University Hospitals of Leicester **NHS**
NHS Trust

TRUST BOARD – October 30, 2014

**National Institute for Health Research Clinical Research Network: East Midlands:
Host Update for University Hospitals of Leicester Trust Board**

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DATE:	October 30, 2014
PURPOSE:	**UHL is the host organisation for the National Institute for Health Research Clinical Research Network: East Midlands. As such, UHL's Trust Board is responsible for its governance. This paper gives the background to the establishment of this network (April 2014) and describes present achievements and challenges, including key performance data.**
PREVIOUSLY CONSIDERED BY:	**Executive Strategy Board, March 28, 2014**

Objective(s) to which issue relates *	
	☐ 1. Safe, high quality, patient-centred healthcare
	☐ 2. An effective, joined up emergency care system
	☐ 3. Responsive services which people choose to use (secondary, specialised and tertiary care)
	☐ 4. Integrated care in partnership with others (secondary, specialised and tertiary care)
	☒ 5. Enhanced reputation in research, innovation and clinical education
	☐ 6. Delivering services through a caring, professional, passionate and valued workforce
	☐ 7. A clinically and financially sustainable NHS Foundation Trust
	☐ 8. Enabled by excellent IM&T

Please explain any Patient and Public Involvement actions taken or to be taken in relation to this matter:	No action required by Trust Board. The network has established a PPI infrastructure.
Please explain the results of any Equality Impact assessment undertaken in relation to this matter:	Not applicable to this report.
Strategic Risk Register/ Board Assurance Framework *	☒ **Strategic Risk Register** ☒ **Board Assurance Framework** ☐ **Not Featured**

ACTION REQUIRED *

For decision ☐   For assurance ☒   For information ☒

♦ **We treat people how we would like to be treated**   ♦ **We do what we say we are going to do**
♦ **We focus on what matters most**   ♦ **We are one team and we are best when we work together**
♦ **We are passionate and creative in our work**

* tick applicable box

National Institute for Health Research Clinical Research Network: East Midlands

Host Update for University Hospitals of Leicester Trust Board

1. Background

1.1   The National Institute for Health Research (NIHR) was established in April 2006, partly in response to a near terminal decline in clinical trial activity within the NHS. This decline was caused by a sluggish and unresponsive clinical trial approval process combined with an inability to recruit the required numbers of patients within the funding and timing envelope of individual clinical trials. We were still reasonable at making basic scientific discoveries but we had become one of the worst countries in the world for clinical trials delivery.

1.2   The NIHR is funded by the Department of Health with a mission to improve the health and wealth of the nation through research. It has developed into the most integrated clinical research system in the world benefiting our patients and the economy. The NIHR has transformed clinical research in the NHS by increasing the volume and quality of applied health research, vastly improving the delivery of clinical trials to time and target, driving faster translation of basic science discoveries into available new treatments and creating a large national cadre of professionals who design, deliver and contribute to applied health research.

1.3   A key early strategy of the NIHR was the establishment of clinical research networks tasked with reversing poor clinical research delivery and restoring the UK as one of the best places in the world to perform clinical research. The first networks covered specific specialities (cancer, stroke, diabetes, medicines for children, mental health, primary care, dementia) in selected geographical areas and, as a result of their success, Comprehensive Local Research Networks (CLRN) were established nationally to cover those specialties not represented in the topic-specific networks. Eventually, more than 100 clinical research networks were established in England hosted by NHS Trusts in adjacent localities. Trusts in the East Midlands hosted 10 such networks (5 hosted in UHL), each with their own budget, senior management team, staff and facilities.

1.4   There is no doubt that the networks have been a great success. For example, they have vastly increased numbers of patients recruited to clinical studies giving early availability to new treatments, reduced study approval times, started to reverse the decline in life science industry investment in the UK, increased public understanding of research and created research cultures in many areas of the NHS where this was lacking.

1.5   However, the historical development of this system of networks led to several problems, especially the creation of a large number of networks and host organisations with examples of inflexible silo working, unclear lines of accountability and inefficient management. Also, the system was often confusing to research partners e.g. clinical researchers, research

funders, life sciences industry. As a result of this, the NIHR embarked upon a national restructuring exercise (termed "transition") to form one clinical research network in England covering all specialities with a "branch" in each NHS region (n=15) known as *Local Clinical Research Networks (LCRN)*.

1.6 In 2013, University Hospitals of Leicester (UHL) NHS Trust applied successfully to host the LCRN in the East Midlands from April 2014. This regional network is also referred to as the *NIHR Clinical Research Network: East Midlands*. UHL's Trust Board approved this application and has subsequently approved the LCRN's annual plan, budget plan and governance framework.

2. Host governance

2.1 UHL's Trust Board is accountable for the good governance of the LCRN. The governance structure and key strategic and operational groups of LCRNs are mandated by the NIHR in the host contract. UHL's Chief Executive is the LCRN Accountable Officer and the Medical Director is the nominated Executive Lead. The Trust has established a LCRN Executive Group chaired by the Executive Lead; its purpose is to oversee and deliver good governance of the LCRN as defined by the host contract and LCRN Operating Framework.

2.2 LCRN issues are included in UHL's risk register and, as of this month, the Board receives key performance data and exception reporting via the Quality and Performance report. Also, the work of the LCRN will be included in the programme of work undertaken by the Trust's auditors (Price, Waterhouse, Coopers).

2.3 UHL has convened the LCRN Partnership Group which is a formal forum of LCRN partners i.e. those receiving significant funding from the LCRN. Its role is to provide active oversight and constructive mutual challenge on LCRN plans, activities, performance and reports in order to support the LCRN to achieve its objectives and raise the ambitions for clinical research of the LCRN Partners. The Trust has appointed an independent Chair (Peter Miller, Chief Executive, Leicestershire Partnership NHS Trust).

2.4 In addition to these oversight/strategic groups, UHL has ensured that the various mandated operational groups and systems have been established.

3. Budget and finances

3.1 LCRN finances are monitored by the LCRN Executive Group chaired by the Board Executive lead.

3.2 The network provides funding to healthcare providers in the East Midlands, mainly NHS Trusts (n=15) and Primary Care (via Clinical Commissioning Groups). These are defined as LCRN partners. At the start of this financial year, we funded 978 posts (259 full time, 719 part time), 238 consultant medical sessions, service support costs and staff support costs. UHL employs the LCRN senior managers as the host. All other posts are employed by the

partners (including UHL in its role as a partner of the LCRN – distinct and separate from its role as host).

3.3   The LCRN budget for 2014-15 is £21.539 M. This is 4.8% less than the indicative budget giving the network a saving target of £ 1.9 M. Overseen by the Executive Group, we have worked to deliver this saving and the target is presently approx. £ 650K. We are confident that, working with partners, we will deliver this by year end. No financial liability with respect to this rests with UHL in their hosting function.

4. Achievements

Significant achievements so far include:

(i).   Through a management of change process involving the senior managers of the previous 10 research networks in the East Midlands and in partnership with other trusts in the region who employed them, we have established a fully operational senior management team.

(ii).   All management structures/groups have been established and are working effectively (although this needs to be improved further).

(iii). NIHR feedback on the NIHR on the Annual Plan and Finance Plan 2014-15 was excellent.

(iv).   We are confident that we will achieve our challenging budget savings (see 3.3).

(v).   We have harmonised several processes/systems throughout the region, although more work is needed.

(vi).   Relationships with network partners has improved significantly.

(vii). We have made significant progress in achieving our aspirational targets on patient recruitment into clinical trials (see below).

5. Challenges

Our present major challenges include:

(i).   Full integration (functional and cultural) of the previous 10 research networks into a single network.

(ii).   Progressing further our ambition to be transparent, flexible, responsive, and patient- and customer-focused.

(iii). Increasing research into dementia is a significant challenge in the East Midlands as this speciality was not well represented previously. We have a detailed and robust action plan and dedicated team to achieve this.

(iv). We need to develop a new financial allocation model for 2015-16 that reflects our ambitions around flexibility, transparency and value for money. This will require major negotiations with partners and others.

(v). We need to improve our performance with respect to commercial studies (see below).

6. Performance data

Key LCRN performance data is now reported to the UHL's Trust Board and Board members may have seen our first submission this month; members may wish to ask questions about this submission when considering this paper. However, some key performance data as of October 14, 2014 taken from our monthly performance report for network staff and partners is presented in the appendix to this paper:

(i). We are 5th of 15 for total patients recruited (page 1) and recruitment related to population (page 2) since April 2014. This is a significant improvement compared with quarter 1 data. We have set an ambitious total target for recruitment; presently, we are achieving 92% of this target (page 3).

(ii). Recruitment by partner organisations in the East Midlands (including study complexity) is shown on page 4.

(iii). Our challenge with respect to commercial studies is highlighted on page 4. Although the number of commercial studies undertaken in the East Midlands is similar to the national average, the numbers of patients recruited is significantly less. The major reason for this is that our present trials require relatively small recruitment for their completion. We are focussing on this presently.

(iv). An important performance measure for the network is the time taken to approve studies before they are allowed to start. Presently, we are better than the NIHR target and 4th of 15 nationally (page 5).

7. Conclusion

UHL Trust Board is requested to note this paper and be reassured as to progress to date. We welcome any further involvement of the Board members in our activities.

David Rowbotham
Clinical Director, NIHR Clinical Research Network: East Midlands

Appendix

Summary Report October 14, 2014

Clinical Research Network: East Midlands

Data Extracted: 2014-10-13 (where not otherwise indicated)

Version 1.1

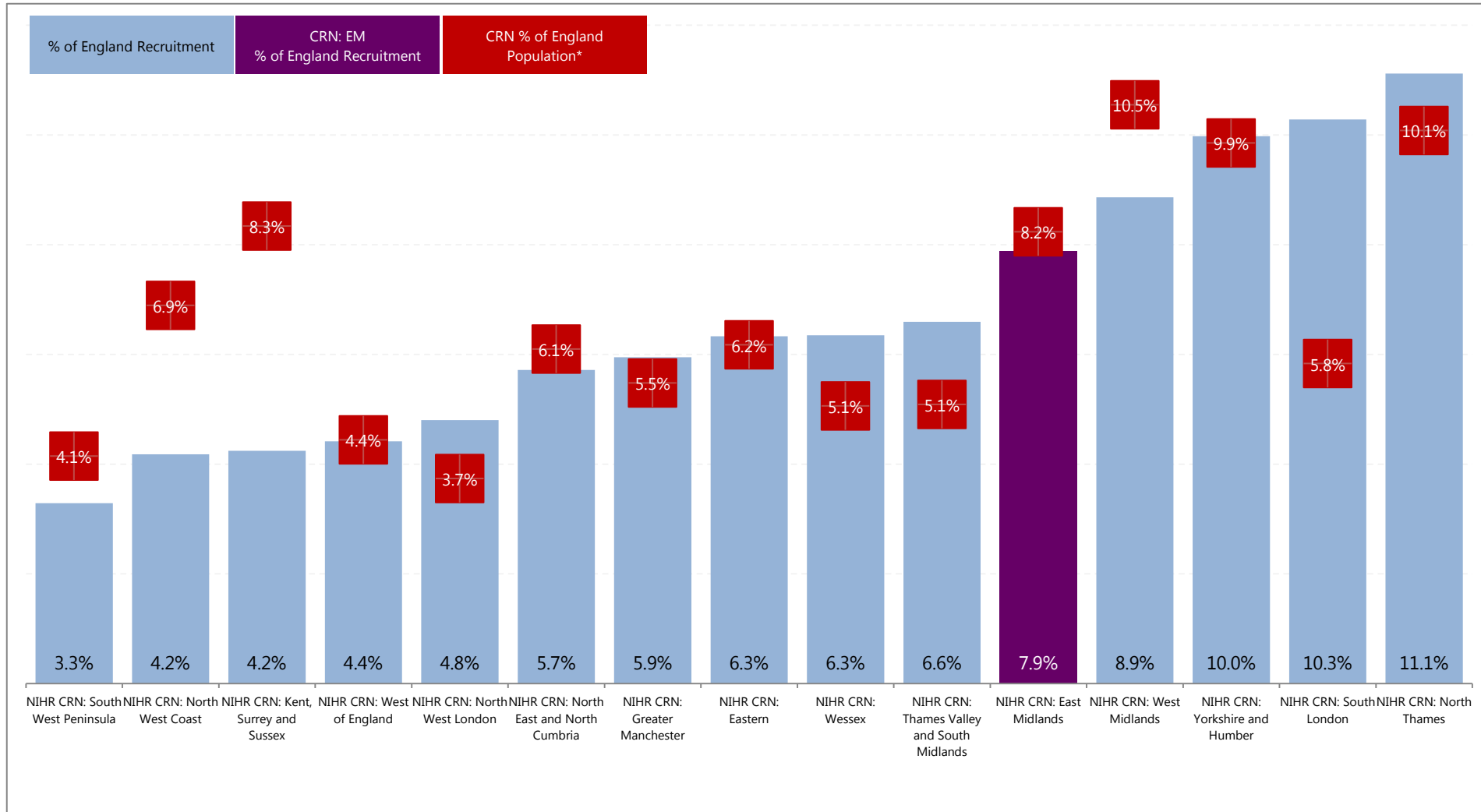**Source**: NIHR Co-ordinating centre RAW data files and the Open Data Platform.

Scope: This reports on recruitment where the participant was recruited into in a complete calendar month - not the *current* month; e.g. For September 2014 reporting, a recorded participant entry of 20/09/2014 would not contribute to the metric (but would do so in October 2014).

National Recruitment into NIHR Portfolio studies by Clinical Research Network

CRN	Band 1 Studies	Observational	Interventional	Total
NIHR CRN: North Thames	9,904	16,443	6,093	32,440
NIHR CRN: South London	13,000	10,482	6,519	30,001
NIHR CRN: Yorkshire and Humber	7,614	15,657	5,835	29,106
NIHR CRN: West Midlands	3,165	15,428	7,262	25,855
NIHR CRN: East Midlands	4,521	13,161	5,321	23,003
NIHR CRN: Thames Valley and South Midlands	9,673	7,230	2,333	19,236
NIHR CRN: Wessex	7,434	7,622	3,460	18,516
NIHR CRN: Eastern	3,243	11,522	3,706	18,471
NIHR CRN: Greater Manchester	3,496	8,269	5,588	17,353
NIHR CRN: North East and North Cumbria	1,458	10,863	4,359	16,680
NIHR CRN: North West London	4,011	7,159	2,843	14,013
NIHR CRN: West of England	1,558	8,403	2,922	12,883
NIHR CRN: Kent, Surrey and Sussex	3,699	5,712	2,967	12,378
NIHR CRN: North West Coast	2,254	7,346	2,601	12,201
NIHR CRN: South West Peninsula	2,778	4,614	2,209	9,601

Legend: Band 1 Studies, Observational, Interventional

Source: NIHR CRN - 2014/15 recruitment data is produced from the recent recruitment figures provided by NIHR CRN, and includes all recruitment reported to the end of the month preceding publication of this report.Where study design is 'not specified' this is counted as an Observational Study. Where a study design is 'both' this is classed as 'Interventional'. This metric relates to NIHR CRN HLO 1, see appendix

National Recruitment into NIHR Portfolio studies as a % of Total Recruited and Total Population

% of England Recruitment	CRN: EM % of England Recruitment	CRN % of England Population*

| | 4.1% | 6.9% | 8.3% | | 4.4% | 3.7% | 6.1% | 5.5% | 6.2% | 5.1% | 5.1% | 8.2% | 10.5% | 9.9% | 5.8% | 10.1% |

NIHR CRN: South West Peninsula	NIHR CRN: North West Coast	NIHR CRN: Kent, Surrey and Sussex	NIHR CRN: West of England	NIHR CRN: North West London	NIHR CRN: North East and North Cumbria	NIHR CRN: Greater Manchester	NIHR CRN: Eastern	NIHR CRN: Wessex	NIHR CRN: Thames Valley and South Midlands	NIHR CRN: East Midlands	NIHR CRN: West Midlands	NIHR CRN: Yorkshire and Humber	NIHR CRN: South London	NIHR CRN: North Thames
3.3%	4.2%	4.2%	4.4%	4.8%	5.7%	5.9%	6.3%	6.3%	6.6%	7.9%	8.9%	10.0%	10.3%	11.1%

Source: NIHR CRN - 2014/15 recruitment data is produced from the recent recruitment figures provided by NIHR CRN, and includes all recruitment reported to the end of the month preceding publication of this report. This metric relates to NIHR CRN HLO 1, see appendix. ***Population data** sourced from "Annual Mid-year Population Estimates, 2011 and 2012", ONS 08-08-2013. England Only, no devolved nation data.

Local Clinical Research Network recruitment into NIHR Portfolio studies
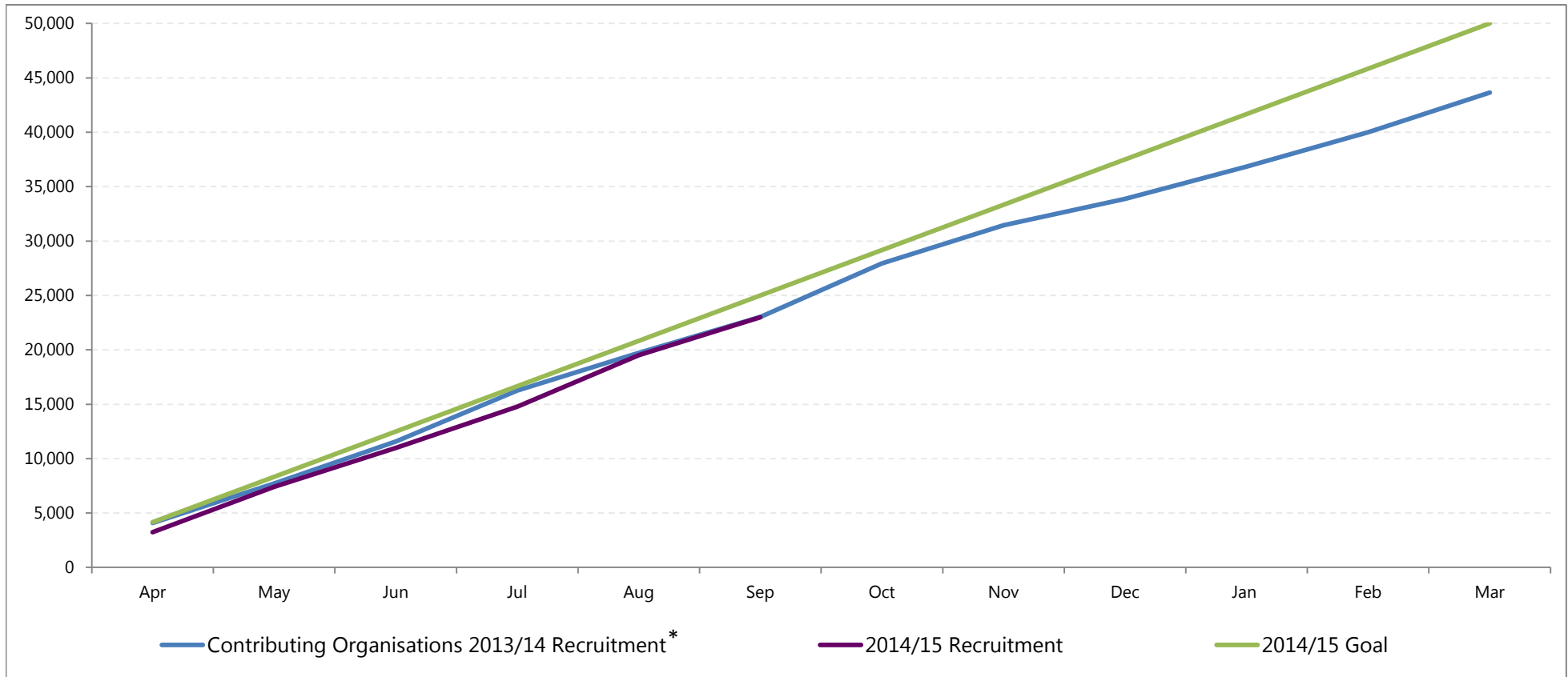
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	YTD to Goal
Goal 2014/15	4,167	8,333	12,500	16,667	20,833	25,000	29,167	33,333	37,500	41,667	45,833	50,000	
YTD 2014/15	3,231	7,403	10,984	14,776	19,514	23,003							92%
							Red	0 - 89%	Amber	90 - 99%	Green	≥ 100%	

Source: NIHR CRN - 2014/15 recruitment data is produced from the recent recruitment figures provided by NIHR CRN, and includes all recruitment reported to the end of the month preceding publication of this report. * 'Contributing Organisations' is defined as the combined recruitment of the local Comprehensive / Topic Networks represented within the contemporary CRN geography. This metric relates to NIHR CRN HLO 1, see appendix

Partners Maximise Engagement in NIHR Research

|	2014/15 Recruitment	Observational	Interventional
Chesterfield Royal Hospital NHS Foundation Trust	243	72%	28%
Derbyshire Community Health Services NHS Trust	0		
Derby Hospitals NHS Foundation Trust	1,565	79%	21%
Derbyshire Healthcare NHS Foundation Trust	721	98%	2%
East Midlands Ambulance Service NHS Trust	0	0%	
Kettering General Hospital NHS Foundation Trust	469	81%	19%
Leicestershire Partnership NHS Trust	554	54%	46%
Lincolnshire Community Health Services NHS Trust	0		
Lincolnshire Partnership NHS Foundation Trust	149	73%	27%
NHS Corby CCG	42		100%
NHS East Leicestershire and Rutland CCG	127	68%	32%
NHS Erewash CCG	15		100%
NHS Hardwick CCG	36	17%	83%
NHS Leicester City CCG	1,672	90%	10%
NHS Lincolnshire East CCG	22	59%	41%
NHS Lincolnshire West CCG	109	18%	82%
NHS Mansfield and Ashfield CCG	71	27%	73%
NHS Nene CCG	333	23%	77%
NHS Newark and Sherwood CCG	69	62%	38%
NHS North Derbyshire CCG	163	7%	93%
NHS Nottingham City CCG	1,318	94%	6%
NHS Nottingham North and East CCG	75	40%	60%
NHS Nottingham West CCG	19	42%	58%
NHS Rushcliffe CCG	1,183	98%	2%
NHS South Lincolnshire CCG	31	13%	87%
NHS South West Lincolnshire CCG	7	86%	14%
NHS Southern Derbyshire CCG	137	44%	56%
NHS West Leicestershire CCG	789	86%	14%
Northampton General Hospital NHS Trust	578	89%	11%
Northamptonshire Healthcare NHS Foundation Trust	373	81%	19%
Nottingham University Hospitals NHS Trust	4,673	58%	42%
Nottinghamshire Healthcare NHS Trust	550	80%	20%
Sherwood Forest Hospitals NHS Foundation Trust	426	81%	19%
United Lincolnshire Hospitals NHS Trust	518	79%	21%
University Hospitals of Leicester NHS Trust	5,966	77%	23%

Source: NIHR CRN - 2014/15 recruitment data is produced from the recent recruitment figures provided by NIHR CRN, and includes all recruitment reported to the end of the month preceding publication of this report.

Industry Proportion of active commercial sites / recruitment

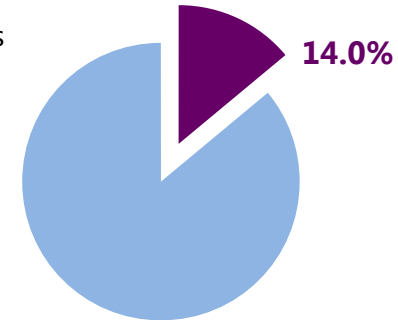## % of Active Study Portfolio (Commercial / Non-Commercial)

All CRNs
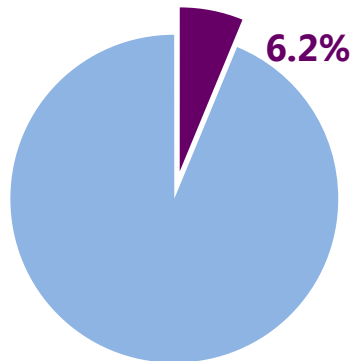
15.4%
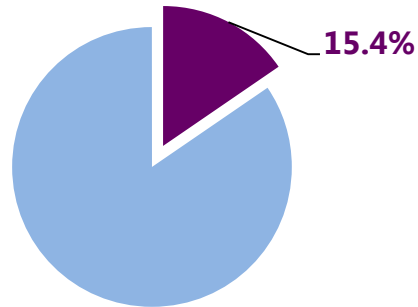
14008 Non-Commercial	2559 Commercial

CRN: East Midlands

14.0%

919 Non-Commercial	149 Commercial

% of 2014/15 YTD Recruitment (Commercial / Non-Commercial)

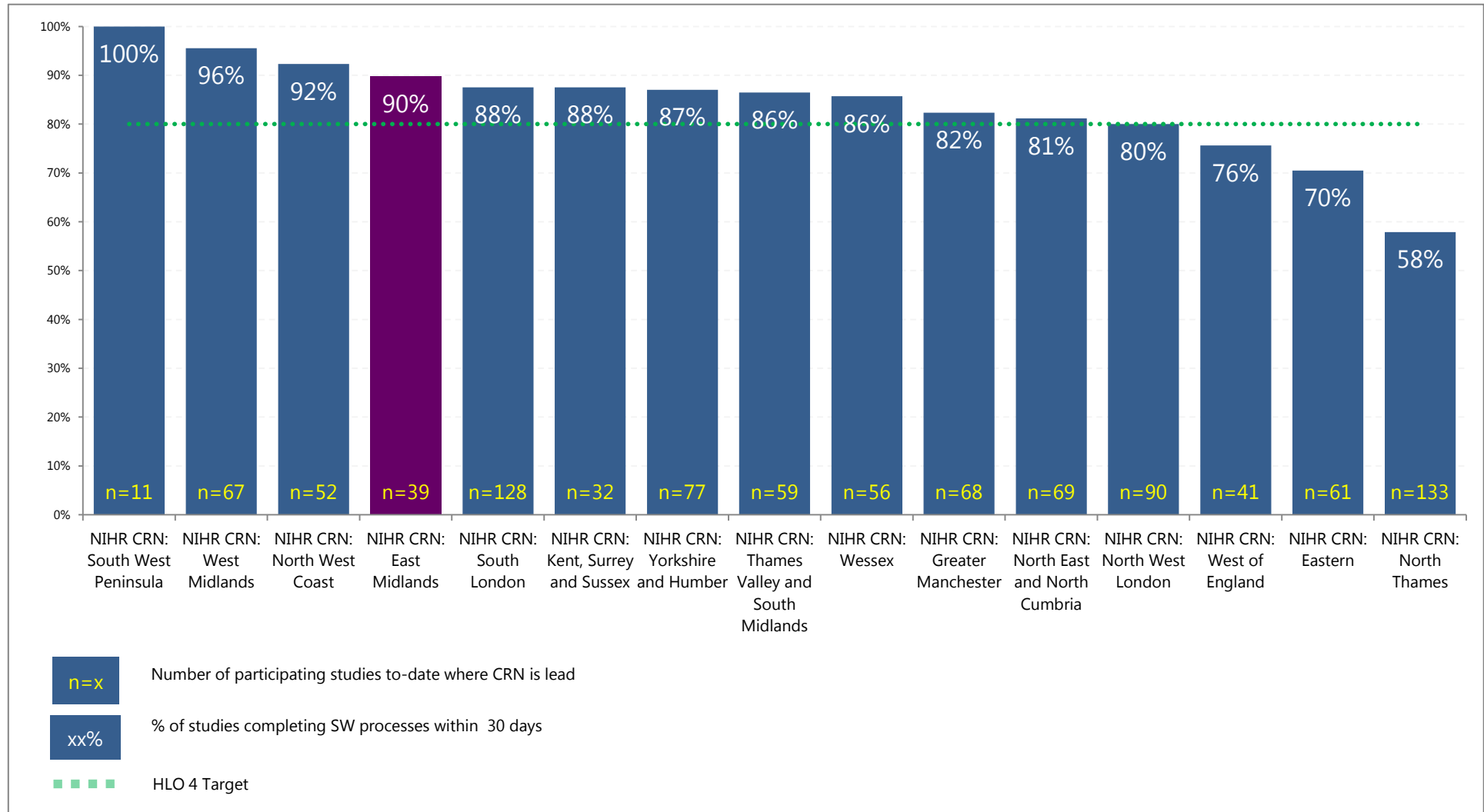All CRNs

6.2%

309346 Non-Commercial	20592 Commercial

CRN: East Midlands

2.9%
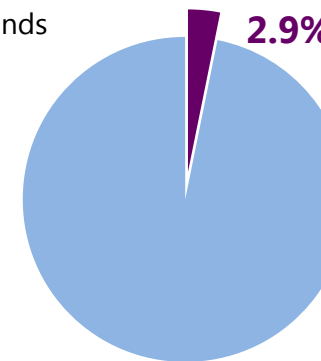
22272 Non-Commercial	731 Commercial

Processes % of Study-Wide processes completed within 30 days

Legend:
- n=x — Number of participating studies to-date where CRN is lead
- xx% — % of studies completing SW processes within 30 days
- ▪ ▪ ▪ ▪ HLO 4 Target

Source: Open Data Platform, 2014-10-14. This metric relates to NIHR CRN HLO 4, see appendix