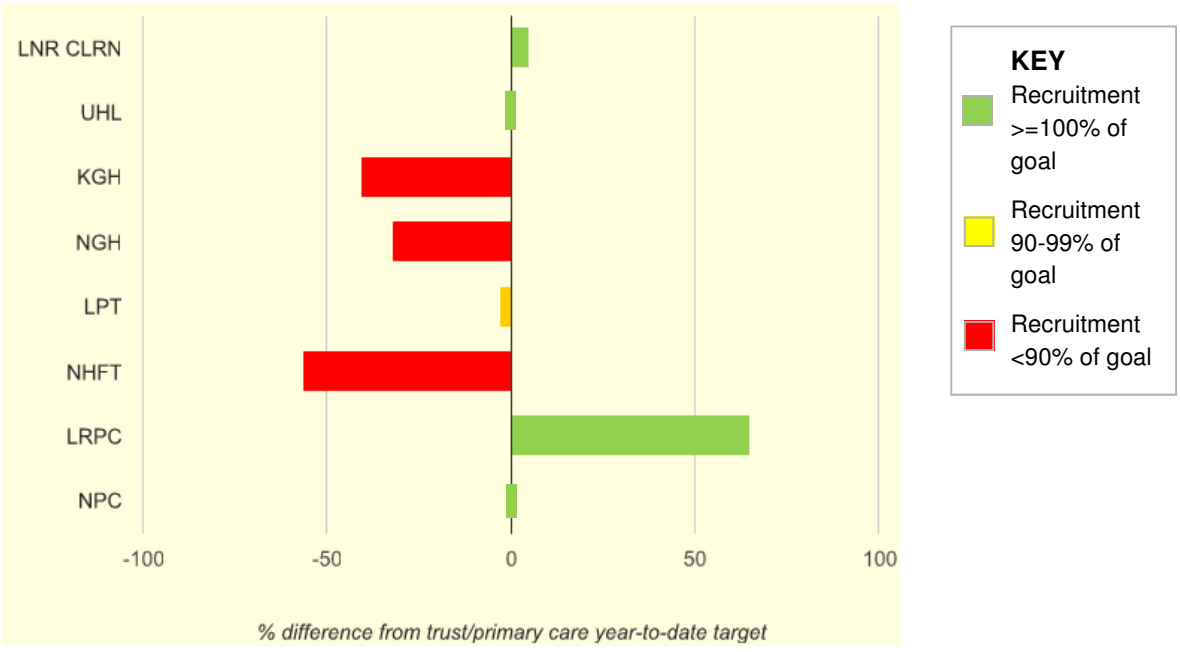
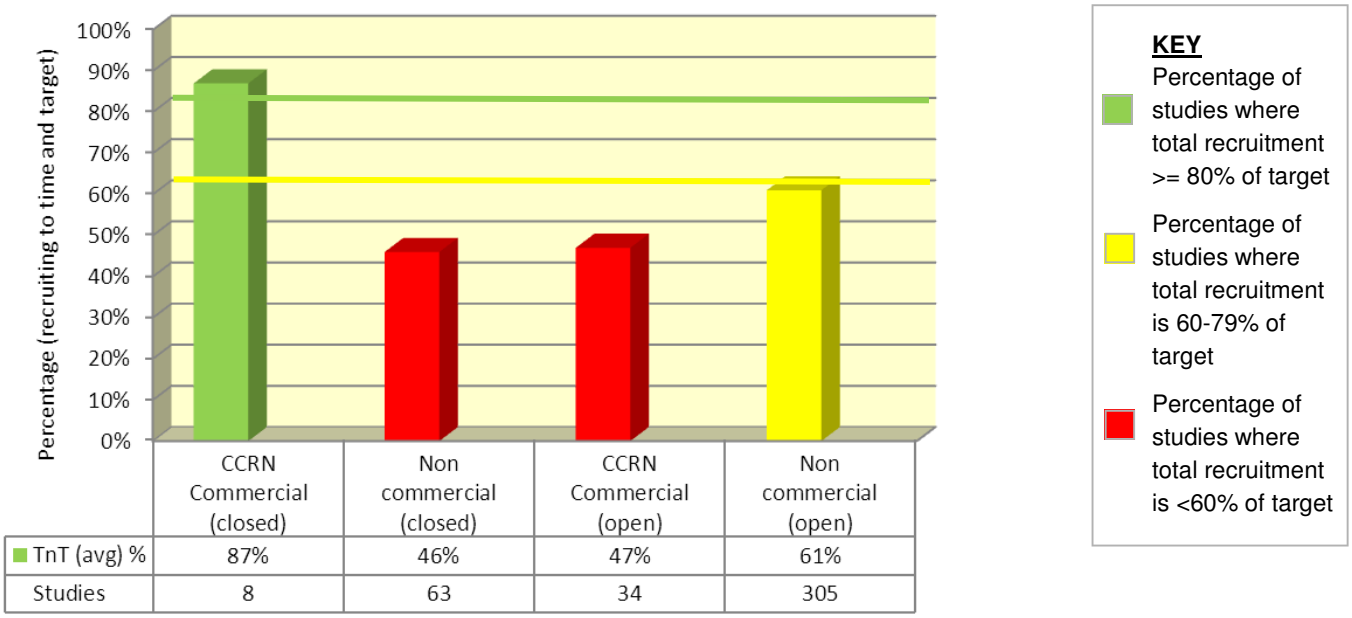


Figure 1.2: Percentage difference between 2013/14 YTD recruitment and YTD recruitment target by Member Organisation

1.3 LNR CLRN recruiting to time and target (NPM 2a.1, 2a.2, 2b and LPM 8.3)

LNR CLRN are performance managed on delivering all portfolio studies to time and target. We have three national performance measures (NPM) and one local performance measure (LPM) to monitor our progress. There are NPMs for open and closed studies for 80% of CCRN commercial portfolio studies to achieve their recruitment targets. The third NPM is for non-commercial studies and is measured at study closure. Open non-commercial studies are monitored locally and have an LPM also set at 80%, to ensure that they are recruiting to time and target throughout the study. Figure 1.3 shows data for all open study sites and those that have closed since 1 April 2013.



	CCRN Commercial (closed)	Non commercial (closed)	CCRN Commercial (open)	Non commercial (open)
TnT (avg) %	87%	46%	47%	61%
Studies	8	63	34	305

Figure 1.3: Percentage of LNR CLRN studies recruiting to time and target 2013/14 YTD

1.4 First Patient First Visit (FPFV) (NPM 4c)

LNR CLRN collects data on the number of days a study site takes to recruit a participant once NHS permission has been granted or site initiation is complete. In 2013/14, CLRNs are performance managed (NPM 4c) on ensuring that study sites recruit their first patients within 30 days of NHS permission or site initiation.

Table 1.4: LNR CLRN performance against First Patient First Visit metrics 2013/14

FPFV Metrics 2013/14	Percentage (%) studies with time taken from NHS permission/site initiation to first patient <= 30 days											
Networks	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**
LNR CLRN		15%										
CCRN studies only		21%										

1.5 Research Management and Governance (RM&G) (NPM 4a and 4b)

All CLRNs are performance measured on the time taken to complete study-wide and local site checks. This is to ensure that studies receive NHS permission as quickly as possible. The measure is for 80% of studies to have all checks completed within 30 calendar days. Figure 1.5 shows the percentage of studies approved each month that have had their study checks completed within 30 calendar days.

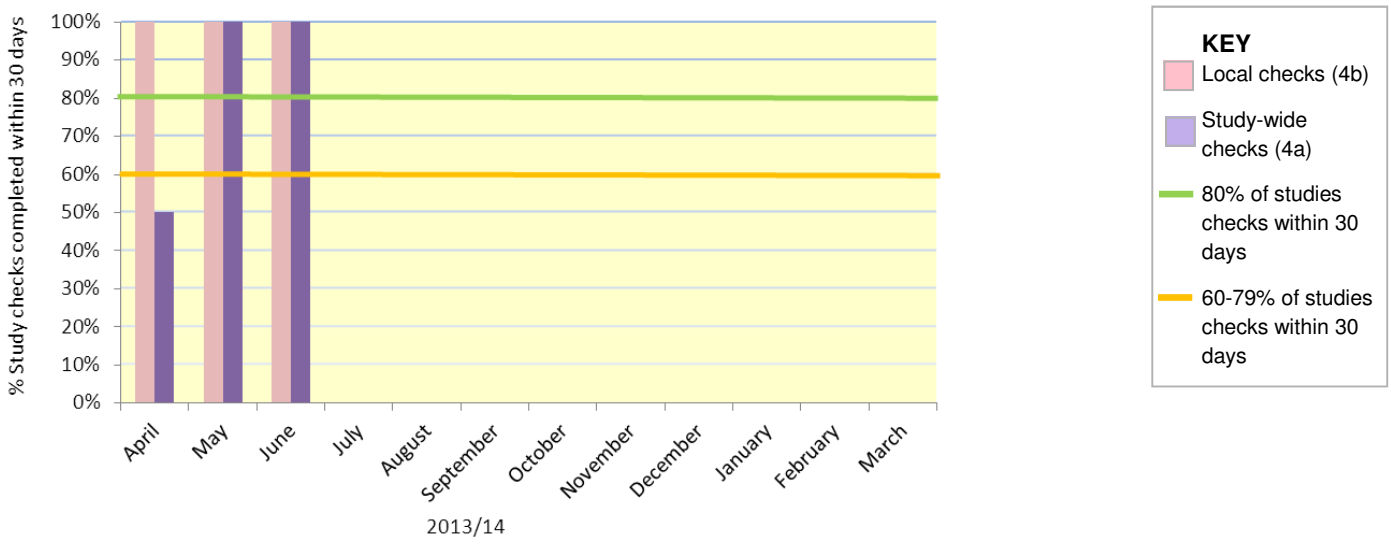


Figure 1.5: LNR CLRN RM&G performance against national metrics 2013/14

1.6 LNR CLRN funding

Figure 1.6a shows the percentage of funding allocated to member trusts and primary care (PC) in 2013/14. Figure 1.6b shows 2013/14 trust/primary care recruitment as a percentage of total LNR CLRN recruitment.

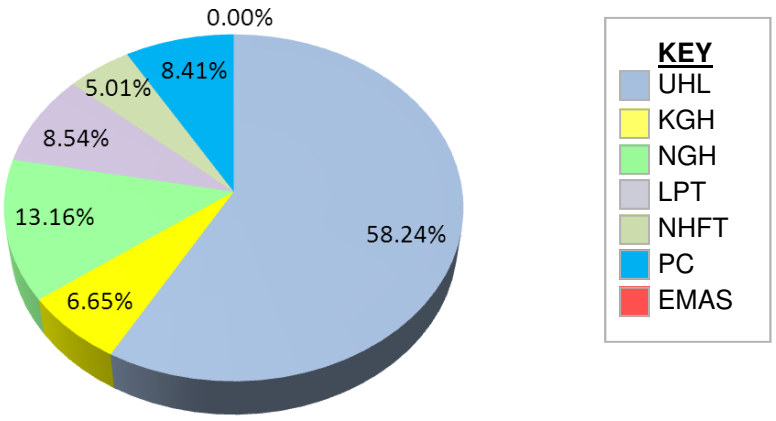


Figure 1.6a: LNR CLRN 2013/14 funding by trust

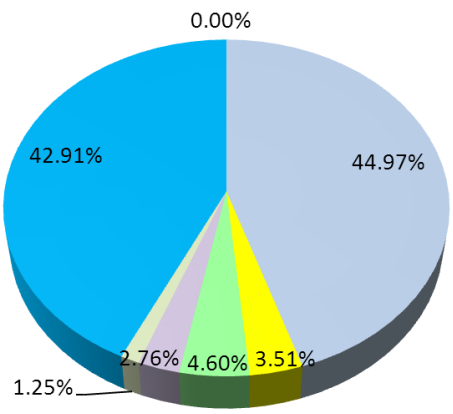


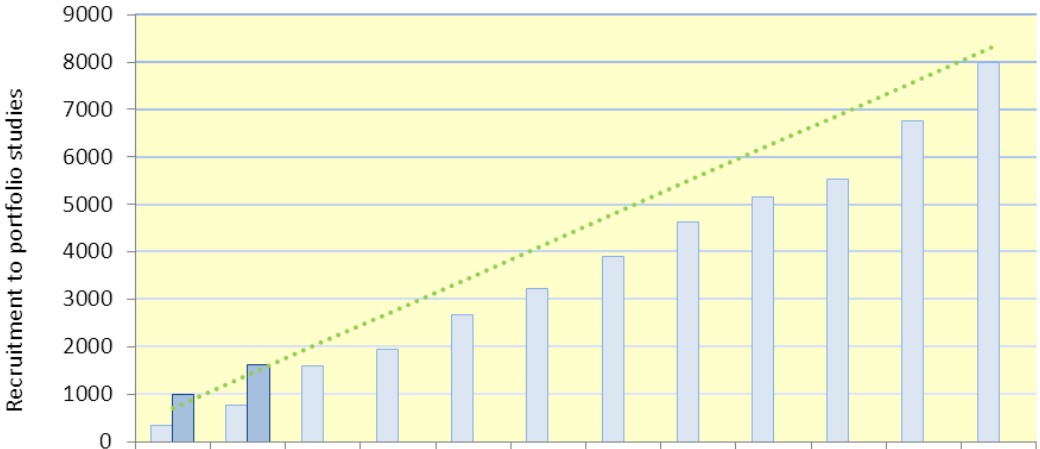
Figure 1.6b: LNR CLRN 2013/14 recruitment by trust

Note: The funding percentage for UHL is skewed as they host three research networks which provide support across a range of other NHS trusts in the region. Some of the funding shown for UHL is utilised in cross network coordinating functions of the South East Midlands Diabetes Research Network, LNR Cancer Research Network and Trent Stroke Network. At present, funding for primary care is considered as a total allocation, rather than by county, in line with the way recruitment is currently reported to us by the NIHR. Primary care funding also includes funding provided to the East Midlands and South Yorkshire Primary Care Research Network (EMSY PCRN). Please note that these figures do not take account of referrals from participant identification centres (PICs) to other sites where the recruitment actually takes place.

Section 2—Trust level information

2.1 2013/14 UHL recruitment against target (NPM 1a.2)

Figure 2.1 provides a cumulative monthly breakdown of reported participant recruitment in portfolio studies by financial year for 2012/13 and 2013/14 year to date (YTD). The chart also shows how well UHL is recruiting towards the 2013/14 recruitment target.



	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR
2012-13 Recruitment	336	769	1596	1937	2662	3222	3912	4618	5158	5530	6756	7982
2013-14 Recruitment	985	1614										
2013-14 Target	698	1397	2095	2794	3492	4191	4889	5587	6286	6984	7683	8381

Figure 2.1: UHL recruitment by month and financial year (2012/13 and 2013/14)

2.2 UHL 2013/14 recruitment by Topic Network and CCRN Specialty Group

Figure 2.2 looks at UHL recruitment by topic network and specialty group. For studies that have been formally co-adopted, recruitment has been counted for all relevant topic networks and specialty groups. Therefore, recruitment may have been counted more than once.

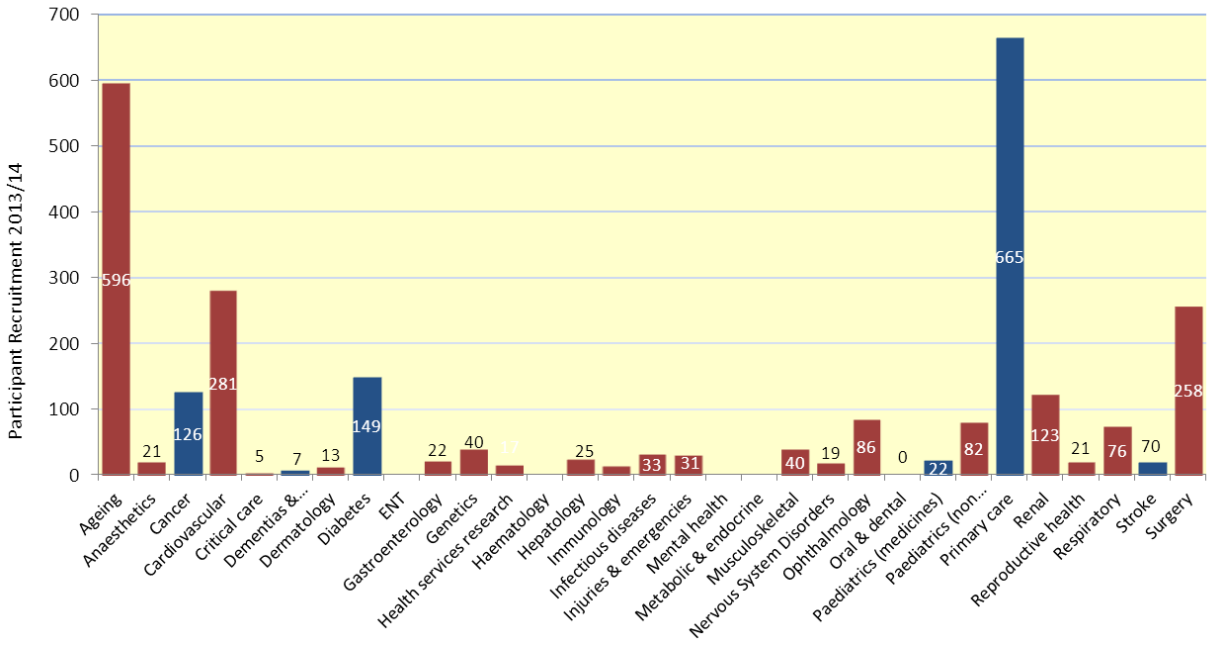
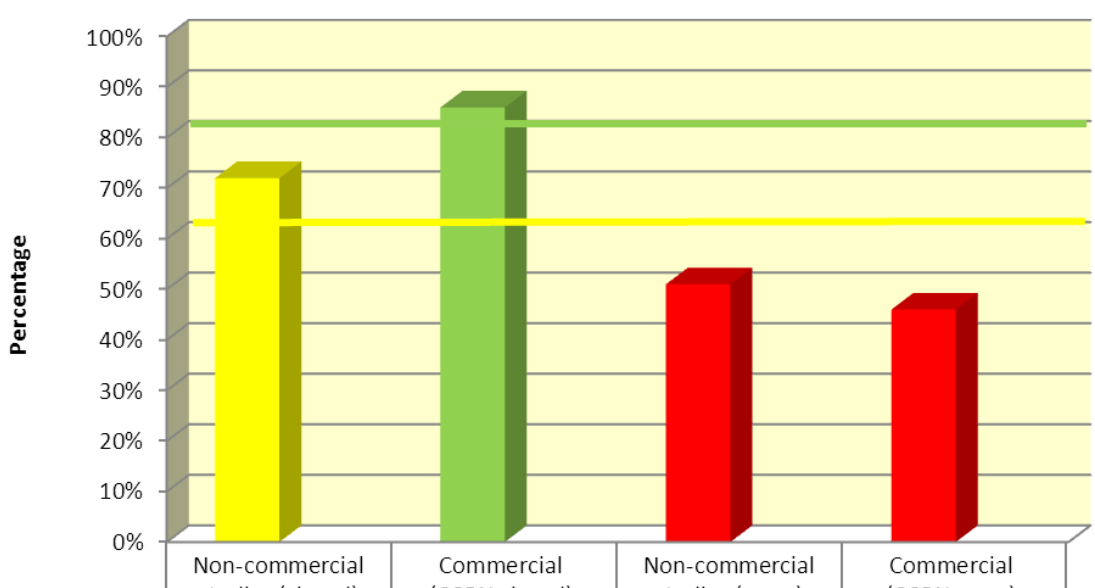


Figure 2.2: UHL 2013/14 recruitment in by Topic Network and CCRN Specialty Group

2.3 Percentage of UHL studies recruiting to time and target

Figure 2.3 shows recruitment to time and target data for open studies at UHL, and those that have closed since 1 April 2013. The data is displayed as an average across all studies that match the criteria, and shows commercial (CCRN only) and non-commercial (all studies) separately.

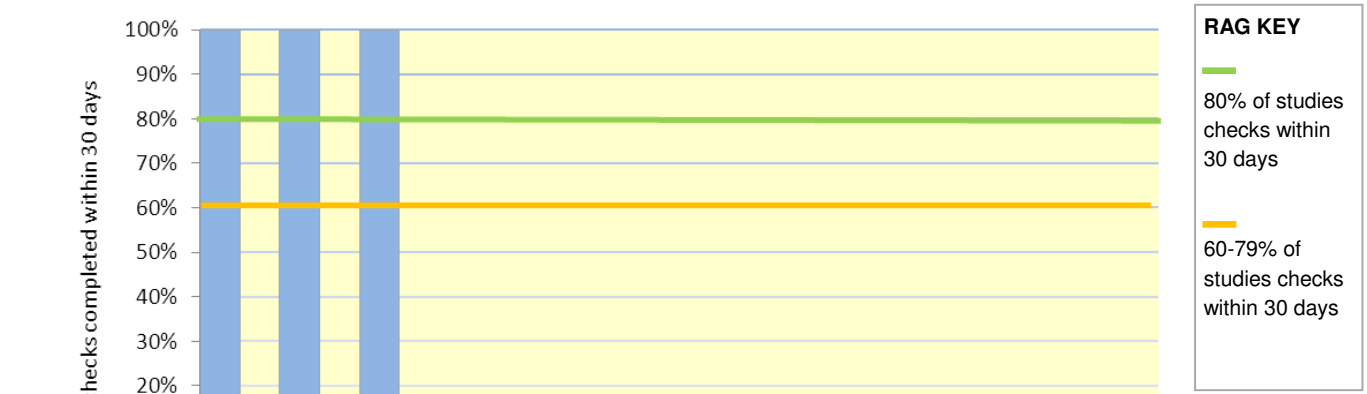


	Non-commercial studies (closed)	Commercial (CCRN closed)	Non-commercial studies (open)	Commercial (CCRN open)
% TnT	72%	86%	51%	46%
No. Studies	25	7	242	28

Figure 2.3: Percentage of UHL studies recruiting to time and target 2013/14 YTD

2.4 LNR CLRN Research Management and Governance (RM&G) for UHL in 2013/14

Figure 2.4 shows the percentage of studies approved each month that had their local study checks completed within 30 calendar days. The CLRN has a national performance measure to ensure 80% of studies obtain NHS permission within 30 calendar days.



	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
% within 30 days	100%	100%	100%									
No. studies	21	6	20									

Figure 2.4: LNR CLRN RM&G performance for UHL in 2013/14

Section 3—Appendices

The first two appendices to this report have been generated using the Time and Target (TnT) database. These reports compare study site recruitment with study site recruitment targets.

Time and Target (TnT) reports

3.1 TnT report—UHL all open studies

The first report captures all portfolio studies open at UHL. This report includes studies that have recruited participants as well as those that are yet to report recruitment.

3.2 TnT report— UHL closed studies

This report includes all studies that have closed for recruitment within UHL during the current financial year (2013/14).

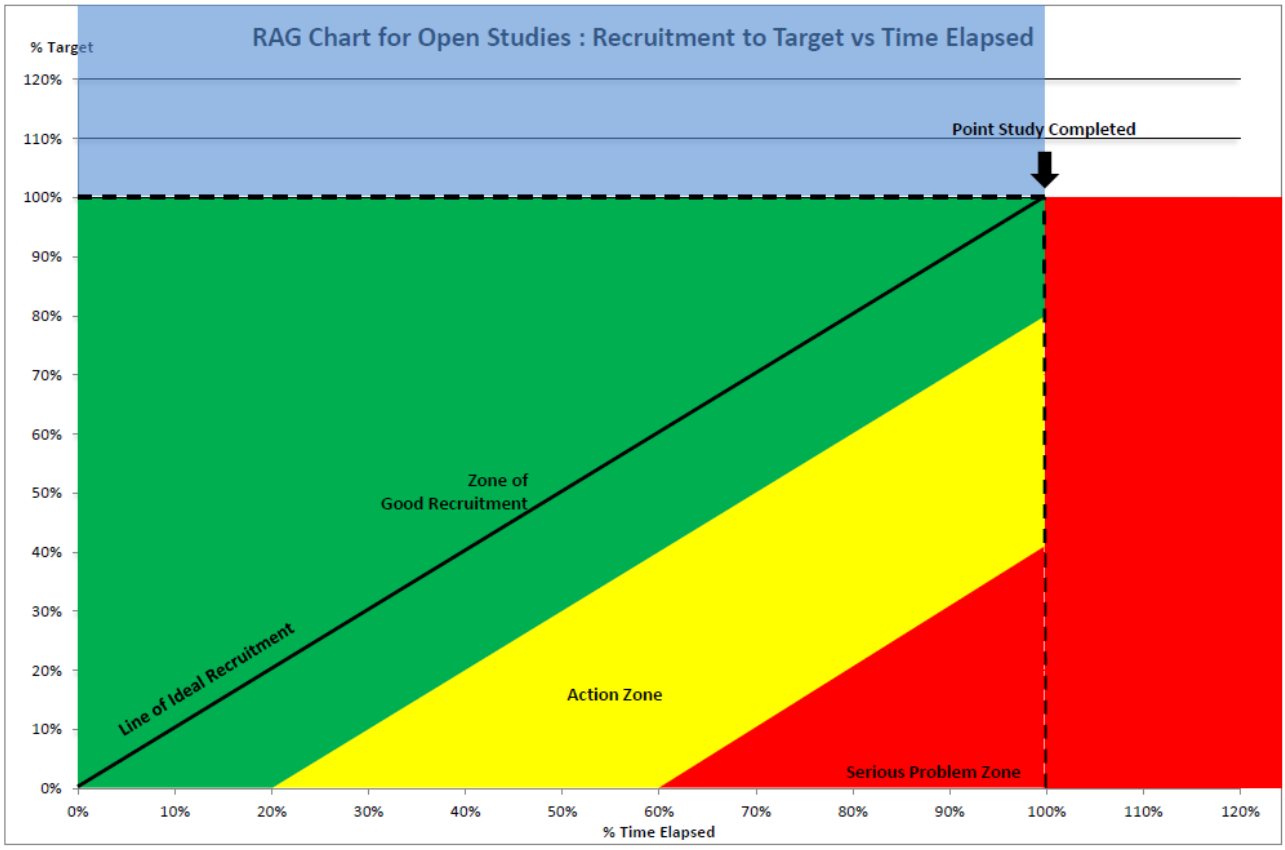
Glossary

Activity Based Funding (ABF)	Funding that is allocated to Comprehensive Research Networks which is based on recruitment and study complexity.
Awaiting response status (CSP report)	RM&G team are awaiting response from a member of the study team before the governance review can commence.
Closed study	A portfolio study that has closed to recruitment (across all study sites).
Commercial study	A commercial study is defined as one that is both industry-funded and industry-sponsored.
CSP	The NIHR Coordinated System for gaining NHS Permission. CSP must be used for all new portfolio studies to gain NHS Trust permission and R&D approval.
Data sourced date	The date the national portfolio performance data is published by the NIHR CRN CC. This data is incorporated into our local TnT database and used to create this report. At present there is a four week lag from when a participant is recruited into a study and when this data will be reported by the NIHR CRN CC.
First Patient First Visit (FPFV)	This National Performance Measure looks at the time taken from NHS permission date (since 1 April 2013) **or** Site Initiation (which ever is later) to first patient recruited in a trial (<=30 days) for 80% of LNR CLRN studies.
Governance checks assigned (CSP report)	A LNR CLRN RM&G Facilitator has been assigned to the study for governance review.
Interventional study	A study where the participants' exposure to a particular intervention (e.g. treatment or lifestyle) is influenced by participating in the study (e.g. whether or not a participant receives a particular treatment will be determined by the research protocol). Clinical trials are the most common type of interventional study.
Lead CLRN—Trust R&D permission granted (CSP report)	The Chief Investigator is based at a trust within LNR. Trust R&D permission is granted at a research site once all governance checks have been undertaken by the CLRN.
LNR CLRN	The Leicestershire, Northamptonshire and Rutland Comprehensive Local Research Network (LNR CLRN) is one of 25 CLRNs across England. It coordinates and facilitates the conduct of clinical research and provides a wide range of support to the local research community. There are nine NHS Trusts and four Higher Education Institutions within the LNR CLRN constituency.
Local Performance Measure (LPM)	An objective decided by the LNR CLRN as a priority area for the financial year. Our progress towards achieving this measure is monitored locally and fed back to our local stakeholders and the NIHR CRN CC.

NHS Permission	Research cannot commence within the NHS without first gaining permission. This is granted as part of a study's research governance process, also referred to as R&D approval.
National Performance Measure (NPM)	An objective decided by the NIHR CRN CC as a priority area for all CLRNs. Our progress towards achieving this measure is monitored locally and fed back to our local stakeholders and the NIHR CRN CC.
NIHR CRN	National Institute of Health Research Clinical Research Network
NIHR CRN CC	National Institute of Health Research Clinical Research Network Coordinating Centre
Non-commercial study	A non-commercial study is one that has some of their research funded by the NIHR, other areas of central Government or NIHR non-commercial partners. However non-commercial studies can also be investigator initiated trials (i.e. commercial collaborative research) or funded by an overseas Government or overseas charity.
Observational study	A study in which the participants' lifestyle or care pathway is not affected by being part of the study i.e. the investigator does not determine whether or not the participants receive or do not receive a particular treatment. The investigator observes the outcome of participants following their exposure (or non-exposure) to a particular interventional or lifestyle.
Open Study	A portfolio study that has received NHS permission and is open to recruit patients. Open dates can vary across multi-centre studies as NHS permission has to be obtained at each study site.
Participant	A patient or individual who is recruited to a study.
Portfolio	A national database of research studies that meet specific eligibility criteria. Portfolio studies have access to infrastructure support via the NIHR Comprehensive Clinical Research Networks and swift R&D permissions through CSP.
QA (CSP report)	Once the governance review is complete, the study undergoes a final quality assurance process by a RM&G manager.
RAG criteria charts	RAG (red, amber, green) provides a key that help measures how well studies are recruiting to time and target. There are different charts for open and closed studies, and are included with this report.
Recruitment	The number of participants consented to a study.

Recruitment target	An agreed target in participant recruitment into portfolio studies in 2013/14.
Report date	The date the report is issued.
Reported recruitment	The sum total of participants consented to a study that is uploaded to the NIHR CRN CC database by a study's recruitment data contact (RDC).
Research Governance	The regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare.
Specialty Group	Within the Comprehensive Clinical Research Network (CCRN), there are 23 national Specialty Groups that provide research expertise in their field. They are designed to increase opportunities for researchers to contribute to national and international NIHR portfolio studies.
Study Complexity	Study complexity (also referred to as study design) is considered along with recruitment when allocating activity based funding. Studies are either categorised as simple, observational or interventional.
Time and Target (TnT)	TnT is a project which monitors how well a study progresses towards their recruitment target before the study recruitment close date. TnT can be applied to an entire study (across several sites) or used for local site analysis.
Study review abandoned (CSP report)	A study review may be abandoned for a number of reasons including problems with the funding, non adoption onto the portfolio or site unsuitability.
Topic Network	There are six topic research networks (Cancer, Diabetes, Dementias and Neurodegenerative Diseases, Medicines for Children, Mental Health and Stroke) and a Primary Care research network within the NIHR CRN. Each research network coordinates and facilitates the conduct of clinical research for their local research community.
Trust R&D permission granted (CSP report)	Trust R&D authorise the study to be undertaken within their trust based on the CLRN RM&G governance review.
Unable to commence local research governance checks (CSP report)	The governance review process is unable to start as not all the relevant documents, authorisations or information has been received by the CLRN RM&G reviewer.
Undergoing research governance review using CSP (CSP report)	The governance review process for a study has commenced using CSP.
YTD	Year to date.

RAG criteria for open studies



RAG criteria for closed studies