

<b>Meeting title:</b>	UHL Public Trust Board	<b>Public Trust Board paper O</b>
<b>Date of the meeting:</b>	8 June 2023	
<b>Title:</b>	CRN East Midlands Quarterly Board Report	
<b>Report presented by:</b>	D Barnes, Deputy Medical Director, E Moss, Chief Operating Officer, CRN East Midlands and A Farooqi, Clinical Director, CRN East Midlands	
<b>Report written by:</b>	Elizabeth Moss, Chief Operating Officer, CRN East Midlands and Carl Sheppard, Host Project Manager, CRN East Midlands	

<b>Action – this paper is for:</b>	Decision/Approval		Assurance	x	Update	x
<b>Where this report has been discussed previously</b>	CRN East Midlands Executive Group on 18 May 2023.					

**To your knowledge, does the report provide assurance or mitigate any significant risks? If yes, please detail which**

The purpose of the report is to provide assurance against the CRN Host Contract. The report does not relate to any significant risks.

**Impact assessment**

The current CRN Host Contract will be extended by six months to 30 September 2024. UHL has submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN) from October 2024. The successful applicant has been notified and a formal announcement is expected in due course.

**Acronyms used:**

CRNCC - NIHR CRN Coordinating Centre  
 CRN - Clinical Research Network  
 CRP - Clinical Research Practitioner  
 DHSC - Department of Health and Social Care  
 LCRN - Local Clinical Research Network  
 NCVR - National Contract Value Review  
 NIHR - National Institute for Health and Care Research  
 HRA - Health Research Authority  
 RDN - Research Delivery Network  
 RRDN - Regional Research Delivery Network  
 HLOs - CRN High Level Objectives

**Purpose of the Report**

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

## **Recommendation**

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

## **Summary**

This report provides a further update on the arrangements for the future hosting of the East Midlands RRDN, a summary of our Dental Practice Research Scheme, an update on the LCRN Partner Satisfaction Survey and details of a national review of the UK commercial clinical trials landscape. The report also includes information pertaining to our 2022/23 financial outturn and year-end position for the 2022/23 CRN High Level Objectives (HLOs).

On the CRN risk register, the two risks (#63 & #64) related to the expiry of the Host contract in March 2024 have been closed as the Host contract will be extended by six months (to 30 September 2024). A new risk (#65) has been added, which states that uncertainty around the future arrangements of the Network (as it transitions to the RRDN) could negatively impact planning and performance of the CRN. A lack of clarity around managing a six-month budget is also contributing to this risk. We are communicating regular updates to staff and partner organisations and will work closely with the CRN Coordinating Centre, Host organisation and recently appointed Transition Lead to manage the transition arrangements. This risk has been scored as possible with moderate impact giving an overall medium risk rating.

On the CRN issue register, issue #07 which related to concerns around our regional performance, has been closed as our performance at year-end improved significantly. Issue #08 relates to current challenges associated with commercial research performance nationally. This issue remains rated as high priority with moderate severity. Locally we continue to take a number of actions to support this as set out on the issue register.

## **Main report detail**

### **1. Current priorities and progress**

#### **i) Reconfiguration of the Network**

In 2024 the NIHR Clinical Research Network will become the NIHR Research Delivery Network (RDN). In December 2022, UHL submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN). There have been some unforeseen delays in the approvals for the procurement of the national Research Delivery Network Coordinating Centre (RDNCC), which has affected the timelines for formally announcing the new regional Host organisations. Consequently, the current Host Organisation contract will be extended by six months to 30 September 2024 and the new RRDN contracts will commence from 1 October 2024. This will allow more time for RDN services to be co-created with current LCRN and Coordinating Centre staff. This extension will also provide additional time for transition from LCRNs to RRDNs for current and future host organisations and our staff.

#### **ii) Dental Practice Research Scheme**

During 2021/22, CRN East Midlands conducted a Community Dental Practice Research pilot involving 11 dental practices. The aim of this pilot was to develop the research infrastructure in primary dental care in the Derbyshire region whilst gathering feedback on challenges that the participating practices face when carrying out research. It is recognised that there is a lack of research in dentistry, especially in primary care so this is an area the CRN is keen to support.

The pilot demonstrated excellent engagement with practices and the findings have been used to set up a more extensive scheme for 2023/24, with 23 practices participating. The Dental Practice Research Scheme will support the delivery of NIHR portfolio research studies and associated activities at dental practice sites in the East Midlands. This work is being supported by the CRN East Midlands Oral and Dental Specialty Lead and two Primary Care Dental Research Champions.

### iii) **LCRN Partner Satisfaction Survey**

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

The survey was circulated to partners on 11 January 2023 and we are pleased to report 100% compliance for partners completing the survey. We are still waiting for the formal feedback that will be provided in a qualitative and quantitative format as in previous years.

### iv) **Commercial clinical trials landscape**

The government has appointed Lord James O'Shaughnessy, Senior Partner at consultancy firm Newmarket Strategy, Board Member of Health Data Research UK (HDR UK), and former Health Minister, to conduct an independent review into the UK commercial clinical trials landscape. The review will offer recommendations on how commercial clinical trials can help the life sciences sector unlock UK growth and investment opportunities. This will also advise on how to resolve key challenges in conducting commercial clinical trials in the UK. Publication of the review is expected soon and the findings are likely to inform further plans to support the delivery of commercial research in the UK. In the East Midlands we will respond accordingly to support any activities arising from the national plan. This is linked to Issue #07 in section 5 of this report.

## 2. **Financial Position**

Our latest Host finance report is attached at Appendix 1. This report provides an update on our 2022/23 year outturn position compared to annual budget along with a summary of any significant variances.

## 3. **Performance**

Within the Performance and Operating Framework for the CRN, there are a range of performance expectations across all areas of work, including the High Level Objectives (HLOs). The HLOs are nationally set objectives for the Clinical Research Network relating to research delivery. The HLOs for 2022/23 are set out in the table below. With the exception of the PRES local ambition, all HLOs are measured at CRN-wide (national) level, however, the Network is keen to show our regional contribution to these national metrics. The below table details our year-end position in relation to these metrics (data cut 21/4/2023).

Objective		Measure	National ambition	East Midlands data (year-end)
Efficient Study Delivery (ESD)	Deliver NIHR CRN Portfolio studies to recruitment target	Percentage of <u>closed</u> to recruitment commercial contract studies which have achieved their recruitment target	80%	93%
		Percentage of <u>closed</u> to recruitment non-commercial studies which have achieved their recruitment target	80%	87%
		<b>(NEW)</b> Percentage of <u>open</u> to recruitment commercial contract studies which are predicted to achieve their recruitment target	60%	65%
		<b>(NEW)</b> Percentage of <u>open</u> to recruitment non-commercial studies which are predicted to achieve their recruitment target	60%	61%
Provider Participation (PP)	Widen participation in research by enabling the involvement of a range of health and social care providers	Percentage of General Medical Practices with recruitment in NIHR CRN Portfolio studies	45%	51%
		Percentage of NHS Acute trusts with recruitment in NIHR CRN Portfolio studies every quarter	99%	100%
		Percentage of NHS Acute trusts with recruitment in commercial contract NIHR CRN Portfolio studies every quarter	70%	75%
		Percentage of NHS Ambulance, Care and Mental Health trusts with recruitment in NIHR CRN Portfolio studies every quarter	95%	100%
Participant Experience (PE)	Demonstrate to participants in NIHR CRN supported research that their contribution is valued through collecting their feedback and using this to inform improvement in research delivery	Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey (PRES)	1,344 (local) 14,000 (national)	1,703

Expanding our work with the life sciences industry to improve health and economic prosperity (ELS)	Sustain or grow commercial contract research	Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total MHRA CT approvals for PHASE II-IV studies	75%	Not locally applicable
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With respect to the data in the above table, we can provide the following supporting commentary:

- We have met the national ambition for the percentage of closed lead studies achieving their recruitment target for both commercial and non-commercial studies, which is a great achievement. Note, these measures only relate to a small sample size (14 commercial studies and 54 non-commercial studies) so are not representative of our performance more broadly.
- For the new Efficient Study Delivery (ESD) measure for percentage of open studies which are predicted to achieve their recruitment target, at year-end we are above the ambition (60%) for both commercial and non-commercial studies. There is now an additional goal of 80% of open commercial studies, nationally, to achieve this target by the end of June 2023, we are currently on track to achieve this locally.
- In the East Midlands, 51% of GP practices are research active against the ambition of 45% at year-end. This is a fantastic achievement and demonstrates continued progress of delivering research within primary care settings in the East Midlands.
- For the percentage of NHS Acute trusts with recruitment in commercial contract NIHR CRN Portfolio studies, our contribution is 75%, which is above the national ambition of 70%.
- We have also exceeded our local target for responses to the Participant Research Experience Survey (PRES). This is another excellent achievement and reflects the hard work of many colleagues across the region. This is important as the survey captures participants' views of their experience of taking part in research and demonstrates that we value their contribution.

Although no longer a formal HLO, our total year-end recruitment is 62,870 participants. This is a significant improvement from our mid-year position, where we had only recruited around 20,000 participants and were forecasting year-end recruitment of around 40,000. Also, we finished the year 8th position out of 15 regional Networks, which is an improvement from our mid-year position of 11th.

Overall, this data demonstrates very strong performance at year-end with all our local contributions for the HLOs meeting or surpassing the national ambition. A significant amount of work was undertaken to address some of the concerns we identified earlier in the year and we would like to thank our colleagues and Partner Organisations for their support.

#### 4. CRN East Midlands Highlight Report 2022/23

In relation to annual reporting, we were required to produce a one-page Highlight Report (similar to last year), which forms part of the 2022/23 CRN Annual Report to DHSC. Our Highlight Report was submitted to the CRN Coordinating Centre on 20 April 2023 and will be shared with the CRN Partnership Group on 8 June 2023. The report focuses on our contribution to the NIHR Research Reset programme, Life Sciences Industry and other local initiatives. The Highlight Report is attached at Appendix 2 for the information of the Board. The Trust Board is not required to approve this report.

## 5. Risks & Issues

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

- Risk #063 - The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for Partner organisations; this could make it difficult to re-appoint to vacant posts on a short-term basis. This risk has been closed and is superseded by Risk #065 due to changes to the Host contract period.
- Risk #064 - The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for roles within the CRN Core team (management & support staff). This risk has been closed and is superseded by Risk #065 due to changes to the Host contract period.
- Risk #065 (New) - Uncertainty around the future arrangements of the Network (as it transitions to the RRDN) could negatively impact planning and performance of the CRN. The current Host CRN contract has been extended by six months to 30 September 2024, prior to formation of a new Regional Research Delivery Network on 1 October 2024. This creates some risk due to a lack of clarity around managing a six-month budget. We are communicating regular updates to staff and partner organisations and will work closely with the Host and recently appointed Transition Lead to manage the transition arrangements. We will also seek advice from the CRN Coordinating Centre regarding the management of the six-month budget. This risk has been scored as possible with moderate impact giving an overall medium risk rating.
- Issue #07 - CRN EM performance for delivery of NIHR studies has decreased over the last 18 months. This could negatively affect HLOs and have a reputational impact which could lead to reduced opportunities for people to participate in research in the East Midlands. This issue has been closed at year-end as our performance has improved significantly due to a number of steps taken during 2022/23.
- Issue #08 - Current challenges associated with commercial research performance nationally. There are concerns around study set-up times, participant recruitment and the future pipeline of commercial studies entering the NIHR portfolio and being delivered across the UK. Another element contributing to delays is a backlog in MHRA approvals. Although a large batch of studies has recently been approved by the MHRA, this has caused challenges due to the increased workload with an expectation to set up these studies quickly. This issue remains a national priority and locally we continue to take a number of actions to support this as set out on the issues register. This issue is still rated as high priority with moderate severity.

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

- Elizabeth Moss, Chief Operating Officer, [elizabeth.moss@nihr.ac.uk](mailto:elizabeth.moss@nihr.ac.uk) or
- Professor Azhar Farooqi OBE, Clinical Director, [azhar.farooqi@nhs.net](mailto:azhar.farooqi@nhs.net) or
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- Carl Sheppard, Host Project Manager, [carl.sheppard@nihr.ac.uk](mailto:carl.sheppard@nihr.ac.uk)

**Supporting documentation**

- Appendix 1 – Finance Update Report
- Appendix 2 – CRN East Midlands Highlight Report 2022/23
- Appendix 3 – Risks & Issues Register

## UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE GROUP

DATE: 18<sup>th</sup> May 2023 REPORTFROM: MAHENDRA WADHWANA - HOST FINANCE LEAD & PARITA YADAV –FINANCE  
BUSINESS PARTNER

SUBJECT: CRN EM FINANCE UPDATE: 22/23 Outturn Summary

**1. Purpose**

This report provides an update on the following issues

22/23 year outturn position compared to annual budget along with a summary of any significant variances.

**2. Outturn 3 22/23 Outturn**

The table below summarises the previous financial year, 2022/23, and year end position.

2022/23	Annual Plan	Forecast @ Q3	Outturn	Variance Plan to Outturn (Under)/Overspend	Annual
	£'000		£'000		£'000
<b>Income</b>					
NIHR Allocation	23,273	24,011	24,583		1,310
<b>Expenditure</b>					
Network Wider Team	600	551	536	(65)	
Host Services	367	366	370	3	
Management Team	975	946	936	(40)	
Study Support Service (SSS) Team	508	504	492	(16)	
DDT Central Team	483	424	428	(55)	
CRN EM CLINICAL & SG LEADS	188	177	176	(12)	
NON PAY NON STAFF	229	264	254	25	
PRIMARY CARE SSC	75	90	122	47	
CRN EM DDT TRANSFORMATION	477	468	467	(10)	
CRN EM TRANSFORMATION NON DDT	279	300	279	0	
CRN EM PUBLIC HEALTH	77	77	75	(3)	
CRN EM ADDITIONAL FUNDING	693	624	613	(80)	
UNDERSERVED COMMUNITIES	462	442	439	(23)	
Partner Organisation Infrastructure	16,978	17,463	17,602	625	
CRN EM RSJ	882	898	881	(1)	
ETC costs (pass through)	0	346	915	915	
Balancing CC	0	71	0	0	
<b>Total</b>	<b>23,273</b>	<b>24,011</b>	<b>24,583</b>		<b>1,310</b>



## **Main points to note:**

### **Overall**

The outturn position is an overall favourable variance of £1.3m compared to the original plan. This is due to additional income received during the year, not reflected in the original plan, most significantly for pay inflation and excess treatment costs. At Q3 actual spend was behind a straight line profile but in line with plans for additional investments through strategic funding and supporting new requests have ensured the outturn has delivered in line with forecasts and funding available.

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

### **Income**

The £1.3m favourable variance to plan primarily relates pay inflation and excess treatment costs (ETC) income pass through payments: additional income for AfC pay uplift £354k and £915K for ETC payments which are passed onto partner organisations.

### **Network Wider Team**

Favourable variance of £65k largely due to vacant posts and slippage in recruitment.

### **Direct Delivery team (DDT Central Team)**

Favourable pay variance is £55k. As reported at Q3, the DDT team has undergone a planned period of expansion, to meet increasing delivery of studies both within and outside of the NHS environment. There have been several challenges in managing and recruiting to the DDT Team - difficulties in recruiting to new posts, variation in WTE, slippage due to leavers and new starters.

### **Additional Funding**

Variance of £80k related to delays and slippage in appointments and delays in starting the projects, or the changes in nature of the bids.

### **Partner Organisation Infrastructure**

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

## **3. Other Issues/Updates**

### **Finance Team Capacity**

It is also worth noting that the last quarter of the year the finance team had capacity issues but despite the difficulties managed to deliver to month end and year end reporting deadlines.

### **Capital Funding Bid**

As reported at Q3, partner organisations were invited to bid for a host led NIHR capital funding call that had a limit of £5m of which up to 20% of the funding for LCRN partners. The bid included approximately £940k for partner organisations. Outcome of the bid was expected in March 23 but this has been delayed.

#### **4. Recommendations**

The CRN Executive Committee is asked to:

- Note the 22/23 outturn position

### CRN East Midlands Highlight Report 2022/23

#### Reset

The CRN took a supportive role in Reset, initially assisting the data cleansing phase, working closely with regional stakeholders to improve data quality and accuracy. We promoted the use of the HRA fast-track ethics review, where appropriate, and actively encouraged and supported regional Sponsor and Funder engagement with the intentions process, including those encountering app difficulties. In December 2022 we opened a targeted funding call to allow organisations to focus on both the set-up and delivery of studies which had been already committed to, with a clear focus on commercial contract research. Throughout Q4 we have also continued close dialogue with partners in relation to Reset studies, including the placement of our agile workforce, where this was likely to see a positive impact.

#### Life Sciences Industry

- 100% acceptance to the NCVR roll out, across all organisations in the region
- Further development of the Performance Review Lead role, where East Midlands is the Lead site for commercial studies, resulting in success in time to target 93% (closed) and 65% (open) studies
- Strong focus to achieve 3 UK First and 1 Global First patient into NIHR commercial trials
- Further focussed on developing commercial research in Community & Mental Health Trusts, this has increased the number of EOIs in this sector, and resulted in a UK first patient in a Mental Health Trust
- Established a Primary Care Commercial group which has delivered a collaborative site for the Harmonie study (CPMS 51978) between an acute trial (Sherwood Forest) and GP site (Brierley Park)

#### Local Initiatives

Transformation/working across new settings:

- Undertaken a Dental Research Pilot scheme, findings presented which demonstrated excellent engagement with practices and has been used to set up a more extensive scheme for 2023/24
- Led work to develop a resource which shares details on under-served investments across all LCRNs to aid collaboration; this has also led specifically to an event (& planned second event) focussed on Learning Disabilities research and communities
- Delivered NIHR portfolio research in many new settings, including: Schools, Local Authorities (fostering services), Health and Social Centres, Hospices and Care Homes
- The East Midlands successfully led the first study to use the new [Be Part of Research service](#), this oral and dental study (CPMS 53482) recruited 3,593 across 6 LCRNs, with 1,486 in region

Delivered well attended events and initiatives to further stimulate and grow research:

- Successful launch event of the agile Direct Delivery Team, to promote awareness across settings
- First CRN [East Midlands Palliative care event](#) showcasing and future planning research in this essential and expanding area, includes a powerful research participant [video](#).
- Dermatology Research Event, aimed at engaging those new to research
- Prostate Cancer Awareness Event, engaging with the African Caribbean community, to aid early identification and treatment; also to raise awareness of the STAMPEDE 2 trial.
- Delivery of a very well attended East Midlands Regional Primary care Conference
- First Dementia Research event aimed at those new to research, to showcase and enthuse
- Developed and launched Research Scholars programme, appointing the first 5 Scholars across various professions: ACP, Physio, Consultant Physician, Health Services Researcher and GP
- Ongoing promotion of CRP Directory & Register, with highest regional uptake in East Midlands
- Supranetwork investment to prepare researchers to work in [wider care and community settings](#)

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

PRE-RESPONSE (INHERENT)										POST-RESPONSE (RESIDUAL)							
Risk ID	Primary category	Date raised	Risk owner	Risk Description (event)	Risk Cause and Effect	Probability	Impact	Value (Pxl)	Proximity	Response Actions	Action owner(s)	Action status	Probability	Impact	Value (Pxl)	Risk status (open or closed date)	Trend (since last reviewed)
R063	Performance	July-22	COO	The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for Partner organisations; this could make it difficult to re-appoint to vacant posts on a short-term basis.	<b>Cause:</b> Host contract expires on 31 March 2024, some organisations may have different approaches to risk, impacting re-appointment of research delivery posts; thus vacancies in the region could increase. <b>Effect:</b> Reduced workforce capacity could impact on ability to deliver all elements of POF and Partner Contracts, this could impact research delivery differently across the region.	3	3	9	April 2023	Communicate future state wrt Research Delivery Network with all partner organisation, HR and R&D teams, to instill confidence for research delivery posts to continue plans	COO and STLs	5	2	3	6	Closed 21.4.23	Decreased
										Ensure posts are advertised as promptly as possible	Senior team / line managers	4					
										Any concerns from partners to be escalated to leadership team, and discussed directly with PO	STL/ Leadership team	1					
										Feedback to be provided and advice to be sought from NIHR CRN CC as required	COO/CD	4					
										Consider appointing joint posts with CRN West Midlands	COO	4					
										Once RRDN Host has been confirmed (Feb 23), begin dialogue as to providing appropriate assurances to Partners	COO	1					
R064	Performance	Nov-22	COO	The CRN Host contract is due to expire in March 2024, which introduces some uncertainty for roles within the CRN Core team (management & support staff)	<b>Cause:</b> Host contract expires on 31 March 2024, which could cause uncertainty around future roles due to a perceived lack of job security. <b>Effect:</b> Experienced staff could leave their posts; there could be difficulties in re-appointing to vacant posts on a short-term basis. This may impact on ability to deliver all elements of POF and Host Contract.	3	3	9	April 2023	Communicate regular updates to staff in relation to future Hosting arrangements and RRDN	COO	4	3	3	9	Closed 21.4.23	Static
										Any concerns from staff to be escalated to leadership team, and discussed directly with staff	Leadership team	4					
										Feedback to be provided and advice to be sought from NIHR CRN CC as required	COO/CD	4					
										Once RRDN Host has been confirmed (Feb 23), begin dialogue as to providing appropriate assurances to LCRN Core team staff	COO	1					
R065	Performance	Apr-23	COO	Uncertainty around the future arrangements of the Network (as it transitions from the LCRN to the RRDN) could negatively impact planning and performance	<b>Cause:</b> Current Host contract has been extended by six months to 30 September 2024 prior to formation of new Regional Research Delivery Network on 1 October 2024. <b>Effect:</b> Lack of clarity around future six-month budget makes planning challenging, potential instability/anxiousness amongst staff, performance goals could be negatively affected as we can only plan on a short-term basis.	3	3	9	April 2024	Communicate regular updates to staff in relation to future Hosting arrangements and RRDN	COO	4	3	3	9	Open	New
										Any concerns from staff to be escalated to leadership team, and discussed directly with staff	Leadership team	4					
										Transition Lead starting in July to support the transition from the current LCRN to the new RRDN arrangements. The lead will work with POs to support this process.	COO/ Transition Lead	1					
										Work with Host to support transition to the RRDN	COO	1					
										Seek advice from CRNCC about managing six-month budget and communicate this to POs	COO	1					

**SCORING:**

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

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

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

**Action RAG Status Key:**

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

## CRN East Midlands Issues Register

Date last reviewed: 18.5.2023

Issue ID	Issue Type	Date Raised	Owner	Description	Severity	Priority	Actions	Action Owners	Action status	Issue status
I07	Performance	Oct-22	COO	<p>CRN EM performance for delivery of NIHR studies has decreased over the last 18 months. This could negatively affect HLOs and have a reputational impact which could lead to reduced opportunities for people to participate in research in the East Midlands.</p> <p><b>Cause:</b> Workforce fatigue &amp; capacity, reduction in high recruiting studies, service pressures, remaining Covid research activity (e.g. follow up), grants “gap” resulting in fewer new studies entering the Portfolio.</p> <p><b>Effect:</b> Reduction in overall volume of participants recruited into NIHR studies, not meeting expected contribution to 'Effective Study Delivery' HLO and negative reputational impact. Potential impact on future research activity in the region.</p>	Moderate	Medium	Meet with Partner R&D teams to review performance	STLs	4	Closed 21.4.23
							Undertake SWOT analysis to understand strengths & weaknesses of regional research portfolio and opportunities for improvements	IOM/RDMs/ROMs	5	
							Identify 3-4 workstreams with T&F groups to address specific performance areas	COO	4	
							Share lists of existing studies which are performing better in other regions, but are open in our region at present	IOM	5	
							Develop app with performance data and share with POs to help review ongoing performance, and use as management tool	IOM	5	
							Discuss performance as part of recently re-instated annual PO review meetings	COO/DCOO/STL	4	
I08	Services	Jan-23	COO / IOM	<p>There are challenges at a national level with respect to commercial research activity in the UK, due to a range of reasons including pressures on the NHS &amp; reduced workforce capacity. This is having an impact on study set-up times, participant recruitment and the future pipeline of commercial studies. This could have a reputational impact on the UK for attracting future commercial research. This is a concern as the East Midlands is part of a national network, and needs to ensure our part is played in improving this situation. Backlog of MHRA approvals is also having an impact in setting up studies.</p>	Moderate	High	Meet with Partner R&D teams to review performance	STLs	4	Open
							Initiated a Targeted Funding call in December - focused on commercial study set-up	COO/IOM	5	
							Explore primary care settings to increase delivery of commercial studies	IOM/Div 2 RDM	4	
							Support national Moderna vaccine UK deal, when it commences	IOM/STLs	1	
							Discuss performance as part of recently re-instated annual PO review meetings. Focus on study set-up timelines and encourage close collaboration with study sponsors to address any issues/delays	COO/DCOO/STL/IOM	4	
							Implementation of National Contract Value Review (NCVR) process to increase study set-up times by standardising costings (100% of NHS Trusts in East Midlands are compliant with use of NCVR)	IOM	4	
							Performance Review Lead role given increased focus and oversight of all commercial lead studies performance, supports with early engagement to identify barriers/enablers to study delivery	IOM	4	

**Key**

Severity	Priority
Minor	Low
Moderate	Medium
Major	High
Catastrophic	Critical

**Action RAG Status Key:**

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