

Meeting title:	UHL Public Trust Board	Public Trust Board paper N			
Date of the meeting:	9 March 2023				
Title:	CRN East Midlands Quarterly Board Report				
Report presented by:	A Furlong, Medical Director, E Moss, Chief Operating Officer, CRN East Midlands and A Farooqi, Clinical Director, CRN East Midlands				
Report written by:	Elizabeth Moss, Chief Operating Officer, CRN East Midlands and Carl Sheppard, Host Project Manager, CRN East Midlands				
Action – this paper is for:	Decision/Approval		Assurance	x	Update
Where this report has been discussed previously	CRN East Midlands Executive Group on 7 February 2023.				

To your knowledge, does the report provide assurance or mitigate any significant risks? If yes, please detail which
The purpose of the report is to provide assurance against the CRN Host Contract. The report does not relate to any significant risks.

Impact assessment
The current CRN Host Contract is due to expire in March 2024. UHL has submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN) from April 2024. This is currently being assessed and it is expected applicants will be notified on the outcome shortly.

<p>Acronyms used:</p> <ul style="list-style-type: none"> CRNCC - NIHR CRN Coordinating Centre CRN - Clinical Research Network DHSC - Department of Health and Social Care LCRN - Local Clinical Research Network NIHR - National Institute for Health and Care Research RDN - Research Delivery Network RRDN - Regional Research Delivery Network HLOs - CRN High Level Objectives
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Purpose of the Report

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute for Health and Care Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network. For the information of the Board, we have prepared this update paper on the recent progress and current priorities of CRN East Midlands. Appended to this report is a summary of CRN East Midlands compliance against the 2022/23 CRN Operating Framework, our latest Finance report and Risks & Issues Register.

Recommendation

We would welcome the Trust Board’s input to review our report and provide any comments or feedback you might have.

Summary

This report provides an update on the application process for the future Host of the East Midlands RRDN, an update on our regional research delivery performance, the LCRN Partner Satisfaction Survey and confirmation of CRN East Midlands compliance against the CRN Operating Framework. The report also includes information pertaining to our current financial position, future CRN funding and the CRN High Level Objectives (HLOs).

There are currently two risks on the CRN risk register, both of which relate to uncertainty due to the expiry of the current Host contract in March 2024. Risk #63 states that within our partner organisations, it could be difficult to re-appoint to research delivery posts on a short-term basis. This risk remains relatively low as we await an update about the future hosting arrangements. Risk #64 relates to uncertainty for roles within the CRN Core team (management & support staff). Similar to risk #063, there has been little change in this risk as we await further information about the future hosting arrangements. This risk is currently rated as medium and we will be monitoring this closely as new information becomes available.

On the CRN issue register, issue #07 relates to previous concerns around our regional performance for delivery of NIHR studies. Since our last report, we are pleased to report a significant improvement in our performance so the priority of this issue has reduced from high to medium. Also, a new issue (#08) has been added in relation to current challenges associated with commercial research performance nationally, which we are responding to at a regional level. This issue is rated as high priority with moderate severity. Further guidance on the national position and priority of this work is anticipated in the near future and we will continue support this as required.

Main report detail

1. Current priorities and progress

i) Reconfiguration of the Network

From April 2024, the NIHR Clinical Research Network will become the NIHR Research Delivery Network (RDN). In December, UHL submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN). This is currently being assessed and it is expected applicants will be notified on the success, or otherwise of their application shortly.

ii) Regional review on research delivery performance

In our previous report, we highlighted some concerns around regional research delivery performance. Although reduced recruitment activity has been an issue across the country, in the East Midlands our contribution has been lower than hoped and we have taken a number of steps to address this.

Over recent months, we have been engaging with Partner organisations and have set up a number of targeted working groups focused on specific aspects of performance. We provided partners with details of high recruiting studies in other regions which were not performing as well in our region, to help focus resources and maximise our recruitment. Internal resources, such as our Direct Delivery & Primary Care teams, have also been targeted to focus on key areas of research performance. Furthermore, a Research Scholars Programme has been launched this year, to raise interest for developing future researchers and investigators in the region, which will help to sustain regional research activity in the longer-term.

Partner organisations have responded very positively to this work and we are pleased to report excellent progress on addressing our performance concerns. Notably, there has been a marked improvement in the year-end regional recruitment forecast for 2022/23. This has increased from a year-end forecast of c.40,000 participants (as at October 2022) to a current forecast of c.57,000 participants. Also, for overall

regional recruitment, out of the 15 local research networks, the East Midlands has moved from 11th (in October) to 7th (in February). A significant increase in recruitment from primary care settings has contributed to this improvement. This has been achieved by opening some larger studies and mobilising our Direct Delivery Team. Although overall regional performance has improved, there are still some areas of underperformance that are being addressed through conversations with senior colleagues within partner organisations, as well as directly with delivery teams.

Commercial recruitment in the region is also beginning to improve, with performance for commercial study set-up times as good, however, there are some broader concerns around commercial research delivery at a UK-wide level. We have added this to the CRN issues register to capture our local response to this (see section 4 for further details). Regional data for the national CRN High Level Objectives (HLOs) are provided in section 3 of this report.

iii) LCRN Partner Satisfaction Survey

The CRN Coordinating Centre (CRNCC) conducts an annual NIHR Local Clinical Research Network (LCRN) Partner organisation survey referred to as the 'CRN Partner Satisfaction Survey'. This seeks to receive the direct and confidential views of LCRN Partnership Group representatives on behalf of their LCRN Partner organisation in respect of the hosting, leadership and management of their LCRN. Response to this survey is an important indicator of Partner satisfaction and our Performance and Operating Framework outlines that LCRNs are expected to achieve a minimum response rate of 90%.

The survey was circulated to partners on 11th January 2023 with a deadline to respond by 31st March 2023. Reminders were sent on 31st January and 17th February. To date we have received 11 out of 17 responses (65%), however, further follow up will take place with a view to achieving closer to 90%.

iv) Compliance with the CRN Operating Framework

Each year the Operating Framework under which the CRN is managed, is revised and updated and an exercise is undertaken to review our compliance. Although there is no longer a formal requirement for us to report this to the CRN Coordinating Centre, we have completed this review for 2022/23, for internal assurance purposes. We are fully compliant with the requirements and there are no concerns to raise to the Board. A summary of our compliance is attached at Appendix 1 of this report for the information of the Board.

2. Financial Position

Our latest Host finance report is attached at Appendix 2. This report provides an update on our year to date financial performance and current forecast.

The NIHR CRN Coordinating Centre has recently advised of a national uplift in CRN funding of c.£14.5m for the 2023/24 financial year. This is in addition to the previously announced uplift of c.£8.5m in relation to NHS pay award cost pressures, therefore a total of £23m additional national funding. DHSC has asked that the CRNCC put together a proposal against this funding, with an expectation that some be focussed on clinical support services for research delivery. As further information becomes available on the local funding amount and direction, a regional plan will be developed.

N.b. We have communicated details of the NHS pay award uplift to our Partners, although not the further income, as details are still pending.

3. Performance

Within the Performance and Operating Framework for the CRN, there are a range of performance expectations across all areas of work, including the High Level Objectives (HLOs). The HLOs are nationally set objectives for the Clinical Research Network relating to research delivery. The HLOs for 2022/23 are set out in the table below. With the exception of the PRES local ambition, all HLOs are measured at CRN-wide (national) level, however, the Network is keen to show our regional contribution to these national metrics. The below table details current progress in relation to these metrics.

Objective		Measure	National ambition	East Midlands data (as of 1/2/23)
Efficient Study Delivery (ESD)	Deliver NIHR CRN Portfolio studies to recruitment target	Percentage of <u>closed</u> to recruitment commercial contract studies which have achieved their recruitment target	80%	89%
		Percentage of <u>closed</u> to recruitment non-commercial studies which have achieved their recruitment target	80%	88%
		(NEW) Percentage of <u>open</u> to recruitment commercial contract studies which are predicted to achieve their recruitment target	60%	NEW - TBC
		(NEW) Percentage of <u>open</u> to recruitment non-commercial studies which are predicted to achieve their recruitment target	60%	NEW - TBC
Provider Participation (PP)	Widen participation in research by enabling the involvement of a range of health and social care providers	Percentage of General Medical Practices with recruitment in NIHR CRN Portfolio studies	45%	44%
		Percentage of NHS Acute trusts with recruitment in NIHR CRN Portfolio studies every quarter	99%	100%
		Percentage of NHS Acute trusts with recruitment in commercial contract NIHR CRN Portfolio studies every quarter	70%	75%
		Percentage of NHS Ambulance, Care and Mental Health trusts with recruitment in NIHR CRN Portfolio studies every quarter	95%	100%

Participant Experience (PE)	Demonstrate to participants in NIHR CRN supported research that their contribution is valued through collecting their feedback and using this to inform improvement in research delivery	Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey (PRES)	1,344 (local) 14,000 (national)	1,240
Expanding our work with the life sciences industry to improve health and economic prosperity (ELS)	Sustain or grow commercial contract research	Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total MHRA CT approvals for PHASE II-IV studies	75%	Not locally applicable

With respect to the data in the above table, we can provide the following supporting commentary:

- We are on track to meet the national ambition for percentage of lead studies achieving their recruitment target for both commercial and non-commercial studies. Note, these measures only relate to a small sample of studies so are not representative of our performance more broadly.
- The calculation method for the new Efficient Study Delivery (ESD) measures is still to be confirmed so currently we have no data to report for this metric.
- In the East Midlands, 44% of GP practices are research active and we are on track to achieve the ambition of 45% at year-end. This is an excellent improvement since our previously reported figure of 32% (in November) and demonstrates the success of our continued engagement work and initiatives in primary care settings.
- We are also on track to achieve our local target for delivery of the Participant Research Experience Survey (PRES). This is a great achievement and reflects the hard work of many across the region. In particular, the Network would like to acknowledge the contribution of CRN Communications and Engagement Lead, Steve Clapperton, who will soon be leaving for a new post, and thank him for all his hard work over the past 4 years.

4. Risks & Issues

Risks and issues are formally reviewed through the CRN Executive Group chaired by Andrew Furlong. A risks & issues register (Appendix 3) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre. Risks and issues are recorded on the register as follows:

- Risk #063 - The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for Partner organisations; this could make it difficult to re-appoint to vacant posts on a short-term basis. To date, there have been no significant concerns raised by our Partner

organisations in relation to this risk and we continue to provide feedback and seek advice from the CRN Coordinating Centre, as required. This risk is relatively unchanged as we are awaiting an update about the future hosting arrangements. The overall risk rating remains relatively low. We will continue to monitor and reassess this risk as new information becomes available.

- Risk #064 - The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for roles within the CRN Core team (management & support staff). Similar to risk #063 above, there has been little change in this risk as we await further information about the future hosting arrangements. In other LCRNs this uncertainty has resulted in slightly above average CRN staff turnover, however, presently this is not a significant impact locally. The risk probability is still scored as possible and the impact score remains moderate, giving an overall medium risk rating. We will continue to monitor and reassess this risk as new information becomes available.
- Issue #07 - CRN EM performance for delivery of NIHR studies has decreased over the last 18 months. This could negatively affect HLOs and have a reputational impact which could lead to reduced opportunities for people to participate in research in the East Midlands. There has been a marked improvement in our performance so the priority of this issue has reduced from high to medium. The severity remains moderate. We will continue with the actions we have started, and will monitor progress of this, both in the current and following financial year.
- Issue #08 (New) - A new issue has been added in relation to current challenges associated with commercial research performance nationally. There are concerns around study set-up times, participant recruitment and the future pipeline of commercial studies entering the NIHR portfolio and being delivered across the UK. These challenges are in part a legacy from the pandemic, where a lot of research studies were disrupted. Also, the wider pressures on the NHS and reduced workforce capacity are having an impact on the ability to support commercial activity. As part of a national network, we must ensure our region steps up to respond to this national challenge. We have set out a number of response actions on the issue register, including ongoing dialogue with our partners regarding performance, a targeted funding call to support commercial activity and further exploring delivery of commercial research in primary care settings. This issue is rated as high priority with moderate severity. Further guidance on the national position and priority of this work is anticipated in the near future, and we will follow the national plan for this in the East Midlands, along with establishing our own local response.

If you have any questions about this report or require any further information, please contact:

- Elizabeth Moss, Chief Operating Officer or
- Professor Azhar Farooqi OBE, Clinical Director or
- Professor David Rowbotham, Deputy Clinical Director or
- Carl Sheppard, Host Project Manager

Supporting documentation

- Appendix 1 – CRN East Midlands Compliance with the NIHR CRN Operating Framework 2022/23
- Appendix 2 – Finance Report
- Appendix 3 – Risks & Issues Register

Appendix 1



CRN East Midlands Compliance with the NIHR CRN Operating Framework 2022/23

The CRN Operating Framework defines mandatory operational structures, processes and systems that LCRNs are required to develop and implement in order to ensure consistency across the LCRN infrastructure; and, where necessary, standards for locally defined arrangements and systems. The table below indicates the compliance of CRN East Midlands against the specific areas of the Operating Framework for 2022/23.

Operating Framework area		CRN East Midlands Compliance rating
16.	General Management	Fully Compliant
17.	Financial Management	Fully Compliant
18.	CRN Specialties	Fully Compliant
19.	Research Delivery	Fully Compliant
20.	Information and Knowledge	Fully Compliant
21.	Communications	Fully Compliant
22.	Patient and Public Involvement and Engagement (PPIE)	Fully Compliant
23.	Health & Care Services Engagement	Fully Compliant
24.	Workforce Learning and Organisational Development	Fully Compliant
25.	Business Development and Marketing	Fully Compliant
26.	National Patient Recruitment Centres	Fully Compliant

Appendix 2

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE GROUP

DATE: 7th FEBRUARY 2023 REPORT

FROM: MAHENDRA WADHWANA - HOST FINANCE LEAD & PARITA YADAV – SENIOR FINANCE BUSINESS PARTNER

SUBJECT: CRN EM FINANCE UPDATE

1. Purpose

This report provides an update on the following issues
22/23 year to date position as at quarter 3 (December) and Forecast outturn.

2. Outturn 3 22/23 Year to Date and Forecast

The table below summarises the current year to date and forecast outturn

	Annual Plan	YTD Actual Apr to December	Forecast	Variance
	£'000	£'000		£'000
Income				
NIHR Allocation	23,273	15,890	24,011	738
Expenditure				
Network Wider Team	600	362	551	(49)
Host Services	367	240	366	(1)
Management Team	975	641	946	(29)
Study Support Service (SSS) Team	508	324	504	(4)
Direct Delivery Team (DDT)	483	270	424	(59)
Clinical & SG Leads	188	113	177	(11)
Non Pay	229	205	264	35
Primary Care SSC	75	60	90	15
DDT Transformation	477	265	468	(9)
Non DDT Transformation	279	120	300	21
Public Health	77	45	77	0
Additional Funding	693	393	624	(69)
Underserved Communities	462	72	442	(20)
Partner Organisation Infrastructure	16,978	11,216	17,463	485
RSI	882	491	898	16
Excess Treatment Costs (pass through)	0	346	346	346
TBC	0	0	71	71
Total	23,273	15,161	24,011	738

Main points to note:

Overall

The plan is still on track to be delivered, with some relatively minor variances in the forecast compared with the original plan. The majority of the variances have been due to vacancies, due to staff turnover and the lead in time for new appointments. However, additional investments through planned strategic funding and supporting new funding requests have ensured forecast outturn is in line with the funding available.

Significant variances of over **£50,000** are explained below:

Income

The £738k favourable variance to plan primarily relates to notified additional income for AfC pay uplift £354k, which was not anticipated at the start of the year. The process for allocating this to partner organisations is currently underway; income has been received and will now flow out to partners by the end of the financial year. Additionally, £346k related to Excess Treatment income which will be passed on to Partner Organisations.

Direct Delivery team (DDT Central Team)

Favourable pay variance is £59k. The DDT team is undergoing a planned period of expansion, to meet increasing delivery of studies both within and outside of the NHS environment. There have been several challenges in managing and recruiting to the DDT Team - difficulties in recruiting to new posts, variation in WTE, slippage due to leavers and new starters. There is a good level of confidence in relation to this variance, with a number of posts soon to be commencing.

Additional Funding

Variance of £69k related to some delays and slippage in appointments and delays in starting the projects, or the changes in nature of the bids. As a result our intention is to continue to review and commit funding, such that any further variance due to slippage can be offset.

Partner Organisation Infrastructure

The variance here relates, as above, primarily increased pay costs for the pay settlement that will be largely offset by the additional income allocation notified on 26 October 2022 totalling £354K. This will be paid to partners organisations over the coming months.

3. Other Issues/Updates

Vacant posts and turnover

At Q2 the level of vacant posts was 5.43% (£1.27m; in Q3 this has fallen to 2.46% (£581k) representing a significant reduction. This figure is still reflective of the impact of an overstretched research and wider NHS workforce. Over half of vacancies arise within partner delivery budgets, which is a mix of ongoing turnover in delivery roles (mostly research nurses), along with some new roles due to investment through strategic funding. A number

of posts have been appointed to recently and there are still some in the process of being appointed.

Capital Funding Bid

For information, partner organisations were invited to bid for a host led NIHR capital funding call that had a limit of £5m of which up to 20% of the funding for LCRN partners. The bid included approximately £940k for partner organisations. Outcome of the bid is expected in March 23.

4. Recommendations

The CRN Executive Committee is asked to:

- Note the 22/23 year to date and forecast outturn

University Hospitals of Leicester NHS Trust
Owner of Risk Register: Executive Group

PRE-RESPONSE (INHERENT)										POST-RESPONSE (RESIDUAL)							
Risk ID	Primary category	Date raised	Risk owner	Risk Description (event)	Risk Cause and Effect	Probability	Impact	Value (Pxl)	Proximity	Response Actions	Action owner(s)	Action status	Probability	Impact	Value (Pxl)	Risk status (open or closed date)	Trend (since last reviewed)
R063	Performance	July-22	COO	The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for Partner organisations; this could make it difficult to re-appoint to vacant posts on a short-term basis.	<p>Cause: Host contract expires on 31 March 2024, some organisations may have different approaches to risk, impacting re-appointment of research delivery posts; thus vacancies in the region could increase.</p> <p>Effect: Reduced workforce capacity could impact on ability to deliver all elements of POF and Partner Contracts, this could impact research delivery differently across the region.</p>	3	3	9	April 2023	Communicate future state wrt Research Delivery Network with all partner organisation, HR and R&D teams, to instill confidence for research delivery posts to continue plans	COO and STLs	5	2	3	6	Open	Static
										Ensure posts are advertised as promptly as possible	Senior team / line managers	4					
										Any concerns from partners to be escalated to leadership team, and discussed directly with PO	STL/ Leadership team	1					
										Feedback to be provided and advice to be sought from NIHR CRN CC as required	COO/CD	4					
										Consider appointing joint posts with CRN West Midlands	COO	4					
										Once RRDN Host has been confirmed (Feb 23), begin dialogue as to providing appropriate assurances to Partners	COO	1					
R064	Performance	Nov-22	COO	The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for roles within the CRN Core team (management & support staff)	<p>Cause: Host contract expires on 31 March 2024, which could cause uncertainty around future roles due to a perceived lack of job security.</p> <p>Effect: Experienced staff could leave their posts; there could be difficulties in re-appointing to vacant posts on a short-term basis. This may impact on ability to deliver all elements of POF and Host Contract.</p>	3	3	9	April 2023	Communicate regular updates to staff in relation to future Hosting arrangements and RRDN	COO	4	3	3	9	Open	Static
										Any concerns from staff to be escalated to leadership team, and discussed directly with staff	Leadership team	4					
										Feedback to be provided and advice to be sought from NIHR CRN CC as required	COO/CD	4					
										Once RRDN Host has been confirmed (Feb 23), begin dialogue as to providing appropriate assurances to LCRN Core team staff	COO	1					

SCORING:

PROBABILITY	IMPACT				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Highly Likely (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Highly Unlikely (1)	1	2	3	4	5

- 1-5 GREEN = LOW*
- 6-11 YELLOW = MEDIUM
- 12-19 AMBER = HIGH
- 20-25 RED = EXTREME

Action RAG Status Key:

Complete	5
On Track	4
Some Delay – expected to be completed as planned	3
Significant Delay – unlikely to be completed as planned	2
Not yet commenced	1

*Only risks with an Inherent Risk of 6 or above are recorded on this Risk Register
* Risks with a scoring of 12 and above should be monitored and escalated

CRN East Midlands Issues Register

Date last reviewed: 7.2.2023

Issue ID	Issue Type	Date Raised	Owner	Description	Severity	Priority	Actions	Action Owners	Action status	Issue status
I07	Performance	Oct-22	COO	<p>CRN EM performance for delivery of NIHR studies has decreased over the last 18 months. This could negatively affect HLOs and have a reputational impact which could lead to reduced opportunities for people to participate in research in the East Midlands.</p> <p>Cause: Workforce fatigue & capacity, reduction in high recruiting studies, service pressures, remaining Covid research activity (e.g. follow up), grants “gap” resulting in fewer new studies entering the Portfolio.</p> <p>Effect: Reduction in overall volume of participants recruited into NIHR studies, not meeting expected contribution to 'Effective Study Delivery' HLO and negative reputational impact. Potential impact on future research activity in the region.</p>	Moderate	Medium	Meet with Partner R&D teams to review performance	STLs	4	Open
							Undertake SWOT analysis to understand strengths & weaknesses of regional research portfolio and opportunities for improvements	IOM/RDMs/ROMs	5	
							Identify 3-4 workstreams with T&F groups to address specific performance areas	COO	4	
							Share lists of existing studies which are performing better in other regions, but are open in our region at present	IOM	5	
							Develop app with performance data and share with POs to help review ongoing performance, and use as management tool	IOM	5	
							Discuss performance as part of recently re-instated annual PO review meetings	COO/DCOO/ STL	4	
I08	Services	Jan-23	COO	<p>There are challenges at a national level with respect to commercial research activity in the UK, due to a range of reasons including pressures on the NHS & reduced workforce capacity. This is having an impact on study set-up times, participant recruitment and the future pipeline of commercial studies. This could have a reputational impact on the UK for attracting future commercial research. This is a concern as the East Midlands is part of a national network, and needs to ensure our part is played in improving this situation.</p>	Moderate	High	Meet with Partner R&D teams to review performance	STLs	4	Open (NEW)
							Initiated a Targeted Funding call in December - focused on commercial study set-up	COO/IOM	4	
							Explore primary care settings to increase delivery of commercial studies	IOM/Div 2 RDM	4	
							Support national Moderna vaccine UK deal, when it commences	IOM/STLs	1	
							Discuss performance as part of recently re-instated annual PO review meetings	COO/DCOO/ STL	4	

Key

Severity	Priority
Minor	Low
Moderate	Medium
Major	High
Catastrophic	Critical

Action RAG Status Key:

Complete	5
On Track	4
Some Delay – expected to be completed as planned	3
Significant Delay – unlikely to be completed as planned	2
Not yet commenced	1