

CRN East Midlands Quarterly Board Report

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		

It has been agreed that it is no longer a requirement for this report to be presented to the Executive Performance Board (EPB) unless there are any specific issues that require EPB consideration. This report has previously been considered by CRN East Midlands Executive Group.

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. The purpose of this regular update paper is to summarise our performance, major achievements, challenges and actions. This report has been considered by CRN East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive Lead for the CRN) in December. Appended to this written report is a dashboard displaying performance figures, Executive Group finance report and current risk register.

Questions

1. In order to provide assurance to the Host, what are the major achievements and challenges of the Network, and performance from 7 September 2019 up to 25 November 2019?
2. What are the current risks affecting the LCRN and are the Board assured of measures in place to address these?

Conclusion

1. Our performance across the HLOs remains very mixed. We are performing strongly for HLO2B (non-commercial study recruitment to time & target) and HLO8 (Patient Research Experience Survey responses), and we are the top regional Network for contribution to these objectives. Our primary concern remains our performance for the commercial HLOs. Unfortunately, we are forecasting that we will not achieve our targets for HLO1B (commercial study recruitment) and HLO6B (Trusts recruiting to commercial studies) this year, however, we are taking a number of actions to ensure we can finish the year in as strong a position as possible. Our primary focus is on HLO2A (commercial study recruitment to time & target), which will have an impact on our future budget and we have recently stepped up our activities to manage this.
2. In relation to current challenges and risks, the HR issues with NUH employed members of the core team have improved following some further support from HR. The delays in the payment of invoices have also improved and we will continue to monitor this for the remainder of the financial year. The risk around visibility of performance data still needs to be monitored closely and this remains a medium risk. The risks in relation to HLOs are being addressed with mitigating action plans in place. A new risk has been added that we may receive a budget reduction for 2020-21 so we are taking early actions to prepare for this possibility.

Input Sought

We would welcome the Trust Board's input regarding:

- (i) Review our performance and progress to date providing any comments or feedback you might have.
- (ii) Review our current challenges, risks and mitigating actions, providing 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
- If an EIA was not carried out, what was the rationale for this decision? - N/A as this report provides an update on the performance of the CRN and does not relate to a UHL business case/decision making.

4. Risk and Assurance

Risk Reference:

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

- 5. Scheduled date for the **next paper** on this topic: April 2020
- 6. Executive Summaries should not exceed **5 sides** My paper does comply

CRN East Midlands Quarterly Board Report

Progress, Challenges and Performance

DATE: 4 December 2019

AUTHORS: Elizabeth Moss - Chief Operating Officer & Carl Sheppard - Project Manager

EXECUTIVE EDITOR: Professor David Rowbotham - Clinical Director

1. INTRODUCTION

- 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 and Social Care (DHSC) to take overall responsibility for the monitoring of governance and performance of the Network.
- 1.2 This report provides a summary of 2019-20 year to date performance for CRN East Midlands and an update on current challenges and risks. Appended to this written report is a dashboard displaying performance figures, Executive Group finance report and current risk register.
- 1.3 This report will be taken to the CRN East Midlands Executive Group in December 2019. It will then be submitted to UHL Trust Board for review in January 2020. It has been agreed that it is no longer a requirement for this report to be presented to UHL Executive Performance Board (EPB) unless there are any specific issues that require EPB consideration.

2. CURRENT PERFORMANCE 2019-20

- 2.1 Appendix 1 presents data extracted on 25 November 2019 reflecting our year to date performance for 2019-20. This shows the various NIHR High Level Objectives (HLOs) which the CRN is managed against. We wish to highlight the following for the Board's specific attention:
 - i. Our overall participant recruitment (HLO1A) remains at 94% (as previously reported) of our year to date target with 30,401 participants recruited. Our overall recruitment figure is lower compared to this time last year, however, based on a reduced portfolio pipeline for 2019-20 we agreed a target (54,000) that is lower than last year's total outturn. This is the target our performance will be measured against and linked to our future budget. We are not unduly concerned about our present position but will continue to monitor performance closely to ensure this is not the beginning of a downward trend in future years. Based on our current forecasting, we are reasonably confident we will achieve this HLO metric by year end.
 - ii. HLO1B measures participant recruitment into commercial studies. We are currently at 54% (previously 66%) of our year to date target with 834 participants recruited against a target of 2,044; we are in 12th position out of 15 regional networks. This new HLO was highlighted as a concern in our September report, since then we have instigated some measures to address this, however, we remain concerned as performance has dropped further. As previously reported, the attainment of this HLO relies heavily on a small number of high recruiting studies, of which only a few

are open in the East Midlands. Despite significant efforts, it has been very difficult to identify any suitable high recruiting studies that could be opened at new sites in-year, although we continue to explore opportunities that arise. We have been looking at ways to maximise recruitment into existing studies using our Research Support Team, although there have been some challenges around capacity in the short term. We are also working with partners prospectively to ensure studies which may have previously been designated as non-commercial, but for a number of reasons have the ability to be recorded as commercial, are indeed badged in this way in due course. This will increase the activity attributed to this metric in the future. Moreover, we have seen an increase in the number of new companies approaching the Network and we are engaging to ensure upcoming studies are included on the NIHR Portfolio. Unfortunately, we do not expect to meet our target at year end, however, several of our ongoing activities in response to this new HLO should put us in a stronger position to attain this next year. At present, the performance of this HLO does not directly impact upon our future income, therefore our primary focus for this year is to achieve HLO2A & B.

- iii. For the proportion of closed commercial studies recruiting to time and target (HLO2A), we are currently at 78% (previously 79%) against a target of 80% and in fifth position out of the 15 regional networks. Although this figure has remained relatively stable, we are mindful the performance may drop as there are a large number of open studies still to close this year. We have taken steps to address this, and are working closely with our partners, in particular NUH & UHL, where there are a significant number of commercial studies. One key area where we have made progress is working with Oncology departments to address performance. This joint working will support better delivery of commercial studies in Oncology on an ongoing basis, although may take a little time to be borne out in the data due to study duration. We have also been further engaging with Clinical Specialty Leads earlier in the study life cycle process and are working more closely with the CRN Coordinating Centre to manage underperforming studies. Based on our forecasting model, we think that currently we will fall slightly short of the 80% target at year end. Performance in this metric does have an impact on our future budget, and as such we will continue to give this significant attention; however, it is not a pass/fail metric, but is also linked to study volumes, and in the region we do have a significant commercial portfolio share which will assist in the budget calculation.
- iv. For the proportion of closed non-commercial studies recruiting to time and target, where the lead site is in the East Midlands (HLO2B), we remain at 100% against a target of 80% and in first place out of the 15 LCRNs. In our previous report, we expressed some concerns our performance could fall below target. Whilst we are still expecting our performance to drop, our latest forecast is predicting we should be close to achieving the target at year end. As with HLO2A, we are continuing to hold regular review meetings and are working with our Partner organisations closely to

monitor performance. We are also conducting regular monitoring of data quality to ensure this is as reliable as possible (see risk #48).

- v. The next group of HLOs (HLO6) are intended to measure local engagement across the regional health economy. From this point forward, none of these are linked to future budget.
- We previously reported that we achieved our target for the proportion of NHS Trusts recruiting into NIHR studies (HLO6A) with 100% of Trusts recruiting.
 - For the proportion of NHS Trusts recruiting into commercial studies (HLO6B), we remain at 56% (as previously reported) against a year end target of 70%. This objective is proving difficult this year, primarily due to the low number of suitable studies (particularly in Mental Health & Dementia) for our Healthcare and Community Trusts and some internal restructuring within these organisations. We are working with our Dementia Specialty Lead and the national Coordinating Centre to identify new studies which could be suitable for sites within our region. We have recently set up commercial working groups to support collaboration between some of our Partner organisations. This aims to enable the sharing of infrastructure across different organisations to deliver studies that may otherwise have not been feasible. We are forecasting that it is unlikely we will achieve this objective at year end.
 - The proportion of GP sites recruiting into NIHR studies (HLO6C) is currently at 43% (previously 37%) against a target of 45%. We are confident we will meet this target before year end.
 - The new objective for the number of non-NHS sites recruiting into NIHR CRN Portfolio studies (HLO6D) is being measured nationally so we are not formally reporting any local data for this metric.
- vi. For recruitment into Dementia and Neurodegenerative studies (HLO7), we are currently at 126% (previously 128%) of our year to date target with 980 participants recruited against a year end target of 1,300. Whilst our performance is strong to date, we are still expecting our recruitment rate to drop due to the imminent closure of two high recruiting studies. We continue to scope potential new studies to replace these, although the pipeline is quite small at present. We are also working with our Dementia Specialty Lead to grow our own investigators who could develop studies in the future. Based on our forecasting, we still have modest confidence that we will achieve our target by year end.
- vii. HLO8 measures the number of NIHR CRN Portfolio study participants responding to the Patient Research Experience Survey. We have performed very well for this new objective and have received 1,368 responses, already surpassing our year end target

of 1,000. Based on the national data cut at the end of October we are ranked as the top regional Network for this new HLO, and have recently received very positive feedback from the NIHR CRN Coordinating Centre.

viii. HLO9A & 9B are objectives to reduce study site set-up times for NIHR CRN Portfolio studies; these have replaced HLO4&5. For commercial studies (9A), we are currently at 65 days (previously 50 days) against a target of 80 days so we remain well within the target. For non-commercial studies (9B), we are currently at 69 days (previously 57 days) against a target of 62 days, slipping slightly below the expected target. There are two main issues that have affected this. The first relates to data discrepancies as CCG performance has been included in this metric, which should have been excluded, and will be in final year end data. We would expect the figure to improve once this has been resolved. Secondly, there is one site (Nottinghamshire Healthcare NHS Foundation Trust) in the region that has a number of studies which have exceeded the expected set up time significantly (over 100 days) and the SSS Operations Manager is working with this organisation to see what support is required to get studies opened in a more timely fashion. There have been some resource issues at this organisation which have now been resolved but continue to have an impact on workload.

2.2 Our latest Executive Group Finance Report is included at Appendix 2. This outlines our 2019-20 year to date financial position and forecast, and shows that we expect to end the year in a balanced position. The report highlights a recent finance engagement event held with all CRN Partner Organisations. We are also pleased to report there has been a significant improvement in the timely payments to LCRN stakeholders by UHL as the Host for CRN East Midlands. Reporting shows that 96% (53/55) of invoices were paid on time in October and 100% (25/25) were paid on time in November. We will continue the monitoring process to ensure performance is maintained. Further detail is included in the Finance Report and an update on the risk score is provided in Section 4 below (risk #46).

3. PUMP PRIMING SOCIAL CARE RESEARCH

3.1 When it was established, the remit of the NIHR Clinical Research Network (CRN) was to support commercial and non-commercial health care research. Since 2018 this remit has expanded to include wider public health research outside traditional NHS settings and more recently social care research. The Department for Health and Social Care (DHSC) have confirmed a one off, non-recurrent investment of £15,000 to be used to support the expansion of the NIHR CRN Portfolio for social care research (ongoing, planned, and anticipated research). All local Networks are expected to use the funding this financial year to undertake scoping and preparedness activities to support this work.

The aim for this project is to gain further knowledge of the social care environment in the East Midlands and an understanding of the support needs to participate in social care research. We are undertaking some work with collaborators across the region to ensure we are connected with social care researchers (including early career researchers), Local Authorities and have policies and plans in place to facilitate social care research at local level. We will also look to connect with national initiatives as they arise, share practice and achieve regional coherence in our approach for social care research in the NIHR CRN.

We will keep the Board informed of any significant developments as to how this work progresses over the coming months.

4. RISK REGISTER & CURRENT CHALLENGES

- 4.1 Risks and issues are discussed through the CRN Executive Group chaired by Andrew Furlong. A risk register (Appendix 3) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC).
- 4.2 Risks are recorded on the register as follows:
- Risk #45 - Ongoing issues with NUH employed members of the core team which have not been well supported by NUH HR. Further meetings have taken place with HR representatives from UHL (in a Hosting, supportive capacity) and NUH and there have been some improvements to how this risk is being managed. The probability of this risk has reduced from highly likely to possible and the overall risk score has reduced from high to medium. We will continue to monitor this closely with further meetings planned. We would like to thank UHL HR team (specifically Tina Larder and Smita Ganatra) for the support provided to the CRN.
 - Risk #46 - Ongoing delays to payment of invoices from suppliers and partners could negatively impact the reputation of CRN & UHL, and impact on the delivery of some contractual elements. Since the last report, we have seen further improvements in the proportion of invoices being paid on time (further detail is included in the Finance Report at Appendix 2). The probability of this risk has reduced from likely to possible and the overall risk score is now relatively low. We will continue to monitor this and report to the Host Trust Board in our next quarterly update.
 - Risk #47 - CRN EM will not deliver against HLO7 target for 2019-20. Our recruitment to date remains strong, however, it is still possible we may not achieve our target at year end. The overall risk score is unchanged and this remains relatively low risk overall (as detailed above in section 2.1 of this report).

- Risk #48 - Lack of visibility of performance data for all studies making it difficult to manage key HLOs. This remains a concern nationally as there are still some issues around the data accuracy, however, locally we are managing this very well. We have a reporting dashboard in place and will continue to check verified data closely for the remainder of the year, while the new process is embedded. Currently, the risk score is unchanged as a medium risk.
- Risk #49 - CRN EM will not deliver against HLO1B target for 2019-20. The risk probability has increased to highly likely as we do not think we will achieve the target this year (see above section 2.1 of this report).
- Risk #50, #51 and #52, correspond to concerns that we may not achieve our targets for HLO2A, 2B and 6B respectively. These risk scores remain unchanged and updated actions are recorded on the risk register (also detailed above in section 2.1).
- Risk #53 - Potential reduction to CRN East Midlands budget for 2020-21. This has been added as a new risk due to uncertainty over the future national budget, some changes to the national model and how this will be implemented, as well as changes to employer pension contributions, which bring additional cost pressures. We are modelling a range of budget scenarios to aid planning and forecasting. We are communicating regularly with our Partner organisations and have provided early notification regarding a potential budget reduction. Currently, the risk probability is possible with moderate impact.

5. SUMMARY

- 5.1 Our performance across the HLOs remains very mixed. We are performing strongly for HLO2B, and HLO8 and we are the top regional Network for contribution to these objectives. Our primary concern remains our performance for the commercial HLOs. Unfortunately, we are forecasting that we will not achieve our targets for HLO1B and HLO6B this year, however, we are taking a number of actions to ensure we can finish the year in as strong a position as possible. Our primary focus is on HLO2A, which will have an impact on our future budget and we have recently stepped up our activities to manage this.
- 5.2 In relation to current challenges and risks, the HR issues with NUH employed members of the core team have improved following some further support from HR. The delays in the payment of invoices have also improved and we will continue to monitor this for the remainder of the financial year before making a decision to close this risk. The risk around visibility of performance data still needs to be monitored closely and this remains a medium risk. The risks in relation to HLOs are being addressed with mitigating action plans in place. A new risk has been added that we may receive a budget reduction for 2020-21 so we are taking early actions to prepare for this possibility.

6. RECOMMENDATIONS

6.1 UHL Trust Board is asked to:

- (i) Review our performance and progress to date providing any comments or feedback you might have.
- (ii) Review our current challenges, risks and mitigating actions, providing any comments or feedback you might have.

Appendix 1 - HLO Dashboard



2019/20 High Level Objectives

Data cut on: Monday 25 November 2019 - (Next planned update: Monday 2 December 2019)

HLO	Objective	Metric	Goal	YTD Achievement	YTD Performance / Year End RAG Assurance
HLO1a	Deliver significant levels of participation in NIHR CRN Portfolio studies	Overall number of participants recruited to NIHR CRN Portfolio studies	54,000	30,401	▼ -6%
HLO1b		Number of participants recruited to commercial contract NIHR CRN Portfolio studies (Subset of HLO1a)	2,044	834	▼ -46%
HLO2a	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	Proportion of commercial studies achieving or surpassing their recruitment target during their planned recruitment period	80%	78%	▼ -2%
HLO2b		Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	80%	100%	▲ 20%
HLO6a	Widen participation in research by enabling the involvement of a range of health and social care providers	Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	100%	100%	-
HLO6b		Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial studies	70%	56%	▼ -14%
HLO6c		Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	45%	43%	▼ -2%
HLO6d		Number of non-NHS sites recruiting into NIHR CRN Portfolio studies	-	244	-
HLO7	Deliver significant levels of participation in NIHR CRN Portfolio Dementias and Neurodegeneration	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR	1,300	980	▲ 26%
HLO8	Demonstrate to people taking part in health and social care research studies that their contribution is valued	Number of NIHR CRN Portfolio study participants responding to the Research Participant Experience Survey	1,000	1,368	207%
HLO9a	Reduce study site set-up times for NIHR CRN Portfolio studies by 5%	Median study site set-up time for commercial studies	80 days	65 days	-
HLO9b		Median study site set-up time for non-commercial studies	62 days	69 days	-

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE COMMITTEE

DATE: 4th DECEMBER 2019

REPORT FROM: MARTIN MAYNES – HOST FINANCE LEAD

SUBJECT: CRN EM FINANCE UPDATE

1. Purpose

This report provides an update on the following issues:

- 19/20 financial forecast
- Accounts Payable

2 2019/20 Finance Forecast

The table below summarises the 19/20 year to date and forecast position to 31st March 2020.

	Annual Plan	April to October	Forecast Expenditure	Forecast Variance
	£'000	£'000	£'000	£'000
Income				
NIHR Allocation	20,979	11,945	21,104	126
Expenditure				
Network Wider Team	541	299	513	-27
Host Services	325	186	325	0
Management Team	827	462	803	-24
Study Support Service (SSS) Team	578	265	467	-111
Research Study Team (RST)	555	181	390	-166
Clinical & SG Leads	143	50	101	-42
Research Site Initiative	664	387	664	0
Primary Care Service Support Costs	200	117	200	0
NON - Primary Care SSC	200	117	200	0
Partner Organisation Infrastructure	16,569	9,559	16,598	29
ETC	0	125	125	125
CRN EM Non Pay Non Staff	194	105	205	11
Innovation Fund	400	93	477	77
Vacancy Factor	-218		0	218
To be allocated			36	36
Total	20,978	11,945	21,104	126

The main points to note are as follows.

Income

The favourable variance is due to receiving more income for ETC QTR 4 than accrued at the year end. Accrual information was provided by NHS England for ETC payment. Additional income received was passed onto to relevant partners as shown in the table.

Network Wider Team

There is a favourable pay variance of £27k due to an Information Administrator leaving the post. This post is not being replaced. Also, the Business Support officer successfully obtained a post within SSS team. This post is being replaced but there is

slippage as a replacement candidate started and then left within a short period of time. In addition, there is a non pay favourable variance of £5k due to savings in overheads for vacant posts.

Management Team

There is a favourable forecast variance due to non pay underspend against budget.

Study Support Team

There is a favourable pay variance is due to starters and leavers within SSS Team. Also Network related ETC funds have not been fully utilised.

Research Study Team

Overall underspend is due to facing several challenges in expanding the RST team, i.e. sourcing and negotiating accommodation for posts, recruiting the right candidates, readvertising vacancies etc.

Clinical & SG Leads

The favourable pay variance with associated non pay and overhead is £42k. There are also savings related to slippage in recruiting to posts.

Partner Organisation Infrastructure

Adverse variance is due to:

Infrastructure budget is overspent by £13k as net effect of budget allocated to Extracted Organisations not materialising at an anticipated level and allocating additional funding to some partners.

Primary Care - Based on the budget setting, currently there is a vacancy factor of £47k as net effect of staff leaving and additional allocation for Super Practice pilot scheme.

Network budget is underspent by £30k largely due to leavers and retirement.

Excess Treatment Costs

£126k expenditure allocated to POs to match additional income received.

3. Finance Engagement Event

Over the past five years, we have held bi-annual Finance Engagement event for R&D/I and Finance leads from Partner Organisations. We recently held one in November to discuss the budget planning for 2020/21 including Health Needs of the Region funding and some changes to the way we fund unmet service support costs. This event is always well attended and ensures that we have good engagement with our partners regarding financial matters. As per the Partnership Group recommendations, the budget model has been largely unchanged but we have planned for a budget cut as per NIHR CRN CC recommendations. This has been communicated as early as possible to allow partners to plan their budgets for the upcoming year.

4. Accounts Payable

To date this financial year 85% of invoices have been paid within 30 days against the target of 90%. The payment of invoices by value shows that 90% have been paid on time, which meets the target.

The responsiveness of the AP team and financial management focus in this area is starting to deliver solid and consistent improvements in performance.

This compares very favourably with last year where only 10% of invoices had been paid within 30 days.

Overall, there has been significant improvement but we will continue the monitoring process to ensure performance is maintained.

5. Recommendations

The CRN Executive Committee is asked to:

- Note the 19/20 forecast
- Note the current Accounts Payable performance

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 (PxI)	Proximity	Response Actions	Action owner(s)	Action status	Probability	Impact	Value (PxI)	Risk status (open or closed date)	Trend (since last reviewed)
R045	Performance	Jan-19	COO	Ongoing issues with NUH employed members of the core team resulting in disproportionate amounts of time spent on staff management/support for the these team members and concerns around how well both staff and managers are supported. This also impacts on our overall ability to focus on other aspects of CRN delivery under the Host contract	Cause: Inconsistency in local policies/procedures (NUH/UHL); lack of and poor HR support (NUH); ongoing, badly managed HR cases; very few NUH employed managers in core team; lack of understanding/clarity at NUH of network and staffing arrangements Effect: Focus diverted from CRN core business; real concerns that staff are not being given appropriate advice and support; managers not well supported, quite vulnerable	5	3	15	Jan-19	To discuss with Host HR (Tina/Smita) for advice and support	COO	5	3	3	9	Open	Decreased
										Begin discussions with NUH HR/Corporate Governance	COO & Host HR	5					
										Quarterly meetings with Senior HR (UHL & NUH) & CRN	COO	4					
										Monthly meetings with operational HR (NUH) & CRN	COO	4					
										To raise options with staff as and when appropriate	COO	1					
R046	Reputational	Mar-19	COO	Ongoing delays to payment of all CRN invoices from suppliers and partners, breaching the contractual obligation, to negatively impact reputation of CRN & UHL and effect some elements of study and business delivery	Cause: CRN invoices not being paid on time by UHL Accounts Payable. Effect: Negative effect on future engagement with our Partners with potential to impact on ability to deliver research. For suppliers, where invoices are late, the risk is for services to cease, e.g. Google and Edge which which are underpinning systems to allow our business to proceed, and ultimately deliver the contract. Non compliance with the Host contract. This could also have an adverse effect on reputation of UHL for future re-bids related to NIHR infrastructure.	5	3	15	Mar-19	Highlight to Accounts Payable the need to make BACS payments promptly by end of Q2	DCCO	5	3	2	6	Open	Decreased
										Continue to monitor performance and provide updates to key groups as appropriate	DCCO/COO	4					
										To report this to Host trust board through quarterly reporting arrangements	COO/PM	4					
R047	Performance	Jun-19	Div 4 RDM	CRN EM will not deliver against HLO7 target for 2019-20 (number of participants recruited into Dementias and Neurodegeneration NIHR studies) Currently 126% of YTD Target	Cause: Challenging target, due to previous strong performance, however there is a reduction in the national pipeline for new portfolio dementia studies, especially those with large sample sizes. Effect: Unable to meet this HLO, which we are contractually expected to do. Potential reputational risk. At present there is no financial impact. This area is something which will be considered nationally, as this is a concern from all CRNs.	3	2	6	Mar-20	Scope pipeline for potential studies open to new sites	Div 4 RDM/OM	4	3	2	6	Open	Static
										As this is a national issue, SL to raise concerns to national group	Dementia SL	4					
										Raise and review issue at Division 4 Steering Group	Div 4 RDM	4					
										To work with SL and IMH to look for ECR and grow our own PIs/CIs to generate our own studies	Div 4 RDM	4					
R048	Information	Jun-19	DCCO	Lack of visibility of performance data for all studies/sites, due to changes in data upload methods, making it difficult to manage key metrics (esp. HLO 1A&B, 2A&B, HLO7 and 9)	Cause: Change in systems from central to local upload has resulted in lack of local visibility, not helped by ODP not displaying full data in an accurate way. Effect: We don't have an accurate reflection of our current performance, which makes it difficult to plan and understand our local landscape.	4	3	12	Jun-19	Lobby the CRNCC nationally to address this issue of how data is shared with LCRNs	DCCO/COO	4	3	3	9	Open	Static
										Communicate this to our Partners, and seek to explain how and when this will improve	Comms Lead/STL/DCCO	4					
										Continue to work locally with our LPMS systems, including implementation of our data quality strategy, key link through TLAs	BDM/DCCO	4					
										Now that RA confirmation is live, to continue our relationships with regional CIs	BDM/DCCO	4					
										Continue checking verified data closely for remainder of year	BDM/DCCO	4					
R049	Performance	Sep-19	IOM	CRN EM will not deliver against HLO1B target for 2019-20 (Number of participants recruited to commercial contract NIHR CRN Portfolio studies) Currently 54% of YTD Target	Cause: Multiple: Lack of high recruiting commercial studies; large number of studies with lower targets and annual target set is significantly higher than EM baseline. Effect: Potential reputational impact for the region, if viewed that we do not deliver for commercial, companies will; be reluctant to place studies with us. Additionally, we will have to report non-compliance for this new HLO.	4	3	12	Mar-20	Explore options with Sr Nurse to target additional resource at high sample size studies within the region	IOM/SN	4	5	3	15	Open	Increased
										Work needed to verify/check data as due to recent system changes, some anxiety around this	IOM/DCCO	5					
										Work needed to understand if we have sufficient studies/targets to achieve this, or not, to give realistic plan	IOM	5					
										Ensure that all Senior Managers are aware of this issue as part of the regular monthly performance meetings with DCCO	IOM/DCCO	4					
										Senior Team Links to work with partner organisations to promote the importance of this measure and link with IOM for action plans	STL/IOM	3					
										Support and engage with new companies to ensure studies are included on the NIHR Portfolio	IOM	4					
										Ensure commercially sponsored studies which have an element of public funding are badged as commercial studies	IOM	4					

R050	Performance	Sep-19	IOM	CRN EM will not deliver against HLO2A target for 2019-20 (proportion of commercial studies delivering to time & target) Currently 78% (target: 80%)	<p>Cause: Multi-factorial - one of the biggest is historic studies within cancer, Div 1 with high targets which are not well performing; changes also in CC management</p> <p>Effect: Future budget impact - Budget: 5% of next year's funding is linked to this performance, also, may impact on any future RCF for trusts; Reputational: damage to East Midlands reputation and impact upon loss of future commercial contract research for the region; Compliance: will have to record underperformance against a HLO measure under NIHR CRN CC-Host contract.</p>	4	3	12	Mar-20	Regular progress review meetings as part of HLO2A reporting schedule	IOM	4	4	3	12	Open	Static
										Increased involvement with partners in performance calls	IOM	4					
										Focus on early engagement specifically in Oncology at UHL and NUH	IOM/RDM Div 1	4					
										Develop a post for performance in commercial studies, based on the model for HLO2b.	IOM/ SSS OM	3					
										Ensure metric is discussed at monthly performance meetings and action plans to be developed with divisional managers and DCOO	IOM/RDM/ DCOO	4					
										Update partner organisations regularly not only from an individual organisation perspective but as a network wide issue and potential effects on budget	DCOO/C OO/STL	3					
R051	Performance	Sep-19	DCOO	CRN EM will not deliver against HLO2B target for 2019-20 (proportion of non-commercial studies delivering to time & target) Currently 100% (target: 80%)	<p>Cause: Some locally led studies which did not come through pipeline from the beginning, for feasibility support etc. or more independent CIs</p> <p>Effect: Budget: 5% of next year's funding is linked to this performance, also, may impact on any future RCF for trusts; Reputational: damage to East Midlands reputation for research delivery; Compliance: will have to record underperformance against a HLO measure under NIHR CRN CC-Host contract.</p>	3	3	9	Mar-20	Monitor closely studies at high risk of not meeting time and target and implement action plan for recovery where possible	DCOO/ PM	4	3	3	9	Open	Static
										Ensure metric is discussed at monthly performance meetings and action plans to be developed with divisional managers and DCOO	DM/IOM/D COO	4					
										Update partner organisations regularly not only from an individual organisation perspective but as a network wide issue and potential effects on budget	DCOO/ COO/ STL	4					
										Ensure that performance is discussed at Early Contact meetings to ensure accurate targets and responsibilities are highlighted as soon as possible.	SSS Team	4					
										Work needed to verify/check data as due to recent system changes, some anxiety around this	DCOO	4					
R052	Performance	Sep-19	IOM	CRN EM will not deliver against HLO6B target for 2019-20 (proportion of NHS Trusts recruiting into commercial NIHR studies) Currently 56% (target: 70%)	<p>Cause: Multi-factorial - Low number of suitable studies for Healthcare, Partnership & Community Trusts, challenging studies to set-up at some sites, reduced number of investigators and Trust restructuring.</p> <p>Effect: Recorded by the NIHR CRNCC as underperformance against a HLO measure; potential reputational risk. At present there is no financial impact.</p>	4	2	8	Mar-20	Review pipeline for potential studies in mental health, dementia and community setting - link with Dementia Specialty Lead and CC to support this	IOM/ RDMs	4	4	2	8	Open	Static
										Support set-up of existing studies at relevant Trusts	IOM	4					
										Conduct analysis of the non-commercial research at relevant Trusts to identify opportunities to undertake commercial studies	IOM	4					
										Conduct analysis of submitted Eols to identify reasons for non-selection and areas for improvement	IOM	3					
										Senior Team Links to engage with Partners re developing plans for commercial research	IOM	4					
										Identify commercial partners and target for raising the profile for the East Midlands and encourage use of naive and less experienced sites	IOM	3					
										Set up commercial working groups to support collaboration between partner organisations for the delivery of new studies	IOM	4					
R053	Financial	Nov-19	COO	Potential reduction to CRN East Midlands budget for 2020-21	<p>Cause: Uncertainty over future national budget; changes to national model and how this will be implemented; changes to employer pension contributions which bring additional cost pressures</p> <p>Effect: Likely reduction in Partner recruitment activity due to reduced funding for research infrastructure; potential inability to provide funding for workforce; inability to be as responsive and flexible as we would like with budget next year; negative effect on reputation and relationship with Partners; concern over job losses</p>	3	3	9	Apr-20	Model a range of budget scenarios to aid planning and forecasting	COO / DCOO	4	3	3	9	Open	New
										Regular communication and providing early notification to Partners re potential budget reduction	COO / DCOO	4					
										Lobby nationally to get an early indication of budget	COO	4					
										Communicate planning to Partnership group, for agreement as to planned approach	COO	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