

CRN East Midlands Quarterly Board Update

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong

Trust Board paper G

Purpose of report:

This paper is for:	Description	Select (X)
Decision	To formally receive a report and approve its recommendations OR a particular course of action	
Discussion	To discuss, in depth, a report noting its implications without formally approving a recommendation or action	
Assurance	To assure the Board that systems and processes are in place, or to advise a gap along with treatment plan	X
Noting	For noting without the need for discussion	

Previous consideration:

Meeting	Date	Please clarify the purpose of the paper to that meeting using the categories above
CMG Board (specify which CMG)		
Executive Board		
Trust Board Committee		
Trust Board		

This report was reviewed by CRN East Midlands Executive Group on 16 March 2021.

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). 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 quarterly update on the recent progress and current priorities of CRN East Midlands. Appended to this report is our current risks & issues register. Please note, at the request of the Trust Board Chairman, this report has been deferred from the April Trust Board to the May Trust Board meeting.

Questions

1. Since our January report, what have been the key areas of progress for CRN East Midlands and do the Board require any further information or assurance in relation to this?
2. What are the main risks and issues currently affecting CRN East Midlands and does this paper provide sufficient assurance as to mitigating actions?

Conclusion

1. This report provides an update on the recent progress of CRN East Midlands in supporting COVID-19 Urgent Public Health (UPH) research, including vaccine clinical trials; an update on recovery and future planning (including expansion of our research portfolio); our provisional year-end performance against the CRN Performance Management Standards and an update on our recent audit. The report also acknowledges the contribution of our staff to the wider pandemic response over recent months.
2. Our risks and issues register is attached at Appendix 1 to the report. The risk related to our ability to deliver specific COVID-19 protocols, considered as urgent public health (UPH) studies has been closed as this never materialised and our contribution to these studies has been very strong. The risk that we will not deliver against some of the new NIHR Performance Standards has been closed at year-end. Although we did not meet one of the measures, the impact of this is insignificant as we were not formally performance managed against these for 2020/21. A new risk has been added around the risk of a potential underspend for CRN East Midlands budget for 2021/22, however, this is being well managed and the overall risk score is currently quite low. We will be developing our plans to support the recovery of the NIHR portfolio over the coming weeks and will report any new risks or emerging issues to the Board, along with final year-end performance data in our next report in July 2021.

Input Sought

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

For Reference

This report relates to the following UHL quality and supporting priorities:

1. Quality priorities

Safe, surgery and procedures	Not applicable
Safely and timely discharge	Not applicable
Improved Cancer pathways	Not applicable
Streamlined emergency care	Not applicable
Better care pathways	Not applicable
Ward accreditation	Not applicable

2. Supporting priorities:

People strategy implementation	Not applicable
Estate investment and reconfiguration	Not applicable
e-Hospital	Not applicable
More embedded research	Yes
Better corporate services	Not applicable
Quality strategy development	Not applicable

3. Equality Impact Assessment and Patient and Public Involvement considerations:

- What was the outcome of your Equality Impact Assessment (EIA)? N/A - This report does not relate to a business case/business decision making process.
- Briefly describe the Patient and Public Involvement (PPI) activities undertaken in relation to this report, or confirm that none were required - N/A
- How did the outcome of the EIA influence your Patient and Public Involvement ? - N/A as this report provides an update on the CRN and does not relate to a UHL business case/decision making.
- If an EIA was not carried out, what was the rationale for this decision?

4. Risk and Assurance**Risk Reference:**

Does this paper reference a risk event?	Select (X)	Risk Description:
Strategic: Does this link to a Principal Risk on the BAF?	N/A	
Organisational: Does this link to an Operational/Corporate Risk on Datix Register	N/A	
New Risk identified in paper: What type and description?		
None		

5. Scheduled date for the **next paper** on this topic: July 2021
6. Executive Summaries should not exceed **5 sides** My paper does comply

CRN East Midlands - Quarterly Board Update, 28 April 2021

1. Introduction

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 and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

This report provides an update on: the delivery of Urgent Public Health (COVID-19) research; research recovery and future planning (including expansion of our research portfolio); CRN performance standards (provisional year-end figures); risks/issues and other Host related matters. Appended to the report is our current risk register. We would also like to make an acknowledgement to the contribution of our staff to the wider pandemic response over recent months. This report was reviewed by the CRN East Midlands Executive Group in March 2021 and submitted to UHL Trust Board for review in May 2021. Please note, at the request of the Trust Board Chairman, this report has been deferred from the April Trust Board to the May Trust Board meeting. Our next Board report, due in July 2021, will include confirmed, final year-end data for 2020/21.

2. Urgent Public Health (COVID-19) research including COVID-19 vaccine research

As of 28 April, we have supported the delivery of 41 Urgent Public Health (UPH) research studies, which have in total, recruited around 81,000 participants in the East Midlands; across the UK, just over 1,000,000 participants have been recruited into these UPH studies.

We are continuing to support the delivery of COVID-19 vaccine research studies in the East Midlands with collaboration across a range of healthcare systems. In Nottinghamshire, the Cripps GP Practice has recently completed recruitment to the Com-Cov (Oxford) study, which is the world's first COVID-19 vaccine study researching alternating doses of two approved vaccines. Nottingham University Hospitals NHS Trust has been selected for the Valneva commercial vaccine trial, which is planned to open at the end of April. In Leicestershire, the NIHR Patient Recruitment Centre (PRC) is continuing to deliver the ENSEMBLE-2 commercial vaccine trial (Janssen) and is the second highest recruiting site in the UK. In Northamptonshire, a large primary care site, Lakeside is supporting the Novavax crossover study to ensure patients who initially received a placebo now receive an active vaccine. Our Derbyshire hub is due to open its first commercial vaccine trial (Medicago) imminently. We are supporting our Lincolnshire hub in preparation for the next wave of vaccine studies (e.g. studies with multiple boosters, comparator studies, vaccines for new variants, specific patient groups etc).

3. Recovery, Resilience and Growth

With the intense COVID-19 pressures on the NHS over recent months, this has of course impacted upon capacity to deliver research, the DHSC Restart programme has been renamed to reflect that it is now focusing on Resilience, Recovery and Growth (RRG). This recognises that the pandemic has not just placed a one-off need for research to be restarted as pressures ease, but for a continuous process of making research more resilient to such pressures, recovering from times when research has been paused or recruitment slowed, growing research and the strength of the research system as a whole.

This system-wide RRG programme has been established to bring together the key partners across the clinical research ecosystem to ensure the UK is well-positioned to take a coordinated national approach to achieving the recovery of the UK's clinical research delivery and restore a full, diverse and active research portfolio as soon as practicable. In the East Midlands we are working with a wide range of stakeholders, both to restore our research activity to pre-pandemic levels and to grow this for the future.

4. Budget and planning for 2021/22

To aid us in delivering this growth, we have recently been advised of additional CRN funding for 2021/22. Following the announcement of the Comprehensive Spending Review, DHSC has confirmed an additional £30m of nationally recurrent funding to be provided to the LCRNs from 2021/22. An allocation methodology for this funding has been agreed, and of that the East Midlands, will receive c.£2 Million.

This funding has been allocated for three areas of focus:

1. To alleviate known cost pressures (due to flat/falling budgets over the past 5 years), c.£550k and has been allocated to partners based on current proportional share of the main CRN budget.
2. To sure up the UPH portfolio such that it continues to deliver well and to focus on non-UPH studies as these re-start and we see growth in these areas, c.£740k, to date 30% is committed and the rest is going through a review process.
3. To build a targeted workforce to support emerging areas including social care, primary care & community, including care homes, LA services etc., £909k, plans have recently been submitted to the NIHR CRN CC.

This additional funding gives us increased scope to support key regional priorities and new areas of growth (see section 5 below).

Due to a delayed deadline, pending DHSC sign-off of key objectives, we are currently preparing the content for our 2021/22 Annual Plan, which sets out the strategic direction for the LCRN for the reporting year. The submission deadline is 28 May 2021, our intention will be to submit our Annual Plan to the Trust Board for approval in due course.

5. Expansion of CRN East Midlands research portfolio

Prior to the pandemic, we reported to the Board our plans to expand our research portfolio into areas outside of traditional NHS settings, such as social care and public health. Some of our plans have been on pause over the last year, however, we are now keen to move forward with this. Notably, we have recently appointed two social care posts to support the expansion of social care research and we have appointed to a public health research post (with a further post to follow) as part of a national NIHR initiative. The NIHR has published their new primary care research strategy and we anticipate further focus will be needed here as the landscape continues to evolve. It is recognised these settings will be of even greater priority for research given some of the wider impacts of the pandemic on society. The ongoing expansion of our portfolio will require additional resources and we are planning appropriate management arrangements to support this.

6. CRN Performance Standards

As we have reported to the Board previously, our performance priorities for this year have been incorporated into a set of slimmed down Performance Management Standards. These are ambitions rather than targets. Our provisional year-end performance is presented in the following table. We will confirm finalised year-end data in our next report.

Objective	Ambition	Year-end East Midlands Performance
New Commercial Studies recruiting to time and target	70%	100%
Provider Participation in Research	(A) NHS Trusts - 100%	100%
	(B) Commercial Activity in NHS Trusts - 70%	56%
	(C) Research Activity at GP Practices - 45%	57%
	(D) Non-NHS Organisation Active Research Sites - 2250	491 (National measure only)
Research Participant Experience	12,000 (National) 400 (East Midlands)	1,177
Urgent Public Health Study Set Up	9 Days	2 days
Restart of studies paused due to the pandemic	80%	84%

7. Risks & Issues

Risks and issues are formally reviewed through the CRN Executive Group chaired by Andrew Furlong. A risks & issues register (Appendix 1) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC).

Risks and issues are recorded on the register as follows:

- Risk #55 - Significant staff absence and/or diversion of staffing resource across the East Midlands CRN funded workforce due to COVID-19 will impact on ability to deliver specific COVID-19 protocols, considered as urgent public health (UPH) studies. Since this risk was added to the register at the onset of the pandemic, the probability has reduced significantly and this has now been closed on the register. This risk was very well managed and the East Midlands have delivered a fantastic contribution to UPH studies.
- Risk #58 - We will not deliver against NIHR Performance Standards on "Provider Participation" measure B (Commercial Activity in NHS Trusts) and "Restart of paused studies due to COVID-19". This risk has been closed at year-end. Unfortunately we did not meet these measures, however, the impact is insignificant as we were not formally performance managed against these for 2020/21. Previously, this risk included a concern that we would not achieve Provider Participation measure C (Research Activity at GP Practices), however, we have met this target, so this element has been removed.
- Risk #59 - A new risk has been added relating to the risk of a potential underspend for CRN East Midlands budget for 2021/22 due to a significant uplift in funding. The risk probability is currently scored as unlikely as a number of actions have been taken to plan and manage the additional funding. The risk impact is scored as moderate meaning the overall risk score is relatively low.
- Currently there are no open issues on our issue register.

8. Host Related Matters

We have recently received the final report from the host auditors (PwC), in relation to the audit which was conducted between November 2020 and January 2021. The report was classified as low risk overall, with four findings (one medium and three low risk). This will be submitted to the Host Audit Committee for review and will be considered through the CRN Executive Group and Finance Working Group. An action plan has been prepared to address the findings and meet any recommendations or actions. This report and associated action plan will also be shared with the NIHR CRN Coordinating Centre.

We would also like to highlight to the Board the wider contribution that our hosted staff have made in supporting the response to the pandemic over recent months, stepping away from their normal duties. A number of our clinically trained colleagues responded to requests for staffing support and have been redeployed to ITU at UHL to support in caring for COVID-19 patients. Additionally, some of our non-clinical staff worked within R&D teams at our partner organisations to help free up their delivery/support staff to deliver COVID research studies. In addition, members of our team were involved in the capacity as Co-Business Lead (CRN East Midlands Chief Operating Officer) and Project Manager in leading and supporting the UK COVID-19 Vaccine Research Delivery Programme (June 2020-Jan 2021), which has had a significant impact on the global research response to the pandemic. During this period, the CRN East Midlands Clinical Director also significantly increased his contribution to the leadership of the LCRN, through moving towards a much closer to full time working arrangement. We are proud of the wider support and contributions the CRN team has made.

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

- Elizabeth Moss, Chief Operating Officer, elizabeth.moss@nhr.ac.uk or
- Professor David Rowbotham, Clinical Director, david.rowbotham@nhr.ac.uk or
- Carl Sheppard, Host Project Manager, carl.sheppard@nhr.ac.uk

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)
R055	Services	Mar-20	COO	Significant staff absence and/or diversion of staffing resource across the East Midlands CRN funded workforce due to COVID-19 will impact on ability to deliver specific COVID-19 protocols, considered as urgent public health studies	<p>Cause: COVID-19 pandemic will lead to staff absence (illness, self-isolation or caring for family members) or other reduced capacity in the workforce due to movement to clinical & supporting duties</p> <p>Effect: Unable to deliver priority Public Health COVID-19 research studies in all necessary sites</p>	4	4	16	Mar-20	Communicate regular updates and advice to core team staff and partners	COO / Comms Lead	4	2	4	8	Closed 3.3.21	Decreased
										Ensure national and Host guidance is followed	COO / all	4					
										Implement and follow CRNEM Urgent Public Health Plan	COO, RDM (D6)	4					
										Report any disrupted research studies to CRNCC	COO / all	5					
										Established regional vaccine group to support delivery of UPH vaccine studies with broad stakeholder representation. Group informs regional planning approach as a collective, with strong partner engagement.	IOM / BDOM	5					
										Regional workforce planning for vaccines, leadership through the above group	WFD Lead/ BDOM	5					
										Successful in application to national VTF funding for vaccines research studies	DCOO	5					
										Continued close communication with sites to understand workforce issues and support where needed	IOM / BDOM	4					
Review of UPH study performance through study leads	DCOO	4															
R058	Performance	Nov-20	DCOO	<p>CRN EM will not deliver against NIHR Performance Standards on:</p> <ul style="list-style-type: none"> Provider Participation measure (B) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies (ambition 70%) Restart of paused studies due to COVID-19 	<p>Cause: Impact of COVID-19 - prioritisation of UPH studies, low number of suitable studies for Healthcare, Partnership & Community Trusts, challenging studies to set-up at some sites. Closure of high recruiting study in primary care.</p> <p>Effect: We are not formally performance managed against these objectives this year, however, the effect of not meeting this is that the lack of pipeline commercial studies would impact on the availability of novel treatments for patients across the region. Delays in restarting studies could impact on study outcomes and the overall delivery of the portfolio.</p>	5	2	10	Mar-21	Increase knowledge of new studies via the Expression of Interest Website	Divisional Teams	4	5	1	5	Closed 23.4.21	Decreased
										Supporting partners to identify commercial studies which could contribute to their pipeline for 2021/22	Divisional Teams/ Senior Team Link	4					
										Support collaborative working between partner organisations, such as community Trusts and Acute Trusts to support the delivery of studies.	Divisional Teams/ IOM	4					
R059	Financial	Mar-21	COO	There is a risk of an underspend for CRN East Midlands' budget for 2021/22 due to a significant uplift	<p>Cause: Increased funding of c.£2.2 million (over 10%) to CRN EM annual budget for 2021/22.</p> <p>Effect: Budget surplus at end of year, which means funding intended for the region does not get sufficiently well invested to offer more research to our patients. Also this could impact on future funding if there is a perception we do not need the funding provided.</p>	3	3	9	Mar-22	Robust financial monitoring and reporting on a monthly basis, with oversight from Finance Working Group	DCOO/ FWG	4	2	3	6	Open	New
										Three separate funding streams, 1. Cost pressure funding (£550k), as at 26/04/21, all partner cost pressure is allocated and committed, thus reducing risk of u/spend	STLs	5					
										Three separate funding streams 2. Targeted funding for UPH/RRG (£740k), call opened to allocate funding promptly, as at 26/04/21 c.30% allocated, thus reducing risk	Leadership Team	4					
										Three separate funding streams 3. Transforming research (£909k) required plans submitted to NIHR CC, approved, beginning to action plans, funding not yet allocated	COO	4					
										Early identification of areas of underspend with timely targeting and redistribution of funding	COO/ Senior Team	4					

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

*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

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

CRN East Midlands Issues Register

Currently there are no open issues on our issue register.