

## CRN East Midlands - Host Board Report

Author: Prof. D Rowbotham Sponsor: Mr A Furlong 1 September 2016 Trust Board paper I

# Executive Summary

## Context

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute of Health Research (NIHR) Clinical Research Network: East Midlands, (CRN). Whilst there are appropriate governance arrangements in place, UHL is contracted by the Department of Health to take overall responsibility for the monitoring of governance and performance of the network. The purpose of this paper is to report our final year end performance for 2015-16 and summarise year to date performance for 2016-17 along with current risks and issues. This paper has been reviewed by the CRN: East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive lead for the LCRN) and also by the UHL Executive Performance Board on 23 August 2016. It is submitted for formal approval by the UHL Trust Board.

## Questions

1. How has the CRN performed at year end 2015-16 and what feedback has been received?
2. How has the CRN performed against the plans made at the start of 2016-17?

## Conclusion

1. In 2015-16, the network performed well against a number of indicators, notably improving the delivery of commercial studies; maintaining and improving study set-up times above the national goals and engagement with partner organisations, especially within primary care settings. We received positive feedback from the NIHR with respect to our Annual Report and Performance Review meeting.
2. Work is progressing well in relation to the work programme set out in the Annual Plan for 2016-17, however, the report highlights some concerns with respect to falling recruitment numbers. This reflects a national trend but also issues specific to the East Midlands which are adding significantly to the problem. We also describe how we are seeking to mitigate against these.

## Input Sought

We would welcome Trust Board comments on EMCRN's performance.

# For Reference

Edit as appropriate:

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

Safe, high quality, patient centred healthcare	[Not applicable]
Effective, integrated emergency care	[Not applicable]
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	[Not applicable]
Clinically sustainable services with excellent facilities	[Not applicable]
Financially sustainable NHS organisation	[Yes]
Enabled by excellent IM&T	[Not applicable]

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: [N/A]

4. Results of any **Equality Impact Assessment**, relating to this matter: [no adverse impact identified]

5. Scheduled date for the **next paper** on this topic: January 2017

6. Executive Summaries should not exceed **1 page**. My paper does comply

7. Papers should not exceed **7 pages**. My paper does comply

**UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST**

**NIHR Clinical Research Network: East Midlands**

**Quarterly Host Board Report: Progress, challenges and performance update**

**Executive Summary**

This report provides a summary of 2015-16 performance for the Clinical Research Network: East Midlands. The network has performed well against a number of indicators, notably improving the delivery of commercial studies; maintaining and improving study set-up times above the national goals and engagement with partner organisations, especially within primary care settings. The Network was visited in June for a formal annual review, where John Adler was present, with feedback provided that: *“The CRN Coordinating Centre (CRNCC) was very pleased to see such a strong commitment from the senior leadership and management team to the delivery of a dynamic and effective network and I would like to congratulate you and your LCRN colleagues on the achievements to date.”*

The report also summarises our plans for 2016-17, along with current performance, risks and issues. It highlights some concerns with respect to falling recruitment numbers which reflect the national trend but also issues specific to the East Midlands which are adding significantly to the problem. We also describe how we are seeking to mitigate against these.

Finally, and in response to a previous request from the UHL Chairman, Karamjit Singh CBE, the report provides a brief update on a particular change or development within the wider research environment: the introduction of the Study Support Service.

**1. Background**

1.1 University Hospitals of Leicester (UHL) NHS Trust is the Host organisation for the National Institute for Health Research (NIHR) Clinical Research Network: East Midlands (CRN). UHL is contracted by the Department of Health to take overall responsibility for the monitoring of governance and performance of the network.

1.2 This paper will be taken to the CRN: East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive lead for the CRN) in August 2016. It will then be considered by the UHL Executive Performance Board, and submitted for UHL Board in September 2016. Appended to this written report are dashboards detailing year end performance measures for 2015-16 (Appendix 1) and current performance for 2016-17 (Appendix 5).

## 2. Overall performance: 2015-16

2.1 The 2015-16 dashboard report (Appendix 1) displays the year-end figures for 2015-16. Due to the timing of our previous report, the figures presented did not give a final, accurate end of year position, as all the data had not been uploaded to the national database. Appendix 1 provides further detail of performance against all measures. Preliminary figures have been previously reviewed by the Board during the sign off and submission process for our end of year Annual Report, thus this narrative provides only the headline information:

- i. High Level Objective (HLO) 1 measures the total number of participants recruited into NIHR studies. In 2015-16 we recruited 45,508 participants; this recruitment is below our target and lower than the previous year's recruitment, however recruitment across the country is lower overall. We have retained our 5<sup>th</sup> position overall out of 15 regional networks in the national league tables.
- ii. A target which is considered as critical by the NIHR/DH is the proportion of commercial studies recruiting to time and target (HLO2a). We finished in overall joint 3<sup>rd</sup> position with 72% of studies recruited to time and target. This falls slightly short of the target of 80%, however, it represents a significant improvement from the previous year (51%).
- iii. For Research Governance and Management (HLO4), which reflects the time taken to set-up a study, we are measured on "study wide and local" approval processes, both with a target for 80% of studies to fall within in set time based limits. We finished the year achieving and surpassing these targets with 87% and 94% respectively.

2.2 Annual performance is reviewed by the NIHR through analysis of the Annual Report along with an Annual Performance visit. Formal feedback in relation to the Annual Report was received on 28<sup>th</sup> June 2016 (Appendix 2). This recognised our achievements and performance for 2015-16, with feedback largely positive overall and particular recognition to a solid improvement in HLO2a (commercial study recruitment to time and target), strong performance across communication activities and engagement, valuable PPIE work and a noteworthy Community Pharmacy plan. We resubmitted a final version of the Annual Report containing the confirmed year-end figures on 15<sup>th</sup> July 2016.

2.3 Our Annual Review Meeting with the NIHR CRN Coordinating Centre took place on 29<sup>th</sup> June 2016, feedback has since been received. In the feedback letter (Appendix 3) the CRNCC highlighted its appreciation of the excellent LCRN leadership team and emphasised the importance of strong and capable senior leaders to the success of the CRN. A number of senior staff were individually thanked for their significant contribution to national CRN delivery. Some requests for further information, feedback and support were made, and these are now being addressed.

## 3. 2016-17: current performance & progress

3.1 The NIHR also wrote to Andrew Furlong as UHL LCRN Executive Lead on 17<sup>th</sup> June 2016 with feedback on our Annual Plan for 2016-17 (Appendix 4). The plan has been formally approved

and the feedback was very positive overall. Our proposed target of 48,000 participants for HLO 1 (overall recruitment into NIHR Portfolio studies) has been accepted; however, there was encouragement from the Coordinating Centre for us to stretch this further.

- 3.2 The feedback letter raised several points in relation to the Financial Plan. The letter suggests that 8.1% of our budget was unallocated; however this is a little misleading. The TBA (to be allocated) figure comprised of identified funding for unmet service support costs which will be provided to trusts on a quarterly basis in arrears, however the exact allocation of those costs to each specific trust is not known at the start of the year. Also, whilst the Strategic funding of £430k, was not fully committed at the beginning of the year, this has now been confirmed and we will be reported at the end of in Quarter 1. Although the initial plan included a number of vacant posts, we do have assurances now from many of our partner trusts regarding the progress of these posts, however will continue to seek this assurance to ensure there is no risk of underspend. All technical and minor corrections raised have also now been addressed.
- 3.3 Appendix 5 presents data extracted on 31 July 2016 reflecting performance to date; however, it should be noted that there is a delay of approximately 4 weeks in reporting of recruitment data. The following is of particular note:
- i. Our recruitment rate, High Level Objective (HLO) 1 is currently 56% of our YTD target, representing significant underperformance at this early stage of the year; we are concerned about this and some of the key actions we are taking in mitigation are summarised in Section 4 below. There are some well recognised national issues in relation to the current portfolio and pipeline, a fall in the number of high recruiting studies, and national delays in the new research approvals system. We are currently looking for local solutions which are within our influence; unfortunately, some of these are not.
  - ii. For the proportion of commercial studies recruiting to time and target (HLO2a) we are currently at 72% against a target of 80% and rated 4<sup>th</sup> of the 15 regional networks. We are more confident that the target of 80% will be achieved this year.
  - iii. Performance remains strong for NHS engagement with all trusts recruiting to NIHR portfolio studies, and high levels of engagement with GPs.

#### **4. Concerns and Challenges**

- 4.1 Risks and issues are formally discussed through the Executive Group for the CRN, which is chaired by Andrew Furlong. A risk register is maintained for the CRN with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Co-ordinating Centre.
- 4.2 The table below details current issues and how these are being addressed or managed.

Challenge or concern	Associated action
Reduced levels of recruitment, concerns about performance in relation to HLO1	<ul style="list-style-type: none"> <li>▪ Continually reviewing national portfolio to identify pipeline studies to deliver locally</li> <li>▪ Work to encourage local portfolio generation</li> <li>▪ Escalation to CRN Co-ordinating Centre, who confirmed a need to focus more on time to target, (HLO2 a &amp; b) thus delivering the studies we have as well as possible</li> <li>▪ Communicating this to partners and working with them to better achieve time to target</li> </ul>
Concern in relation to performance of some key partners, due to low recruitment output and potential impact on overall East Midlands budget	<ul style="list-style-type: none"> <li>▪ Working closely with partner colleagues to support recovery in recruitment</li> <li>▪ Actively involved in local groups and work programmes to support this</li> <li>▪ Modelling budgets earlier this year to forecast potential reduction and thus be clear on impact.</li> </ul>
Working with non-NHS partners to deliver research in these settings to expand the research opportunity for patients	<ul style="list-style-type: none"> <li>▪ Recognition that private providers under contract for NHS service delivery are well placed to provide NIHR research</li> <li>▪ Incorporating the activity of these providers in our monthly reports &amp; featuring in local publications//promotions to raise awareness among the research community</li> <li>▪ Establishing relationships with Nuture, Circle, CityCare, St Andrews Healthcare, Loros and potentially BMI Hospitals; and others as year progresses</li> </ul>

## 5. Research Highlights

5.1 As part of this quarterly report we would also like to bring to highlight a national change to the support environment for researchers. Appendix 6 provides details of the Study Support Service which is for researchers in all health care settings delivering both commercial and non-commercial studies, with a range of services across the research pathway to help study feasibility, set up and delivery to time and target. This can be further discussed, as required.

## 6. Summary and recommendations

6.1 CRN East Midlands experienced a challenging year in 2015-16; however, excellent progress was made in some areas along with other key milestones. Work is progressing well in relation to the work programme set out in the Annual Plan for 2016-17 but recruitment rates remain a real concern. UHL Trust Board is asked to:

- (i) Review our final year end performance for 2015-16 providing any comments or feedback you might have.
- (ii) Review our current performance figures for 2016-17, achievements, challenges and mitigating actions, providing any comments or feedback you might have.

Appendix 1 - Dashboard 2015-16 (Year End)

Clinical Research Network: East Midlands

Refreshed: 03/06/2016

2015-16 YEAR END FIGURES

(Previous: 13/04/2016)

Network Progress Overview

HLO Description	Study Type	Target		Progress/Summary			Commentary	Status	Owner	Year End RAG Assurance		
		England	East Midlands	Year End	Previous	Trend						
1	Number of patients recruited into NIHR studies	All	650,000	56,688	45,508	42,160	↑3%	80% of Year End goal (56,688) (previously 77%) CRN: East Midlands in 5th position out of 15 LCRNs (n.b. 86% of local Year End goal)	-Loss of LIFE Study (c. 2,500 - 4,000 recruits) -Reduced pipeline in some specialties -Impact of CPMS launch -Significant fall in NUH recruitment performance	Complete Year End	Chief Operating Officer	Red
2	Proportion of NIHR studies delivering to recruitment target and time	Commercial	80%	80%	72%	72%	↔	121 studies recorded as closed and reported recruitment. CRN: East Midlands in 3rd position out of 15 LCRNs	-Improvement on last year (51%) -Data improving as old studies close -Significant improvement in Primary Care	Complete Year End	Industry Operations Manager	Amber
		Non-commercial	80%	80%	72%	70%	↑2%	72% (116) for 161 closed HLO studies	Same performance as last year (72%)	Complete Year End	Chief Operating Officer	Amber
4	Proportion of eligible NIHR studies obtaining NHS permission within 30 calendar days of valid research application	All	80%	80%	94%	93%	↑1%	Implementation of the HRA approval system may affect the CRN's control over this HLO.	Target achieved - excellent result based on reduced workforce	Complete Year End	Lead RM&G Manager	Green
6	Proportion of NHS Trusts recruiting into NIHR studies	All	99%	99%	100%	100%	↔	16 out of 16 Trusts reported recruitment.	Target achieved	Complete Year End	Chief Operating Officer	Green
		Commercial	70%	70%	63%	63%	↔	10 out of 16 Trusts reported commercial recruitment. Need 12 out of 16 to achieve target	-Improvement on last year (56%) -Delays in study set-up and abandoned studies affected ability to achieve target, outside of local control	Complete Year End	Industry Operations Manager	Amber
	Proportion of General Medical Practices recruiting into NIHR studies	All	25%	25%	66%	58%	↑8%	395 out of 601 GPs, Surgeries & Health care sites reported recruitment.	Target achieved	Complete Year End	Division 5 Research Delivery Manager	Green
7	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) NIHR studies	All	13,500	1,250	1,096	983	↑2%	88% of Year End goal (1,250) (previously 86%)	Lower than target due to lack of potential studies	Complete Year End	Division 4 Research Delivery Manager	Amber

Sources: Commercial Reporting on ODP 03/06/2016, Portfolio ODP Last update: 31/05/2016, Portfolio ODP 1415 Annual Cut Last update: 28/05/2015, CSP Reporting on ODP Last update: 31/05/2016

Network Summary Report 31/05/2016, Commercial Team update: 03/06/2016

Provided by: CRN: East Midlands Business Intelligence Team

N.B: HLO 3 & HLO 5 are not included as these relate to national objectives

CRN: East Midlands Executive Paper E



Mr Andrew Furlong  
Medical Director  
University Hospitals of Leicester  
NHS Trust  
Gwendolen House  
Gwendolen Road  
Leicester  
Leicestershire  
LE5 4QF

Clinical Research Network Coordinating Centre  
Fairbairn House  
71-75 Clarendon Road  
Leeds  
LS2 9PH  
Tel: 0113 343 2314  
Fax: 0113 343 0336  
Email: [crn@nihr.ac.uk](mailto:crn@nihr.ac.uk)  
Web: [www.crn.nihr.ac.uk](http://www.crn.nihr.ac.uk)

28 June 2016

Dear Mr Furlong,

#### **LCRN Annual Report 2015/16**

Thank you for submitting your LCRN Annual Report (including your year-end finance return) for 2015/16. The timescales for development, sign-off and submission of your Report following release of the guidance were challenging and we would like to thank you for all the hard work that went in to producing the Report, and for providing it within the requested deadline.

I am pleased to confirm that the review panel recommended your Annual Report was approved.

#### **1. 2015/16 year-end performance data**

We recognise that the extension of the implementation date of CPMS meant that LCRNs were not in a position to submit final cleansed 2015/16 performance data in Annual Reports. In order to ensure the CRN has an accurate record of your network's year end performance we have created a file note detailing 2015/16 LCRN performance against the HLOs (please see attached at Appendix 1). There are two options:

- a) Should you wish to update your Annual Report in light of final performance figures we ask that you send an updated version to us at [lcn.support@nihr.ac.uk](mailto:lcn.support@nihr.ac.uk) at the earliest opportunity and by 15 July at the latest.
- b) Alternatively, if you wish to add the file note only to your report then there is no further action required; we will do this on your behalf. We will assume that the year-end performance figures included in the file note are used for any local communications and engagement purposes.

#### **2. Specific feedback on CRN: East Midlands Annual Delivery Report**

The review panel highlighted a number of points which we hope you will find helpful:



- a) We congratulate the network on good overall performance in 2015/16, including a solid improvement in HLO 2a performance, from 51% to 71% of commercial contract studies recruiting to time and target. Specialties: the report provided an effective summary demonstrating good performance overall against the Specialty Objectives.
- b) The report provided a good summary of the network's strong performance across a range of Communications activities. This function provides a strong voice for the network at national meetings and continues to contribute to and support national campaigns.
- c) The review panel noted the valuable PPIE work done by the network presented in the report. The 'Year in the life of the Network' infographic (pg. 14 of report) is noteworthy, and we encourage the network to share this with other LCRNs. The review panel noted the network has good ambitions for PPIE but resources may be potentially limiting and we would encourage you to consider whether further resource can be made available to support PPIE activities going forwards.
- d) It is clear the network values its workforce. The report highlighted the great work the team has done around engagement, including the successful research awards event and research forum. We encourage the network to seek to demonstrate the impact of these activities during 2016/17.
- e) Your network's comprehensive strategy to develop Community Pharmacy is noteworthy and it was pleasing to see how this has evolved this year, achieving an improved balance between developing workforce capacity and encouraging demand (new study placement).
- f) The network exemplifies a one-Network approach and the CRNCC values the leadership, engagement and national contribution made by CRN: East Midlands.

### **3. Specific feedback on CRN: East Midlands Year-end Finance Return**

There were no specific comments from the review panel.

### **4. General comments that the review panel felt were important to feed back to all LCRNs**

- There was variation in reporting of performance metrics for HLO 2, and particularly HLO 2a. Please note the expectation is that LCRNs monitor the proportion of network sites locally that are recruiting to time and target (not just studies that the LCRN is the Lead LCRN for).
- In relation to the LCRN Development and Improvement Objective b): "demonstrate a 'one-Network' approach to delivery" (clause 2.9, Part A: Performance Framework of Appendix A of the DH/LCRN Agreement), it was evident that networks have interpreted the term 'one-Network' in different ways. CRNCC's expectation is that LCRNs actively contribute to national groups and projects and work in an integrated and coordinated way with other LCRNs, to deliver against the CRN's performance objectives. This is in addition to working collaboratively with local providers, and as relevant with other local initiatives involved in research delivery, and with other parts of the NIHR).
- There were references across multiple reports to periods of absence of senior colleagues and impacts on network delivery. From a risk-management perspective the CRNCC expects to be made aware of extended periods of absence of key staff. We will be in touch with all network

Chief Operating Officers to clarify requirements for reporting absences to the CRNCC in due course.

**Annual Review Meeting**

We look forward to the network's forthcoming Annual Review Meeting, and to reflecting on and discussing the achievements and challenges in your area in 2015/16 as well as progress in the implementation of your 2016/17 Annual Plan.

We very much look forward to working with you in the coming year to support you in building on your strong and successful performance in 2015/16.

Yours sincerely



Amber O'Malley

Head of Performance Management  
NIHR Clinical Research Network

cc Professor David Rowbotham, CRN Clinical Director, CRN: East Midlands  
Elizabeth Moss, Chief Operating Officer, CRN: East Midlands  
Dr Jonathan P Sheffield, CRN Chief Executive  
John Sitzia, CRN Chief Operating Officer  
Nick Lemoine, CRN Medical Director  
Matt Cooper, CRN Business Development & Marketing Director  
Susan Hamer, CRN Director of Nursing, Learning & Organisational Development  
Nick Hirst, CRN Chief Information Officer  
Dr Clare Morgan, CRN Research Delivery Director  
Ruth Jessop, LCRN Finance Manager

John Adler  
Chief Executive Officer  
University Hospitals of Leicester  
NHS Trust  
Gwendolen House  
Gwendolen Road  
Leicester  
Leicestershire  
LE5 4QF

Clinical Research Network Coordinating Centre  
Fairbairn House  
71-75 Clarendon Road  
Leeds  
LS2 9PH  
Tel: 0113 343 2314  
Fax: 0113 343 0336  
Email: [crn@nhr.ac.uk](mailto:crn@nhr.ac.uk)  
Web: [www.crn.nihr.ac.uk](http://www.crn.nihr.ac.uk)

07 July 2016

Dear Mr Adler,

**NIHR CRN: East Midlands Performance Review Meeting 29 June 2016**

Thank you to you and your team for attending the Performance Review Meeting held on 29 June 2016 at Leicester Royal Infirmary to discuss CRN: East Midlands delivery and performance in 2015/16 and plans for 2016/17.

As a record of the meeting, the meeting was chaired by John Sitzia and attended by the following colleagues:

LCRN attendees – John Adler, Chief Executive, University Hospitals of Leicester NHS Trust  
Nigel Brunskill, Director of Research & Development University Hospitals of Leicester NHS Trust  
David Rowbotham, LCRN Clinical Director  
Elizabeth Moss, LCRN Chief Operating Officer  
Julian Barwell, LCRN Clinical Lead (Division 3)  
Hannah Finch, LCRN Research Delivery Manager (Divisions 1 & 3)

CRNCC attendees – John Sitzia, Chief Operating Officer (Chair)  
Clare Morgan, Research Delivery Director  
Chris King, Deputy Chief Information Officer  
Chelsea Drake, Head of Communications  
Amber O'Malley, Head of Performance Management  
Lucy Ainsworth, LCRN Performance Coordinator (Secretariat)

My apologies that I personally was unable to attend on this occasion.

The CRN Coordinating Centre (CRNCC) was very pleased to see such a strong commitment from the senior leadership and management team to the delivery of a dynamic and effective network and I would like to congratulate you and your LCRN colleagues on the achievements to date.

Key points and actions from the meeting:

- The CRNCC highlighted its appreciation of the excellent LCRN leadership team and emphasised the importance of strong and capable senior leaders to the success of the CRN.
- The LCRN team, and specifically Beth Moss, David Rowbotham, Dan Kumar, Hannah Finch and Michelle Eve were thanked for their significant contribution to national CRN delivery.
- Colleagues discussed the importance of having a standard approach for local target setting for non-commercial studies. Clare Morgan to investigate a Business Change Plan for non-commercial reporting at site level, to promote a cross-network focus on delivery to HLO2b and enable intelligent reporting of the network contributions to all studies.
- The issues surrounding enough studies to sustain RATER criteria and variable approach of Industry were discussed. Clare Morgan to speak with Paul Duffy, UK Lead for the TransCelerate programme about an accredited RATER approach by Industry.
- Elizabeth Moss to confirm with the CRNCC finance team that an audit was completed in 2014/15 and to send them a copy of the findings.
- The CRNCC to clarify the definition of 'NHS engagement' for the purposes of LCRN reporting.
- Elizabeth Moss to liaise with Louise Lambert (CRNCC, Non-Commercial Research Initiatives Manager) to offer specific examples of where clinical practice is evolving to meet the needs of patient disease and location and the impact on the portfolio eligibility criteria.
- Hannah Finch to review AcoRD FAQs and suggest any amendments to submit via Laura Bousfield for Department of Health consideration.
- Elizabeth Moss to provide a short summary of initiatives to develop the investigator base in the region, to include timelines and anticipated outcomes

A further letter detailing any general points and themes that have been captured following completion of all LCRN Annual Review meetings will follow in due course.

I would like to thank you and your team once again for the strong leadership you provide for CRN: East Midlands and I look forward to my next meeting with the network team.

If there are any issues in respect of the network that you would like to discuss at this stage, then please contact Amber O'Malley, Head of Performance Management (email: [amber.o'malley@nihr.ac.uk](mailto:amber.o'malley@nihr.ac.uk), tel: 0113 3430313) in the first instance.

Yours sincerely



Jonathan Sheffield OBE, MBChB, FRCPath  
Chief Executive  
NIHR Clinical Research Network



**National Institute for  
Health Research**

Mr Andrew Furlong  
Medical Director  
University Hospitals of Leicester  
NHS Trust  
Gwendolen House  
Gwendolen Road  
Leicester  
Leicestershire  
LE5 4QF

**Clinical Research Network Coordinating Centre**

Fairbairn House  
71-75 Clarendon Road  
Leeds  
LS2 9PH

Tel: 0113 343 2314  
Fax: 0113 343 0336  
Email: [crn@nhr.ac.uk](mailto:crn@nhr.ac.uk)  
Web: [www.crn.nhr.ac.uk](http://www.crn.nhr.ac.uk)

17 June 2016

Dear Mr Furlong,

**LCRN Annual Plan 2016/17**

Thank you for submitting your LCRN Annual Plan (including your Annual Financial Plan) for 2016/17. The timescales for development and submission of your plan following release of the final guidance were challenging and we would like to thank you for providing this information within the requested deadline.

I am pleased to confirm that the panel recommended your Annual Plan was approved.

**1. Specific feedback on CRN: East Midlands Annual Delivery Plan**

The review panel highlighted a number of points which we hope you will find helpful:

- a) The overall plan was clear, well presented and provided assurance the network has appropriate plans in place to deliver against the national targets, strategies and goals.
- b) The CRNCC expectation is that each network puts plans in place to evidence growth and improve performance with the aim of surpassing previous years' achievements. Your provisional HLO 1 forecast is an increase from your 2015/16 baseline but we encourage you to continue to stretch your total recruitment beyond this.
- c) Overall, good analyses of current activities and challenges supported by specific plans for delivering the majority of the individual specialties were presented. We note the network does not have Specialty Leads for all Specialties and we strongly encourage you appoint all 30 Leads.
- d) It was evident that the network has taken a proactive approach to using your LPMS to support provision of the Study Support Service and expected reporting needs.

- e) The panel were pleased to see clear plans and a proactive approach to engagement with the life sciences.

## 2. Specific feedback on CRN: East Midlands Annual Financial Plan

### a) Net Unallocated Funds and Vacant Posts

- Your TBA is 8.1% of total funding, which is relatively high but, within CRNCC guidelines. It is noted that this is the result of an unexpected increase in CRN: East Midlands funding allocation.
- Your Vacancy Factor is (4.0%), which is also relatively high. You have noted that this will largely be offset against TBA by the Quarter 1 return.
- You have reported vacant posts with a total value of £991k (4.7% of total funding). You have noted any risk of underspend will be closely monitored.

### b) Minor Points / Technical Corrections

Our review of the Annual Financial Plan noted some further minor points or technical corrections. A member of the CRNCC Finance Team will send these directly to the Chief Operating Officer and the LCRN Finance contact within your network. We ask that any issues are addressed for the Q1 return.

## 3. General comments that the review panel felt were important to feed back to all LCRNs

- We will be developing an audit framework to monitor compliance with the CRN Performance and Operating Framework and we will be in touch separately regarding this.
- The CRNCC will be working with all LCRNs on recovery of commercial funding. We will be in touch in due course regarding this.
- A number of LCRNs have commented on difficulties in recruiting to CRN funded posts due to recruitment freezes. We ask that Host and Partner organisations work together to address any issues given that CRN funding should be ring fenced to support NIHR CRN Portfolio research delivery.
- There are some additional aspects of plans that some Specialty Cluster teams and Directorate colleagues would like to follow-up informally so please expect this contact.
- The risk registers submitted showed wide variation in structure and content. CRNCC is considering specifying a number of minimum elements to standardise the information available for review and enable better oversight of risks across the CRN.

## 2016/17 HLOs

Thank you for providing details of your forecast contributions for HLOs 1 and 7, and supporting rationale(s). The collated forecast contributions for all LCRNs indicate that there will be a shortfall of approximately 64,000 participants under HLO 1.

Therefore, for 2016/17 we will adopt each LCRN's forecast contribution for HLO 1 (to be known as 'LCRN total recruitment forecast') and each LCRN will also have a 'LCRN HLO 1 target'. If individual LCRNs wish they may review their total recruitment forecast for HLO 1 in light of actual year-end recruitment figures and advise CRNCC of a higher forecast.

There is no shortfall in the collated forecast contributions for HLO 7. Each LCRN's forecast contribution for HLO 7 will be adopted as the 'LCRN's HLO 7 target'. Again, LCRNs may advise of an increased local target for HLO 7 if they so wish. Details of the recruitment targets for all LCRNs and the method of calculation of LCRN HLO 1 targets are provided in Appendix 1 to this letter.

We are pleased to confirm the following recruitment goals for CRN: East Midlands for 2016/17:

- LCRN provisional total recruitment forecast: 48,000
- LCRN HLO 1 target: 48,000
- LCRN provisional HLO 7 target: 1,250

In performance reports and for monitoring purposes the CRNCC will use both LCRN total recruitment forecast figures and LCRN targets for HLO 1. For HLO 7 we will refer to the LCRN targets for HLO 7. CRNCC national Research Delivery, Specialty Cluster colleagues and Specialty National Leads, will continue to liaise with you so please make use of their Specialty knowledge and experience to support you to achieve your targets.

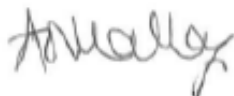
As discussed and noted previously, improving delivery to the CRN High Level Objective 2 ("Increase the proportion of studies in the CRN Portfolio delivering to recruitment target and time"), with a particular emphasis on commercial contract studies, remains a priority for 2016/17.

#### **Annual Review Meeting**

We have recently been in contact with Elizabeth Moss to arrange an Annual Review Meeting with you and your senior team during the summer this year. We look forward to discussing the achievements and challenges in your area in 2015/16, and progress to date in 2016/17.

We very much look forward to working with you in the coming year to support the implementation of your Plan. Please do not hesitate to escalate any performance issues or areas needing support from the CRN Coordinating Centre as they arise during the year via the CRN Performance Management team ([cmcc.performance@nihr.ac.uk](mailto:cmcc.performance@nihr.ac.uk)) or the lead responsible for the relevant function.

Yours sincerely



Amber O'Malley

Head of Performance Management  
NIHR Clinical Research Network

Appendix 5 - Dashboard 2016-17 (Year to Date)

Clinical Research Network: East Midlands

Refreshed: 31/07/2016

Network Progress Overview

HLO Description	Study Type	Target		Progress/Summary			Actions	Status	Owner	Year End RAG Assurance		
		England	East Midlands	Curr. YTD	Previous	Trend						
1	Number of patients recruited into NIHR studies	All	650,000	48,000	8,935	-	-	56% of Year to Date goal (16,000) CRN: East Midlands in 6th position out of 15 LCRNs n.b. in 5th position based on weighted recruitment	- Ongoing review of UKCRN database for potential studies and open new sites - Shift focus to recruitment to time and target	Ongoing	Chief Operating Officer	TBC
2	Proportion of NIHR studies delivering to recruitment target and time	Commercial	80%	80%	72%	- %	-	36 studies recorded as closed and reported recruitment across all Network supported sites. CRN: East Midlands in 4th position out of 15 LCRNs	- Divisional performance review meetings - Review of performance of closed studies for last year to identify areas for improvement	Ongoing	Industry Operations Manager	Green
		Non-commercial	80%	80%	66%	- %	-	66% (25) for 38 closed HLO studies	- Analysis of reasons and concerns has been requested	Ongoing	Chief Operating Officer	Green
4	Proportion of eligible studies achieving NHS set up within 40 calendar days	All	80%	80%	- %	- %	-	No data to report as awaiting NIHR guidance on key data points to be collected and reported		Ongoing	Lead RM&G Manager	TBC
6	Proportion of NHS Trusts recruiting into NIHR studies	All	99%	99%	100%	- %	-	16 out of 16 Trusts reported recruitment	Target achieved	Complete	Chief Operating Officer	Green
		Commercial	70%	70%	56%	- %	-	9 out of 16 Trusts reported commercial recruitment. Need 12 out of 16 to achieve target Unusual to be green at this point in the year	- Monitor studies in set-up at NHCFT, LPT and recently opened study at DHCFT	Ongoing	Industry Operations Manager	Green
	Proportion of General Medical Practices recruiting into NIHR studies	All	35%	35%	42%	- %	-	252 out of 601 GPs, Surgeries & Health care sites reported recruitment	Target achieved	Complete	Division 5 Research Delivery Manager	Green
7	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) NIHR studies	All	20,000	1,250	204	-	-	65% of Year to Date goal (312) Requires 24 recruits per week	- Increase number of studies by actively searching NIHR portfolio	Ongoing	Division 4 Research Delivery Manager	Amber

Sources: Commercial Reporting on ODP 31/07/2016, Portfolio ODP Last update: 31/07/2016, Portfolio ODP 1516 Annual Cut Last update: 31/05/2016, CSP Reporting on ODP Last update: 31/07/2016

Network Summary Report 31/07/2016, Commercial Team update: 31/07/2016

Provided by: CRN: East Midlands Business Intelligence Team

N.B: HLO 3 & HLO 5 are not included as these relate to national objectives

CRN: East Midlands Executive Paper G



## Appendix 6

**Study Support Service: A new resource available to clinical researchers in the East Midlands**

Delivering a clinical trial successfully is, to say the least, a major challenge. It starts with deriving a robust and relevant research question, developing the study protocol, obtaining funding if a non-commercial trial (usually via an extremely competitive application process), ensuring that the protocol is feasible in the current NHS environment, obtaining ethical committee approval, ensuring the study is appropriately governed according to various legislation and guidelines, completing the study within budget and on time, analysing the data, and finally publicising the study findings and implications for clinical practice.

The researcher must deal with many organisations and individuals; often a daunting and frustrating task, especially to those who are just starting their career in clinical research. If not managed effectively, the process can stifle excellent ideas and innovations, and discourage beneficial clinical research.

The NIHR Clinical Research Network supports researchers and the life-sciences industry in developing, setting up and delivering high quality research to time and target in the NHS in England. For any study that is eligible or applying for Network support, whether commercially or non-commercially sponsored, the Study Support Service offers a range of services across the research pathway that will help study feasibility, ethics and regulatory approval, set up and site identification, guidance on study costings, and delivery to time and target. Regardless of the location, study type, study size or therapy area of the research, the service provides consistent and high quality support.

Much of this support was available previously; some was provided by other organisations (e.g. NIHR Clinical Trial Units, NHS Trust R&I Departments). However, it was often not well co-ordinated, sometimes repetitive and not researcher-friendly. In the East Midlands, we have worked with all relevant partners (e.g. NHS Research & Innovation Managers in all sectors, NIHR research infrastructure, universities, MediLink, “shop floor” researchers) and produced suite of clear pathways for the effective delivery of all types of clinical research.

The Study Support Service became operational in July 2016. Page 2 of this presentation gives a simple summary of what the service offers to researchers and page 3 shows a much simplified route map of the processes.

# Clinical Research Network Study Support Service

Research ideas

Study development and planning

Study set-up / start-up

Study recruitment / follow up

Study closure

## Early contact and engagement

Staff in the local Clinical Research Networks advise researchers about the Study Support Service and also provide pre-application support on subjects such as regulatory approvals, attribution of costs and costing templates, recruitment pathways, training requirements and local intelligence.



## Site identification

We coordinate the distribution of study information to enable identification of potential sites. The sites consider the resources, facilities and costs involved in participating in a study, which allow for in-depth capability and capacity discussions with the study sponsor. This service is currently only available nationally for commercial studies.



## Effective study set-up

Using a nationally agreed attribution tool, we work with the Chief Investigator and research teams to develop a study set-up plan that ensures sites are ready to recruit. This plan includes study milestones, study recommendations and a local site's ability to be ready to recruit.



## Network delivery assessment

Our site intelligence service for commercial companies complements existing feasibility by using our site and study intelligence expertise and data from over 500 studies.



For non-commercial studies, the CRN will identify any study challenges which may affect delivery to time and target, which enables us to deliver effective study start-up and performance review services.

## Performance review

A named individual will be allocated to the study and will work with the Chief Investigator and research teams to develop a recruitment plan. Should recruitment start to slip, we will use methods that have been established and improved over a number of years to bring it back on track.



## Early feedback

Using our experts in the NHS, we provide early national advice on the deliverability of multi-site studies in the NHS and wider healthcare environment. We look at the study complexity, patient population, timelines and recruitment strategy, offering suggestions and adjustments that aid delivery. This service is currently only available nationally for commercial studies.

