CRN East Midlands Quarterly Board Report

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong Trust Board paper I

Executive Summary

Context

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute of Health Research (NIHR) Clinical Research Network East Midlands (CRN). 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 taken to the CRN East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive Lead for the CRN) in September 2018. It will then be considered by UHL Executive Performance Board, and submitted for UHL Board review in October 2018. Appended to report is a dashboard displaying performance figures, Executive Group finance report, recent feedback letters from the NIHR CRN Coordinating Centre 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 1 April 2018 up to 13 August 2018?
2. What are the current risks affecting the LCRN and are the Board assured of measures in place to address these?

Conclusion

1. This report presents a mixed picture of our performance across the High Level Objectives (Appendix 1 presents data extracted on 13 August 2018 reflecting performance to date); some aspects are on track, with others presenting areas of concern. We are close to our year to date target for our HLO1 contribution, however, HLO2A, which is a key objective, is underperforming and a recovery plan is being established. We have also noted concerns around some of our other HLO contributions. At this stage of the year, it is difficult to provide accurate year end forecasts for these objectives, however, we are taking steps to address the key areas of concern, which have been discussed as part of the Executive Group, chaired by Andrew Furlong. Since the last report, we have received some more positive feedback from the NIHR CRN Coordinating Centre in relation to both our previous achievements and future plans.
2. In relation to risks, we have made progress with re-establishing our communications function, HLO risks will be addressed and we have implemented the majority of partner contracts. A new risk has been added due to changes to the national process for

management of Excess Treatment Costs and this will need to be monitored closely over the next quarter, for further feedback through the next report. Our risk register is attached at Appendix 5 of the report.

Input Sought

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.

For Reference

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

Safe, high quality, patient centred healthcare	Not applicable
Effective, integrated emergency care	Not applicable
Consistently meeting national access standards	Not applicable
Integrated care in partnership with others	Yes
Enhanced delivery in research, innovation & ed'	Yes
A caring, professional, engaged workforce	Not applicable
Clinically sustainable services with excellent facilities	Not applicable
Financially sustainable NHS organisation	Yes
Enabled by excellent IM&T	Not applicable

2. This matter relates to the following **governance** initiatives:

a. Organisational Risk Register No

If YES please give details of risk ID, risk title and current / target risk ratings.

Datix Risk ID	Operational Risk Title(s) – add new line for each operational risk	Current Rating	Target Rating	CMG
XXXX	There is a risk …			XX

If NO, why not? Eg. Current Risk Rating is LOW

This report does not relate specifically to any risks on UHL's risk register. CRN East Midlands has an internal risk register which is included at Appendix 5 of our report. Any significant risks which may relate to the UHL Organisational Risk Register or Board Assurance Framework would initially be discussed and reviewed with Andrew Furlong through our Executive Group.

b. Board Assurance Framework No

3. Related **Patient and Public Involvement** actions taken, or to be taken: N/A

4. Results of any **Equality Impact Assessment**, relating to this matter: N/A

5. Scheduled date for the **next paper** on this topic: 03/01/2019

6. Executive Summaries should not exceed **4 sides** My paper does comply

7. Papers should not exceed **7 sides.** My paper does comply (excluding appendices)

Clinical Research Network
East Midlands

National Institute for Health Research

CRN East Midlands Quarterly Board Report

Progress, Challenges and Performance

DATE: 20 September 2018

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

1.2 This report provides a summary of 2018/19 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, recent feedback letters from the NIHR CRN Coordinating Centre and current risk register.

1.3 This report will be taken to the CRN East Midlands Executive Group in September 2018. It will then be considered by the UHL Executive Performance Board and submitted to UHL Trust Board for review in October 2018.

2. CURRENT PERFORMANCE, PROGRESS AND FORECAST

2.1 Appendix 1 presents data extracted on 13 August 2018 reflecting performance to date. 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 recruitment level (HLO1) is currently at 93% of our year to date target with 16,071 participants recruited. We are currently in sixth position out of 15 regional networks in the national league table for both total and weighted recruitment (weighted activity is a measure which in part, determines our future funding). Our current performance is below target, additionally our target is in fact lower than the level of recruitment attained last year. 2017/18 was a record year for the East Midlands and we are forecasting a lower level of activity this year due to a notable fall in our study pipeline. This year's target is set at 52,000, however, an analysis of the pipeline at the start of the year, forecast our recruitment of 40,000 - 42,000, thus this is an ambitious target, with a level of stretch. Considering this, our performance of 93% against YTD is demonstrating good progress. Furthermore, we have seen a slight lag in data over the summer months and we anticipate some additional recruitment to be reported over the coming weeks. At this stage, it is difficult to confidently provide a full year forecast, however, we have recently agreed to review all specialty targets and performance critically at the end of Q2.

ii. For the proportion of commercial studies recruiting to time and target (HLO2A), we are currently at 71% against a target of 80% and in sixth position out of the 15 regional networks. Of note, none of the 15 LCRNs are currently achieving the 80% target. Whilst only a small proportion of the closed study data has been reported at this stage in the year, our current performance is still of concern. We believe the reasons for this fall in performance are multi-factoral, including an increased number of small target studies, some changes in the central management approach, some local staffing concerns, and the impact of study performance/approach within one partner organisation. We are in the process of establishing a recovery plan to address these issues, and we are keen to

work hard to attain the 80% level by year end, which will take considerable focussed effort as our current year end forecast is c. 73%.

iii. For the proportion of non-commercial studies recruiting to time and target, where the lead site is in the East Midlands (HLO2B), we are currently at 95% against a target of 80% and in first place out of the 15 LCRNs. Whilst this is encouraging, the number of studies is relatively small (21), which would be expected at this time of the year. We are anticipating that c.50 further studies will close in-year, with many currently not on target to achieve this metric. This is not a significant area of concern and we do have a strong track record of delivering this metric due to established protocols and approaches locally. We will continue to actively monitor this, to keep this HLO on track for year end.

iv. For our objective to reduce the time taken for studies to achieve set up in the NHS (HLO4), we are currently at 82% of studies in the required timeframe against a target of 80%. This demonstrates very strong progress, as last year's out-turn performance was 69%. We believe that we have seen this change for two reasons, in part due to DHSC changes to reporting requirements for trusts in relation to set-up data; also due to improvements in data quality in line with our data quality strategy and related work with partners. This requires continued focus, which we are committed to in order to sustain this performance, including some comms activities to promote the importance of this objective.

v. HLO5A & 5B are objectives to reduce the time taken to recruit the first participant into NIHR CRN studies. For commercial studies (5A), we are currently at 57% and for non-commercial studies (5B), 58%; this places us around mid-position of the national standings for these objectives. Both are measured against a national target of 80%. In 2017/18, we attained 33% and 52% at year end, thus we are making progress with these objectives. As we have previously reported, many of the contributing activities for this objective are outside of the scope of influence of the CRN, however, we continue to work with our partners to further improve this.

vi. For the proportion of NHS Trusts recruiting into NIHR studies (HLO6A), we have achieved this objective with 100% of trusts recruiting. For the proportion of NHS Trusts recruiting into commercial studies (HLO6B), we are below target, currently at 44% against a target of 75%; this is however, a year end target. Based on our current forecast, we are unlikely to achieve this metric by year end. This is due to a reduced pipeline of commercial studies (in mental health and dementia) suitable for our Healthcare & Partnership trusts, which are crucial for us to attain this metric. We are planning to undertake further analysis of this pipeline and support the studies currently in set-up. The proportion of GP sites recruiting into NIHR studies (HLO6C) is of some concern, currently at 23% against a target of 45%. This has been affected by GDPR regulations, as we are required to ensure all non-contracted practices are willing to receive expressions of interest in relation to research studies with a range of response rates across the counties from 40-70%. We have recently channelled some resource into this activity, but should flag this of potential concern at this stage in the year.

vii. For recruitment into Dementia and Neurodegenerative studies (HLO7), we are currently at 66% of our year to date target with 278 participants recruited. This is significantly behind target as we are currently struggling with study pipeline. We plan to review a new batch of studies and identify any which are open to new sites. As the remit of the CRN is

focused on research delivery, we are reliant on study pipeline, which is largely outside our control. Several of the LCRN regions are also finding this objective challenging and our Dementia Specialty Lead plans to highlight this issue to the national group. We are forecasting that we are unlikely to achieve this target by year end.

2.2 Our latest Executive Group Finance Report is included as Appendix 2. There are no significant areas of risk; the previously reported accounts payable delays are improving, although are still under review; additionally the PwC audit undertaken in December 2017 is now fully resolved and closed.

3. NIHR CRN COORDINATING CENTRE FEEDBACK

3.1 The NIHR wrote to Mr Andrew Furlong as UHL (Host) LCRN Executive Lead on 4th July 2018 with feedback in relation to our 2017/18 Annual Report. The report has been formally approved and the feedback recognised our achievements and performance for 2017/18. Further details can be found in the letter at Appendix 3.

3.2 Our Annual Review Meeting with the NIHR CRN Coordinating Centre took place on 11th July 2018 and feedback has since been received. The feedback letter (Appendix 4), was very positive, noting our strong performance across a number of HLOs and activities. No major concerns were identified.

4. RISK REGISTER & CURRENT CHALLENGES

4.1 Risks and issues are formally discussed through the CRN Executive Group chaired by Andrew Furlong. A risk register (Appendix 5) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre.

4.2 Risks are recorded on the register as follows:

- Risk #31 - Reduced communications function will affect ability to deliver all elements of the communications action plan. This has been realised in the first half of the year, however, a Communications & Engagement Lead has now been appointed. This will enable us to focus on key deliverables from our Annual Plan and further develop our comms action plan. We are establishing a regional 'Engagement Group' and an operational 'Communications & PPIE Working Group' to support this work. Furthermore, a Business Delivery Operations Manager has been appointed, who will have oversight of the communications function as part of their role. In light of this progress, the risk impact is now minor and the overall risk score has reduced from high to medium.

- Risk #32 - Budget reductions of up to 8% for some Partner organisations will be difficult to manage in 2018-19. This remains medium risk and we have added a new action to address this; our Senior Team Links will conduct meetings with all Partners who are showing significant vacancy factors at end of Q2 and ensure there is a plan of action to meet this with support of the CRN.

- Risk #35 - Recognition that not all Partner B & C contracts have been executed, and a need to action this, in order to be fully compliant with the Host contract. New management and monitoring processes have been established and the majority of contracts have been implemented with no major concerns. As a result of these actions, the probability and impact scores have reduced and this risk has been closed on the risk register.

- Risk #36 - CRN EM will not deliver against HLO1 target for 2018-19 (total number of participants recruited). We have made reasonable progress with recruitment to date, however, are still below target. This remains medium risk at present with several actions ongoing to improve the position by year end.

- Risk #37 - CRN EM will not deliver against HLO4 target for 2018-19 (time taken to achieve study set up in the NHS). We are currently on target and this risk has reduced to medium. Mitigating actions are detailed on the risk register, and there remains further work to be done.

- Risk #38 - CRN EM will not deliver against HLO5 targets for 2018-19 (time taken to recruit first participant into studies). We are currently below target for both commercial and non-commercial studies. Whilst it is unlikely we will achieve these targets, we have reduced the risk impact score to minor as there are no financial consequences linked to this HLO. Mitigating actions are detailed on the risk register, and we will continue to work towards improving the progress of this HLO.

- Risk #39 - Insufficient level of data quality and completeness in LPMS for primary care research activity. This remains low risk and is being actively managed as part of our broader Data Quality Strategy.

- Risk #40 - CRN EM will not deliver against HLO2A target for 2018-19 (proportion of commercial studies delivering to time & target). This has been added as a new risk with a high risk score as it is currently unlikely that we will achieve this target. Mitigating actions are detailed on the risk register.

- Risk #41 - Uncertainty around the national process change for the management of Excess Treatment Costs (ETCs) may cause delays in study set up and delivery and impact upon HLO attainment. This has been added as new risk with medium risk score. From October 2018, there will be a national change to the process of identification, management and payment of ETCs in non-commercial research. There will be a national budget for ETCs, which has been top sliced from CCG budgets (5.2p per capita per CCG p.a.). LCRNs will be required to undertake attribution and costing activities, along with processing payments to providers, once thresholds have been reached. The expectations within this process remain unclear at present, as does the throughput of studies, which make planning for this problematic. Another area of uncertainty is in relation to the establishment of ETC thresholds, under which providers are expected to absorb costs; levels are thought to be set at 0.01% of operating costs. Some of our provider partners have raised concerns that this will affect research delivery, which in turn impacts upon HLO performance, especially HLO1 and 4. Full implications should become evident over

the coming months, which will enable us to undertake a more informed review and analysis of this risk, and instigate further actions to mitigate impact. Current plans and actions are detailed on the risk register.

- Risks #42, 43 & 44 have been added as new risks as there is an expectation from the NIHR CRN Coordinating Centre that any HLOs that are not on track should be documented on our risk register. These risks correspond to concerns that we will not deliver against our targets for HLO6B (proportion of NHS Trusts recruiting into commercial NIHR studies), HLO6C (proportion of General Medical Practices recruiting into NIHR studies) and HLO7 (number of participants recruited into Dementias and Neurodegeneration NIHR studies) respectively. All have been scored as medium risk as the risk probability is likely, however, impact is minor and there are no financial implications linked to these metrics. A series of related actions for each risk are detailed on the risk register, and steps are in place to work closer towards attaining these goals.

5. SUMMARY

5.1 This report presents a mixed picture of our performance across the High Level Objectives to date; some aspects are on track, with others presenting areas of concern. We are close to our year to date target for our HLO1 contribution, however, HLO2A, which is a key objective, is underperforming and a recovery plan is being established. We have also noted concerns around some of our other HLO contributions. At this stage of the year, it is difficult to provide accurate year end forecasts for these objectives, however, we are taking steps to address the key areas of concern, which have been discussed as part of the Executive Group, chaired by Andrew Furlong.

5.2 Since the last report, we have received some more positive feedback from the NIHR CRN Coordinating Centre in relation to both our previous achievements and future plans. We intend to build on this, giving increased focus towards achieving HLO targets and working closely with the Host to deliver the activities outlined in our Annual Plan.

5.3 We have made progress with re-establishing our communications function, HLO risks will be addressed and we have implemented the majority of partner contracts. A new risk has been added due to changes to the national process for management of Excess Treatment Costs and this will need to be monitored closely over the next quarter, for further feedback through the next report.

6. RECOMMENDATIONS

6.1 UHL Trust Board is asked to review and comment upon:

(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 - Dashboard 2018/19

Clinical Research Network East Midlands **Refreshed: 30/08/2018** **2018-19 YEAR TO DATE** **Network Progress Overview**

	HLO Description	Study Type	Target		Progress/Summary				Actions	Status	Owner	Year End RAG Assurance
			England	East Midlands	YTD	Previous	Trend					
1	Number of participants recruited into NIHR studies	All	650,000	52,000	93%	-	-	93% of YTD goal (16,071 participants) CRN East Midlands in 6th position out of 15 LCRNs Also in 6th position based on weighted recruitment	- Further analysis of current portfolio - Review all specialty targets and performance critically at the end of Q2	Ongoing	Chief Operating Officer	Amber
2	Proportion of NIHR studies delivering to recruitment target and time	Commercial	80%	80%	71%	-	-	71% (35) for 49 studies recorded as closed and reported recruitment across all Network supported sites. CRN East Midlands in 6th position out of 15 LCRNs	- Increase frequency of performance review meetings - Establish recovery plan	Ongoing	Industry Operations Manager	Amber
		Non-commercial	80%	80%	95%	-	-	95% (20) for 21 closed HLO studies CRN East Midlands in 1st position out of 15 LCRNs	- Continue to review and actively monitor	Ongoing	Chief Operating Officer	Green
4	Proportion of eligible studies achieving NHS set up within 40 calendar days	All	80%	80%	82%	-	-	82% (53) for 65 closed HLO studies	- Comms activities to promote the importance of this HLO	Ongoing	Deputy Chief Operating Officer	Green
5	Proportion of studies achieving first participant recruited within 30 days at confirmed Network sites (from "Date Site Confirmed" to "Date First Participant Recruited ")	Commercial	80%	80%	57%	-	-	57% (4) for 7 qualifying studies	- Continue to work with our partners to improve this HLO	Ongoing	Deputy Chief Operating Officer	Red
		Non-commercial	80%	80%	58%	-	-	58% (15) for 26 qualifying studies	- Continue to work with our partners to improve this HLO	Ongoing	Deputy Chief Operating Officer	Red
6	Proportion of NHS Trusts recruiting into NIHR studies	All	99%	99%	100%	-	-	16 out of 16 Trusts reported recruitment	Target achieved	Complete	Chief Operating Officer	Green
		Commercial	70%	70%	44%	-	-	7 out of 16 Trusts reported commercial recruitment.	- Review pipeline for potential studies in MH and dementia - Support set-up of existing studies	Ongoing	Industry Operations Manager	Red
	Proportion of General Medical Practices recruiting into NIHR studies	All	45%	45%	23%	-	-	130 out of 555 GPs, surgeries & health care sites currently reporting recruitment	- Channel additional resource into this area to ensure EoIs can be received	Ongoing	Division 5 Research Delivery Manager	Amber
7	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) NIHR studies	All	25,000	1,510	66%	-	-	66% of YTD goal (278 participants)	- Scoping pipeline for potential studies open to new sites - National issue, SL to raise pipeline to national group	Ongoing	Division 4 Research Delivery Manager	Red

Sources: Commercial Reporting on ODP 13/08/2018, Portfolio ODP Last update: 13/08/2018, Portfolio ODP 17-18 Annual Cut Last update: 20/04/2018, Portfolio ODP Reporting Last update: 13/08/2018

Network Summary Report 30/08/2018 Provided by: CRN East Midlands Business Intelligence Team

N.B: HLO 3 is not included as this relates to a national objective

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE COMMITTEE

DATE: 19th SEPTEMBER 2018

REPORT FROM: MARTIN MAYNES – HOST FINANCE LEAD

SUBJECT: CRN EM FINANCE UPDATE

1. Purpose

This report provides an update on the following issues:

- 18/19 financial position
- Financial Health Checks
- Accounts Payable Update
- Internal Audit Review

2 2018/19 Financial Position and Forecast

The table below summarises the 18/19 current financial position and forecast out turn.

	Annual Plan	YTD April to July 2018	Forecast Expenditure	Variance
	£'000	£'000	£'000	£'000
Income				
NIHR Allocation	20,597	6,866	20,602	5
Expenditure				
Network Managed Team	645	157	496	(149)
Host Services	300	89	300	0
Core Management Team	761	216	714	(47)
SSS Team	373	156	497	124
RST Team	394	131	427	33
Clinical & SG Leads	95	22	87	(8)
Research Site Initiative	363	120	361	(2)
Primary Care Service Support Costs	170	55	171	1
General Service Support Costs	170	46	170	0
Partner Organisation Infrastructure	16,776	5,521	16,780	4
CRN EM Non Pay Non Staff	201	63	214	13
Innovation Fund	350	0	350	0
To Be Allocated	0	0	35	35
Total	**20,598**	**6,576**	**20,602**	**4**

The key issues are reported below.

Network Managed Team
There is a favourable pay variance is £149k. £82k relates to staff being recoded to the SSS team, so there is a corresponding overspend there. The remainder of the variance relates to staff leaving and delays in appointing replacements.

Core Management Team
Favourable pay variance is £57k.This is due to Clinical Co Director being employed at NUH, rather than UHL, two senior managers reducing WTE, and slippage in recruiting to the Business Delivery Operational Manager's post. There is an adverse variance of £10k in general non pay.

Study Support Service Team
There is an adverse pay variance is £108k, of which £82k is the offset underspend in the Network Managed Team budget. In addition, there is an additional A&C band 5 Study Support Service Officer post costing £21k. There is also an adverse non pay variance of £11k, largely due to travel costs.

Forecast Out Turn
The CRN is forecast to break even in line with budget. As of July there is £35k of accrued underspend which needs to be reallocated. The CRN has plans to utilise any potential funding available.

3. Financial Health Checks

CRN East Midlands is contracted by the Department of Health (DoH) to undertake timely and accurate budgetary monitoring and reporting on funds paid directly to Partner Organisations. Additionally, the CRN is required to provide sufficient assurance that NIHR CRN funding is used only on eligible CRN activity, in accordance with DoH funding agreement terms. CRN East Midlands gains this assurance through a range of mechanisms, including this newly introduced Financial Health Check Questionnaire and Partner visits to support this assurance.

We began a rolling programme of partner finance health-check visits, and so far have visited the following PO's

- Northampton General Hospital
- Nottinghamshire Healthcare
- Nottingham University Hospitals

The next visit to Kettering General Hospital is planned in September.

To date no major issues of concern have been identified, although all the visits have proved very useful. It is intended to provide a report at the end of the financial year identifying the main findings from the visits, and lessons that can be learned or shared more widely.

4. Accounts Payable

Following the introduction of a new process the Network is receiving an improved service in respect of the prompt payment of invoices from suppliers and partners. As at 28th August there were four invoices over 30 days old, with a total value of £106,092. The delays were all due to authorisation dates, and not Accounts Payable performance. This improved performance has been consistent for the past three months, and will continue to be monitored.

5. Internal Audit Review

The scope of the Internal Audit review was agreed with LCRN and UHL, and the review took place in December 2017. The report was issued on 20th February, with the following findings. Overall the report was classified as low risk, which was an improvement on the medium risk report in 2014/15. There were three low risk findings, and one medium risk. The key findings were as summarised below.

1. Delays in paying LCRN Partner invoices (medium risk)

2. Assurance gathering (low risk)
3. Funding is being used in accordance with NIHR criteria.(low risk)
4. Declaring conflicts of interest (low risk)
5. Reviewing reconciliations (low risk)

Action plans have been agreed with Internal Audit to address all of the issues identified. All but two recommendations have now been cleared by Internal Audit.

6 Recommendations

The CRN Executive Committee is asked to:

- Note the forecast 18/19 financial position
- Note the Finance Health Check Programme
- Note the current Accounts Payable performance
- Note the current Internal Audit review

Appendix 3 - Annual Report 2017/18 Feedback Letter

National Institute for Health Research

Clinical Research Network Coordinating Centre
21 Queen Street
Leeds
LS1 T2W

Tel: 0113 343 2314
Fax: 0113 343 0336
Email: crn@nihr.ac.uk
Web: www.nihr.ac.uk

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

4 July 2018

Dear Mr Furlong,

LCRN Annual Report 2017/18

Thank you for submitting CRN East Midlands' Annual Report including the Q4 finance return for 2017/18. I am pleased to confirm that the CRNCC review panel recommended the approval of your Annual Report.

1. Specific feedback on CRN East Midlands' Annual Report

Annual Report Section	CRNCC Feedback	Action required
Host Organisation Approval	We noted the Report was agreed electronically by the LCRN Partnership Group with formal review by the Group on 20/06/2018. Host Organisation Board approval scheduled on 05/07/18	No action required
Section 1. Compliance with the Performance and Operating Framework	We noted four areas of partial / non-compliance. Actions identified and/or outlined in Annual Plan 2018/19	Please provide further detail / actions taken on the one Category A Partner who is unable to sign a contract
Section 2. Executive Summary	Clear concise summary of overall activities and some considerable achievements during 2017/18 We noted the strong and stable senior management structure contributing to the ongoing success of the network Thank you for the varied contributions to national initiatives and projects	No action required

Section 3. Key Projects	Well written and detailed section demonstrating breadth of activities We noted that the majority of projects are completed / rag rated green We noted strong performance across the majority of HLOs, in particular HLO 1, HLO 2a and 2b and HLO 7. Further improvements required in HLO 4 and 5 in particular We noted excellent development and delivery for workforce, including the online induction portal and Research Envoy internship programme for non-medical clinical staff	HLO improvement plans outlined in LCRN Annual Plan
Section 4. Specialty Objectives	We noted strong performance and clear improvements in a number of specialties We noted 24/30 specialties met their target We noted efforts to recruit to vacant posts Further monitoring is required for Children and Cancer	The National Specialty Lead will follow-up accordingly
Section 5. Development and Improvement Objectives 2017/18	Multiple examples provided demonstrating strong delivery of these objectives. Examples of collaborative working clearly evident We noted active efforts to support research in non-NHS organisations and the significant recruitment from the Lunchbox Study with over 2000 recruits from schools	We will follow up on the Lunchbox study to investigate lessons learned and sharing of these across the CRN / possible development of a case study
Section 6. Operating Framework Indicators	Overall, we were content with delivery against these performance indicators	No action required
Section 7. Non-Supported Non-Commercial Studies	We noted that zero Non-supported Non-Commercial Studies were reported	No action required
Section 8. Glossary	Good tailored Glossary including local information such as trust acronyms	No action required
Section 9. Appendices	Thank you for providing a number of helpful appendices	No action required
Additional comments	We noted evidence of strong collaborative working across the LCRNs, particularly CRN Eastern and CRN West Midlands	No action required

	Thank you for the varied contributions to national initiatives and projects We noted the 2017/18 Cost Per Weighted Recruit has fallen by 40% from the prior year Overall a very good Annual Report including an informative infographic	
Q4 finance return	We noted high quality financial returns	No action required

2. General feedback to all LCRNs

The review group would like to share some general points on LCRN Annual Reports:

- The CRNCC will be implementing an LCRN contract compliance assurance framework to ensure compliance with Appendix A Performance and Operating Framework of the DHSC/LCRN Host Organisation Agreement. Further details on the approach will be issued shortly.
- LCRNs are expected to execute Category A, B and C Partner Agreements in line with their contractual obligations. Monitoring of contract implementation will actively take place during 2018/19 to ensure contract compliance.
- A number of networks provided information regarding studies their network decided not to support or were unable to support in the 2017/18 financial year. We will be reviewing this information and will follow up with LCRNs as relevant in due course. Please note that the expectation is all LCRNs will prospectively monitor non-supported studies during 2018/19.
- Following review of Appendix 2, Finance section of LCRN Fact Sheets, the CRNCC noted variability of expenditure relating to 'Host supporting costs including Leadership and Management'. The CRNCC intends to undertake further analysis to better understand this funding element.
- We noted that in the majority the work carried out across platforms such as LPMS and ODP is of a level expected after four years of the DHSC / LCRN Host Organisation contract. We would like to explore opportunities to optimise technologies to greater effect at a local level and will look to discuss and share ideas at a future liaison meeting.

Annual Review Meeting

We look forward to meeting with you for the forthcoming CRNCC/LCRN Annual Review Meeting, to reflect on and discuss the achievements and challenges in your area in 2017/18 as well as progress in the implementation of your 2018/19 Annual Plan.

Yours sincerely

Amber O'Malley

Head of Performance Management
NIHR Clinical Research Network

cc Professor David Rowbotham, CRN Clinical Director, CRN East Midlands
Dr Steve Ryder, CRN Co-Clinical Director, CRN East Midlands
Elizabeth Moss, Chief Operating Officer, CRN East Midlands
Dr Jonathan P Sheffield, CRN Chief Executive Officer
John Sitzia, CRN Chief Operating Officer
Professor Nick Lemoine, CRN Medical Director
Dr Susan Hamer, CRN Director of Nursing, Learning & Organisational Development
Dr Matt Cooper, CRN Business Development & Marketing Director/Research Delivery Director
Imogen Shillito, CRN Stakeholder Engagement & Communications Director
CRNCC Senior Management Team

Appendix 4 - Annual Review Meeting Feedback Letter

National Institute for Health Research

Clinical Research Network Coordinating Centre
21 Queen Street
Leeds
LS1 T2W

Tel: 0113 343 2314
Fax: 0113 343 0336
Email: crn@nihr.ac.uk
Web: www.nihr.ac.uk

Professor David Rowbotham
NIHR CRN East Midlands
Knighton Street Outpatients
1st Floor
Leicester Royal Infirmary
LE1 5WW

31 July 2018

Dear Professor Rowbotham

NIHR CRN East Midlands Annual Performance Review Meeting 11 July 2018

Thank you to you and your team for attending the Annual Review Meeting between the CRN Coordinating Centre (CRNCC) and CRN East Midlands ("the LCRN") held on 11 July 2018 to discuss the LCRN's delivery and performance in 2017/18 and plans for 2018/19.

The meeting was chaired by Matt Cooper and attended by the following colleagues:

LCRN attendees: David Rowbotham (DR) - Clinical Director, Elizabeth Moss (EM) - Chief Operating Officer, Andrew Furlong (AF) - Medical Director, University Hospitals of Leicester NHS Trust (Host Nominated Executive Director), Peter Miller (PM) - Chief Executive Officer, Leicester Partnership NHS Trust (Partnership Group Chair). **CRNCC attendees:** Jonathan Sheffield (JPS) - Chief Executive Officer, John Sitzia (JS) - Chief Operating Officer, Matt Cooper (MC) - Business Development and Marketing Director / Research Delivery Director (Chairperson), Susan Hamer (SH) - Director of Nursing, Learning & Organisational Development, Imogen Shillito (IS) - Stakeholder Engagement and Communications Director, Chris King (CK) - Deputy Chief Information Officer (SMT Link), Lucy Ainsworth (LA) - LCRN Performance Coordinator (Secretariat).

LCRN apologies: Steve Ryder (SR) - Co-Clinical Director. **CRNCC apologies:** Nick Lemoine (NL) - Medical Director.

We would like to thank your team for providing the documents and presentation to support the discussions at the meeting.

Actions and matters arising from the last meeting

- All actions from the previous meeting were noted as complete, with the exception of EM9.
- EM and DR gave a helpful update: DR advised that a consultant in Derby has taken on the leadership role for the Musculoskeletal Disorders Specialty; CRN East Midlands does not have a Dental school and is struggling to appoint to the Oral & Dental Health Lead position; the attendance at national meetings by the Local Specialty Lead for Surgery has greatly improved; a new Local Specialty Lead for Cancer has been appointed from the medical oncology team at Nottingham University Hospitals NHS Trust and the CRN East Midlands Senior management team are confident that he will deliver improvements.

Overall Summary
Overall we were content with the LCRN's performance and delivery against plans for 2017/18. JPS congratulated the network on their achievements, particularly the network's best ever recruitment with over 56,100 participants recruited in 2017/18, excellent HLO 7 performance with 5,527 participants recruited (the second highest LCRN performance), and strong recruitment to time and target which was above the national target for both commercial (HLO 2a) and non-commercial studies (HLO 2b), at 85% and 92%, respectively. We also noted strong performance in a number of specialties including Critical Care and Hepatology.

Major Issues to be Addressed
- No major concerns or critical issues were identified which require specific attention.

Medium Issues to be Addressed
- The group discussed the absence of a Communications Lead for the past 9 months and IS expressed concern that the network will not be able to deliver to the National Communications plan with the current lack of resource. EM and DR advised that they may be unable to deliver to expectations but have advertised for a new full time appointment to address this. It was noted that the absentee was on long term sick leave and that concern for staff wellbeing is paramount so no changes were appropriate until this time. IS offered to assist with the recruitment process and will call EM to discuss delivery to this workstream separate to the meeting (see Action EM17).
- EM advised the group of a concern with the Host Organisation delay in paying invoices, notably from Primary care settings. AF advised that the issue has been escalated to the Trust board and that plans have been put in place. He agreed to keep JS informed of any resolution (see Action EM18).
- At the close of 2017/18 it was noted that one Category A contract was still not signed. EM advised that she had been in discussions with Sally Johnson, LCRN Funding and Contracts Manager, but the issue was not resolved in year. Discussions have now closed at the provider is no longer a Category A partner. EM advised that the network are appointing an individual to manage all contracts and this will involve ensuring all Category B/C contracts needed are signed in a timely manner. (The group discussed the importance of having Category B contracts in place with all suppliers as this will be the main access route for payment for Excess Treatment costs from October 2018), (see general points and themes).

Minor Issues
- PM advised the group that the level of seniority of attendance at the Partnership Board meetings was a slight concern and they have written to individual members to address this. As the group is a forum for sharing information and operational issues, not a decision making group this is not a significant concern.
- EM updated the group on the East Midlands Cancer Alliance and advised they are developing an 'app' for Clinicians to access study information and discuss with patients in a 'real time' setting. JPS advised that a similar project might have already been carried out or is underway and agreed to send EM further details (see Action EM19).
- The group discussed the March 2018 LCRN Partner survey and EM suggested that a better response rate might be received if it was distributed differently (three responses received for CRN East Midlands). PM and EM suggested it could be shared locally with Partners that the audience is familiar with. JS agreed to discuss an alternative approach with Amber O'Malley, Head of Performance Management (see Action EM20).

Progress on these issues will be reviewed at the next CRNCC / LCRN Performance Review meeting.

Additional Points to Note

- MC noted a significant improvement in recruitment to the Hepatology Specialty. EM advised that it is a consequence of better engagement and with three new appointments to the area during 2017/18 that have pushed the agenda.
- The group were pleased to hear that the data in Documas (LPMS provider at Nottingham Healthcare NHS Trust) is fairly complete. EM updated the group on the network's data quality strategy which has been in place for the last 9 months, where the team do a series of spot checks on particular studies, paying particular attention to data linked with delivery to HLO 4 and HLO 5. The group were content with this approach.
- It was noted that the CRNCC Finance team are happy with the network finance returns and there are not many comments to address each quarter. Following a recent Host audit four issues were identified and addressed with no concerns noted.
- The group discussed delivery to the Public Health specialty and SH informed the group of an upcoming event in September, building a research ready community event, that might be of interest. EM confirmed that she has already identified relevant attendees and passed on their details as requested.
- The group discussed the Lincolnshire Rural Healthcare initiative and how this will benefit research and patients. BM explained that there is a strong emphasis on targeting a service to meet patients needs in an area identified with deprivation.
- AF confirmed that they are content with the existing Hosting arrangement and are happy to continue. The group discussed the current geographic boundaries and AF and DR felt that they currently complement the clinical research boundaries.
- The group were pleased to hear that CRN East Midlands are very active within non-NHS settings. EM suggested that some recruitment to Public Health may be incorrectly aligned on the NIHR CRN Portfolio (for example, some patients from a care home setting are aligned with the Dementias and neurodegeneration specialty rather than Public health). EM advised that research activity takes place in HM Prison Nottingham, but there is room to develop other opportunities.
- The Risk Register was discussed and one 'red' issue identified has been previously discussed (Communications Lead role).
- We thanked the Senior Management team for their strong leadership. EM's contributions to national projects was noted and MC thanked her for her engagement at a national level working on CPMS/LPMS.

General points and themes for all LCRNs

I am pleased to confirm that all the LCRN Review meetings have now been completed and would like to share the following general points and themes that emerged from this series of meetings:

- 2017/18 was a record breaking year for the CRN with the highest number of new studies added to the NIHR CRN Portfolio, 99% of NHS Trusts recruiting participants into CRN studies and almost three quarters of a million participants (725,333) recruited into studies. A big thank you to all LCRN Hosts, Partner organisations and staff for their hard work and dedication in helping to improve patient care and increasing the opportunity for patients to take part in research. We look forward to an even better 2018/19.

- The importance of LCRNs executing Partner flow-down sub-contracts (Category A, B, C) was discussed at all of the meetings. Linked to this, we highlighted ongoing discussions with DHSC and NHS England regarding a new payment system for Excess Treatment Costs (ETCs) which will be applicable for all NIHR CRN Portfolio studies. Based on current plans, we expect that from 1 October 2018 CCG funding for ETCs will be routed through the CRN. We are in the process of working up the necessary operating arrangements, and will liaise closely with LCRN COOs throughout. At this stage, the key messages were:

- Category A/B/C contracts will need to be in place in order for ETC payments to be made to NHS providers
- CPMS will need to reflect accurate and timely recruitment from the LPMS feeds to enable ETC payments to be made
- LCRNs will need very shortly to estimate the additional costs of (1) AcoRD Specialist resource, and (2) contracts / payments resource.

Payments can only be made through the Category A, B, C contract framework so it is essential these are put in place as soon as possible with all research-active providers.

We shall be in contact with LCRN COOs regarding the additional costs that LCRN management teams will incur in providing this new service e.g. increased work for AcoRD Specialists.

We would emphasise that this was the current thinking at the time of the meetings, and is subject to change.

- It was helpful to have an update from all LCRNs regarding data completeness and data quality in their LPMS. We ask all LCRNs to maintain their efforts and focus to ensure that we are collectively ready for the 'go-live' of LPMS recruitment upload to CPMS by the end of 2018. Primary Care data collection is being tackled either from the LCRN central team entering data on behalf of the GPs or from the LCRN rolling out the LPMS to every research active practice.

- It was useful to hear from all LCRNs about their work to expand research into non-NHS settings and it is likely this topic will be picked up in a future CRNCC / LCRN Liaison meeting. It was evident that some LCRNs had embraced the new opportunities more fully than others and shared learning will be important.

- At all meetings we discussed response rates and feedback from the March 2018 LCRN Partner survey and the high degree of importance that is placed on this by DHSC. For the first time this year's annual survey was circulated by the CRNCC directly to LCRN Partnership Group members and various LCRNs suggested that response rates might be higher if advance notice was given to the Partnership Groups and if future surveys were circulated locally. We will be reconsidering the methodology and revisiting the questions and timelines for next year's survey.

- We noted details in LCRN annual reports of non-commercial studies that networks had been unable to support in 2017/18. As advised in LCRN Annual Report feedback letters we will follow-up in due course. We would like to remind all LCRNs of clause 5.3.6 Part C of the Performance and Operating Framework that states "where the LCRN or any LCRN Partner determines it cannot carry out the role set out in this policy [AcoRD guidance] for any 'high priority' CRN Portfolio study (as defined in the CRN Eligibility Criteria) on grounds other than non-feasibility, the LCRN must advise the National CRN Coordinating Centre in advance of communication of this decision to the investigator." In this event please email supportmystudy@nihr.ac.uk and mark your message 'FAO RDD leadership team' (Sarah Crawshaw, Laura Bousfield and Joanna Knee).

- Looking ahead to beyond March 2022 and the expected reprocurement of LCRN Host Organisations, we were interested to hear any local views on the current network configuration. If colleagues have additional views they wish to share, please let me know now, in writing, as soon as possible.

- In a number of meetings we discussed LCRNs' strategic funding initiatives. To inform wider discussions the CRNCC is having, and to take account of the interest of DHSC to collate

evidence of the impact of our activities, we would like to understand more about the outputs and returns on these investments, and will be in touch with the relevant LCRNs to find out more.

- At one of the meetings it was suggested that it might be helpful for us to develop a standard template for all LCRNs for reporting to Host Trust Boards. The CRNCC will explore this possibility and will consider in light of work to strengthen the assessment of research activity in CQC inspections of NHS organisations.

- There have been changes in the clinical research specialty leadership in many LCRNs and it is expected that robust induction, support and networking arrangements are in place. We are happy to provide some support in this area and to help facilitate sharing of practice. We would be interested to hear from any LCRN Chief Operating Officers who might like to get involved in this activity.

During the meeting challenges that would potentially impact on the ability of CRN East Midlands to deliver against the planned commitments set out in the LCRN Annual Delivery Plan 2018/19 were raised; however LCRN colleagues provides assurance that appropriate plans are in place to address these issues and challenges. Should you wish to discuss progress with colleagues in the CRNCC please do not hesitate to contact us for guidance or support, or speak with your CRNCC Link. Otherwise we will assume that the network remains on track to deliver against commitments documented in the Plan.

The CRNCC would like to thank you formally for the continuing leadership you provide for CRN East Midlands and we look forward to our next meeting with the team.

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

Yours sincerely

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

Cc: David Rowbotham, Clinical Director
Steve Ryder, Co-Clinical Director
Elizabeth Moss, Chief Operating Officer
Andrew Furlong, Medical Director, University Hospitals of Leicester NHS Trust (Host Nominated Executive Director)
Peter Miller, Chief Executive Officer, Leicester Partnership NHS Trust (Partnership Group Chair)
John Sitzia, Chief Operating Officer
Nick Lemoine, Medical Director
Matt Cooper, Business Development & Marketing Director / Research Delivery Director
Susan Hamer, Director of Nursing, Learning & Organisational Development
Imogen Shillito, Stakeholder Engagement & Communications Director
Chris King, Deputy Chief Information Officer (SMT Link)
Amber O'Malley, Head of Performance Management
CRNCC Senior Management Team

Actions

Item	Action	Owner
EM17	IS and BM to have a follow up call to discuss Communications resource	Imogen Shillito
EM18	AF to keep JS informed of any resolution to the Host's delay in paying invoices notably from Primary care settings	Andrew Furlong
EM19	JPS agreed to send further details to BM on the work in progress for an 'app' for clinicians to access study information and discuss with patients in a real time setting	Jonathan Sheffield
EM20	JS to discuss with Amber O'Malley an alternative approach to distribution of the LCRN Partner Survey (i.e. shared locally by people the audience knows)	John Sitzia

Appendix 5 - Risk Register

NIHR Clinical Research Network East Midlands - Risk Register

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**	**Risk status (open or closed date)**	**Trend** (since last reviewed)
R031	Services	Jan-18	COO	Reduced capacity of Communications function meaning full comms plan will be impacted on	**Cause:** Post holder was unwell, away long-term and not returning to work. Cover arrangements ceased and we are currently unable to undertake any new work, and are struggling to meet our Comms requirements within the POF. **Effect:** Will affect comms plans for 2018-19, also the further delay to reappointing is extending this problem.	5	2	10	Q1/2 2018-19	Working with Host HR to seek a swift resolution as post holder has now notified their intent not to return, keen to readvertise asap	COO	5	Open	Decreased
										Appoint new Communications & Engagement Lead	COO	5		
										Appoint new Business Delivery Operations Manager, who will provide oversight of comms function	COO	5		
										Prioritise key deliverables for this year with input from Comms Lead	COO	4		
										Establish regional 'Engagement Group' and operational 'Communications & PPIE Working Group' to support and deliver comms plans	COO	4		
R032	Reputational	Jan-18	COO	Budget reductions of up to 8% for some Partner organisations will be difficult to manage	**Cause:** Relatively poor performance & desire by CRNEM to have stabilised budgets & move towards fair share based on activity. **Effect:** Reputational risk to CRN and will present a challenge locally to ensure we are supporting these organisations and populations sufficiently. This could result in local Partners having insufficient funding to fund their workforce, leading to potential redundancies.	4	3	12	Q1/2 2018-19	Work closely with Partners via their STLs and consider how to ensure PO R&D colleagues are suitably empowered to act	STLs	4	Open	Static
										In some cases, COO & CD to meet with senior staff in these organisations e.g. ULH Medical Director etc.	COO & CD	4		
										Provide support to Partners with managing their budget and prioritising where to invest their CRN funding etc.	COO & DCOO	4		
										Add item for next Partnership Group meeting to discuss flexible approach to budget management	COO & DCOO	4		
										STLs to have meetings with all Partners who are showing significant vacancy factors at end of Q2 and ensure there is a plan of action to meet this with support of CRN.	STLs, COO &DCOO	1		
R036	Performance	May-18	COO	CRN EM will not deliver against HLO1 target for 2018-19 (total number of participants recruited) Currently at 93% of YTD target with 16,071 recruits (annual target: 52,000)	**Cause:** Reduced portfolio pipeline across specialties, current analysis of forecast activity suggests recruitment of 42,000, however target stands at 52,000, need to identify opportunities to bridge this gap. **Effect:** Impact on future budget i.e. reduction in future years also reputational impact for EM slipping down national league tables and appearing less attractive to CIs to place studies if performance drops off.	3	3	9	Mar-19	Work with all specialties to ensure they reach their potential, and look to stretch all specialties/Divisions through the year	COO, RDMs, CLs	4	Open	Static
										Seek opportunities to work with new providers, especially across Public Health, Social care and a range of health settings	COO, RDMs	3		
										Continued focus on HLO2 performance to ensure we get maximum efficiency from current portfolio	COO, RDMs	4		
										Further analysis of current portfolio, three months post AP submission to look for any growth in specialties for year ahead	DCOO/ RDMs	3		
										Review at Q2 to ensure that forecast is accurate	DCOO/ RDMs	1		
R037	Performance	May-18	COO	CRN EM will not deliver against HLO4 target for 2018-19 (time taken to achieve study set up in the NHS) Currently 82% (target: 80%)	**Cause:** The timelines for study set up under HLO4 have not, historically, aligned well with the timelines our Partners are working to. Some elements of the achievement of HLO4 (HRA AAC) are outside of CRN direct control; additionally we are reliant on partners for the provision of this data, which creates some delay in the recording of this metric. It is expected that this metric will change from 2019-20.	3	3	9	Mar-19	Continue to educate Partners about importance of collecting data for HLO4&5 with renewed focus now that 70 day reporting is removed from PID, this is a great opportunity	IOM & SSSOM	5	Open	Decreased
										Work to improve our data quality to ensure where we are achieving this, it is correctly recorded	IOM & SSSOM	5		

					Effect: Recorded by the NIHR CRNCC as underperformance against a HLO measure, thus non-compliance with the contract. Potential reputational risk with Sponsors/CIs. At present there is no financial impact. This area is something which will be considered nationally, as this is a concern from all CRNs.					Undertake some work with SSSOM to unpick the recording of this and the below data points and look for improvements	DCOO/ SSSOM	5		
										Work with the CRNCC to advise on potential changes to this measure and develop a targeted comms plan with clear approach focussing on HLO4	COO/ DCOO	1		
										Potential to include incentive on HLO4 attainment at partner level - conduct budget modelling around this	COO/ DCOO	1		
										Include article in autumn newsletter to raise awareness of HLO4	Comms	1		
R038	Performance	May-18	COO	CRN EM will not deliver against HLO5 targets for 2018-19 (time taken to recruit first participant into studies) 5A: currently 57% (target: 80%) 5B: currently 58% (target: 80%)	**Cause:** The timelines for HLO5 have not, historically, aligned well with the timelines our Partners are working to. The starting point for this metric (HRA AAC process) is largely outside of CRN direct control and from a trust perspective is only one element of the 70 days process they are managed against. This creates an element of ambiguity in reporting and relative priority at trust and CRN level. It is expected that this metric will change from 2019-20. Also there is a lack of evidence that attainment of HLO5 is a clear indicator of high performance in research. **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. 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.	4	2	8	Mar-19	Continue to educate Partners about importance of collecting data for HLO4&5 with renewed focus now that 70 day reporting is removed from PID, this is great opportunity	IOM & SSSOM	4	Open	Decreased
										See above re. working with SSSOM around data points	DCOO/ SSSOM	5		
										Detailed analysis of reasons for not attaining this, identify trends and implement relevant corrective actions	IOM / SSOM	4		
										The continued focus on HLO2A/B (though TnT campaign) should drive behaviours to improve HLO5A/B	DCOO/ Comms	4		
R039	Information	May-18	DCOO	Insufficient level of data quality and completeness in LPMS for primary care research activity (RA)	**Cause:** Lack of awareness/training, capacity of staff and understanding of a process change. **Effect:** Reduction in accuracy of performance monitoring & reporting. Effect on budget planning & management, could lead to poor decision making or inability to make informed decisions. Also reputational impact if the current primary care RA data does not improve.	2	3	6	Q2/3 2018-19	Implementation of Data Quality Strategy (incl. ongoing MDS project)	COO/ DCOO	4	Open	Static
										Focus on primary care data with CRN team, able to influence this, need a tailored approach to primary care	Div 5 RDM & OM	4		
										Working with partners to improve their understanding and will employ a training and communications package to support LPMS users	DCOO/ BI Prog. Manager	4		
R040	Performance	Sept-18	IOM	CRN EM will not deliver against HLO2A target for 2018-19 (proportion of commercial studies delivering to time & target) Currently 71% (target: 80%). forecast c.73%	**Cause:** Multi-factoral - increased number of small target studies; some changes in the central management approach; some local staffing related matters and the impact of study performance/approach within one partner organisation. **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. Damage to East Midlands reputation and impact upon loss of future commercial contract research for the region. Also impacts upon future CRN budget - reduction in performance premium generated from time & target performance. Additionally this may impact on any future RCF for trusts.	4	3	12	Mar-19	Increase frequency of performance review meetings	IOM	4	Open	New
										Intend to establish a recovery plan to address these issues with clear actions	PM	1		
										Targeting studies at NUH with support from R&D Director/Co-CD	Co-CD	1		
										Reviewing staffing in the CRN to understand if we need to appointment staff or re-prioritise current staff	IOM	1		
R041	Performance	Sept-18	COO	Uncertainty around national process change for management of Excess Treatment Costs (ETCs) may cause delays in study set up and delivery	**Cause:** National change to process for management of ETCs following NHS England consultation. Pilot will be trialled from 1 Oct 18 - 1 Apr 19 with LCRNs undertaking attribution AND costing works, and processing payments to partners. **Effect:** There is likely to be additional work for CRN to manage ETC process; also a lack of clarity around role and expectations. Potential delays to study set-up and recruitment, which could have negative impact on performance for several HLOs.	3	3	9	Q3/4 2018-19	Undertake process mapping work with a view to establishing regional process for managing ETCs.	DCOO/ SSSOM	1	Open	New
										Train CRN staff, use of SoECAT template CCAT costing tool - plan how we use this	DCOO / SSSOM	1		
										Ensure any updates are clearly communicated to Partners, R&D and provide signposting for researchers to Early Contact Service for information	COO / DCOO / SSSOM	4		

R042	Performance	Sept-18	IOM	CRN EM will not deliver against HLO6B target for 2018-19 (proportion of NHS Trusts recruiting into commercial NIHR studies) Currently 44% (target: 70%)	**Cause:** Reduced pipeline of commercial dementia and mental health studies suitable for our Healthcare & Partnership Trusts **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. Potential reputational risk. At present there is no financial impact.	4	2	8	Mar-19	Review pipeline for potential studies in mental health and dementia	IOM	4	Open	New
										Support set-up of existing studies at applicable Trusts	IOM	4		
										Raise at Division 4 Steering Group	Div 4 RDM	4		
R043	Performance	Sept-18	Div 5 RDM	CRN EM will not deliver against HLO6C target for 2018-19 (proportion of General Medical Practices recruiting into NIHR studies) Currently 23% (target: 45%)	**Cause:** This is due in part to a reduced pipeline of studies (availability), however is also impacted upon by GDPR regulations, as we are required to ensure all non-contracted practices are willing to receive expressions of interest in relation to research studies, when previously we would have circulated more widely. **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. Potential reputational risk. At present there is no financial impact.	4	2	8	Mar-19	Channel additional resource into this area to ensure EoIs can be received, by further work re GDPR compliance/prcatice confirmation	Div 5 RDM	4	Open	New
										Develop relationships with new practices	Div 5 RDM	4		
										Regional Primary Care Research Conference scheduled for 27.9.18 for further engagement opportunity	Div 5 RDM	1		
R044	Performance	Sept-18	Div 4 RDM	CRN EM will not deliver against HLO7 target for 2018-19 (number of participants recruited into Dementias and Neurodegeneration NIHR studies) Currently at 66% of YTD target with 278 recruits (annual target: 1,510)	**Cause:** Reduced pipeline of portfolio dementia studies, high recruiting studies have closed. **Effect:** Recorded by the NIHR CRNCC as underperformance against a HLO measure. 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.	4	2	8	Mar-19	Scope pipeline for potential studies open to new sites	Div 4 RDM & OM	4	Open	New
										As this is a national issue, SL to raise concerns to national group	Dementia SL	1		
										Raise and review issue at Division 4 Steering Group	Div 4 RDM	1		
R035	Performance	Mar-18	COO	Recognition that few Partner B & C contracts have been executed, and a need to action this, in order to be fully compliant with the Host contract, which will be difficult to manage and a significant workload	**Cause:** Host contract requirement to put in place contracts for all Category B & C Partners (i.e. all organisations in receipt of any level of NIHR funding). This will affect up to 300 GP sites, several hundred dental practices, pharmacists and other stakeholders, some in receipt of under £100 PA. **Effect:** Performance risk due to this being an area of non-compliance presently, also reputational risk to CRN, may deter organisations from conducting research due to additional bureaucracy.	2	2	4	Q1/2 2018-19	Review work programme for managing and monitoring contracts in line with POF	COO/ PM	5	Closed	Decreased
										Increase resource available to this area of compliance to ensure requirements are met	COO/ PM	4		
										Implement any recommendations/actions associated with review of work programme	COO/ PM	5		
										Establish process for managing and monitoring contracts including alignment with Finance team processes	PM/ Finance	5		
										Appoint Contracts & Compliance Officer to support this work programme	COO/ PM	4		

SCORING:

	IMPACT				
PROBABILITY	**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**