

## CRN East Midlands Quarterly Board Update

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Trust Board paper H

### Purpose of report:

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

### Previous consideration:

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

This report was reviewed by CRN East Midlands Executive Group on 8 October 2021.

## Executive Summary

### Context

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute of Health Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

For the information of the Board, we have prepared this quarterly update on the recent progress and current priorities of CRN East Midlands. Appended to this report is our latest financial report and our current risks & issues register.

## Questions

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

## Conclusion

1. This report provides an update on recovery of the CRN Portfolio with details on a new large scale multicentre platform trial (PANORAMIC) as part of the Government's COVID-19 Antiviral Taskforce (ATF), and a new programme of funded work to expand the delivery of research into new settings. The report also includes information pertaining to our latest financial position and an update on our current performance, including our contribution to the CRN High Level Objectives (HLOs). For 2021/22 there is a performance focus on supporting the managed recovery of research studies which have been affected by the pandemic. The majority of HLOs are monitored at a Network-wide level, as opposed to at a regional level. This means that currently there is no data to report for some of the measures. We would like to assure the Board that we are not concerned about this and we anticipate that there will be data to report for these measures in due course.
2. Our risks and issues register is attached at Appendix 1 to the report. The risk (#59) relating to a potential underspend for our 2021/22 budget continues to be well managed and the overall risk score remains quite low. The risk (#61) relating to the impact of a significant increase in COVID-19 hospitalisations and wider winter pressures remains a medium risk. Mitigating actions are in place which focus on communications with our stakeholders and maximising use of staffing resources. A new risk (#62) has been added that research in NHS settings could be negatively impacted due to backlog pressures and challenges linked to restoration of services. This risk is scored as medium and we are continuing to work with our NHS partners to seek all opportunities to deliver research for patients in challenging circumstances. The risk (#60) related to uncertainty over our future budget was moved to our issues register (Issue #03) but has since been closed as this is being well managed.

## Input Sought

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

**For Reference**

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

**1. Quality priorities**

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

**2. Supporting priorities:**

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

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

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

**4. Risk and Assurance**

**Risk Reference:**

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

- 5. Scheduled date for the **next paper** on this topic: February 2022
- 6. Executive Summaries should not exceed **5 sides** My paper does comply

## CRN East Midlands - Quarterly Board Update, 8 October 2021

### 1. Introduction

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute for Health Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

This report provides an update on: the recovery of the CRN Portfolio; our current financial position; CRN performance standards and risks/issues. Our latest finance report and current risk & issue register are appended to the report.

This report was reviewed by the CRN East Midlands Executive Group in October 2021 and is submitted to UHL Trust Board for review in November 2021.

### 2. Update on recovery of the CRN Portfolio

Restoration of the CRN research portfolio continues to be challenging due to the large backlog of clinical care and impact of the pandemic on the workforce. Currently one of our key priorities is supporting the formal 'Managed Recovery' programme across the region. This involves the provision of targeted support and focus to enable rapid recovery of selected studies across a range of conditions.

A national sequencing process has been used to identify studies on which to focus efforts. As of 8 September 2021, there are 293 confirmed studies to receive support as part of Managed Recovery; in the East Midlands, we are involved with 179 of these studies. We are working closely with partners to support the implementation and accurate monitoring of this programme.

There remains significant concern with respect to the restoration of the Life Sciences Industry in the UK, specifically clinical trials. The DHSC wishes to work with the local Networks to demonstrate an immediate improvement in the delivery of Life Science research. To achieve this, all CRNs have recently been awarded further funding which will be used to support commercial studies at three of our commercially research active trusts. We have reviewed the resources that may allow us to deliver this and demonstrate a direct and immediate impact on NIHR commercial study delivery.

The CRN has also received recent notification of the establishment of a new large scale multicentre platform trial (PANORAMIC) as part of the Government's COVID-19 Antiviral

Taskforce (ATF). Through this study it is envisaged that a number of potential treatments will be reviewed and trialled; currently there are some repurposed candidates, along with some novel ones, with activity likely across community, primary and secondary care settings. We understand there will be different models of delivery for this work and we appreciate there will be challenges associated with this very large and fast paced study, with potentially c.10-15,000 participants to be involved. We are very keen to work with all partners across the region to consider how a study like this could be established and delivered.

Furthermore, CRN East Midlands is at the beginning of a 2-3 year programme of funded work to expand the delivery of research into new settings and offer research opportunities to a wider breadth of participants. Through this Transformation work, a number of initiatives will follow, including a digital workstream to seek out innovative approaches to research delivery, and the creation of a Direct Delivery Team to ensure flexibility, capability and capacity to deliver research across a broader range of settings in health and social care. To support this expansion into new settings, we are actively linking with the five Integrated Care Systems (ICS) in the region to ensure research is embedded in new pathways, and that population health outcomes can be supported through research.

### **3. Financial Position**

Our latest finance report is attached at Appendix 1. This report provides an update on our 2021/22 financial performance and forecast. It also includes details on the use of additional funding we have been allocated this financial year.

In relation to the recent Host Audit, all actions have been completed and no further issues have been raised through the UHL internal audit committee.

### **4. 2021/22 Current 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 table below incorporates the key HLOs and summarises current performance for CRN East Midlands

We would like to advise the Board that for 2021/22 there is a performance focus on managed recovery studies, to ensure the CRN is supporting sites to recover research more broadly. Also, as highlighted above, it is essential the UK can demonstrate an effective contribution to the wider Life Sciences sector, thus commercial research recovery is prominent. The majority of performance measures are monitored at a Network-wide level, as opposed to at a regional level.

The table over page presents data extracted on 30 September 2021 to report our year to date performance against the HLOs. Please note, currently there is no East Midlands data to report

for the 'Efficient Study Delivery' measures. This is because there are no closed studies, led within the East Midlands that meet the criteria for these measures. This is a national objective so it is not unexpected that there would be limited local data to contribute to this at present. We wish to inform the Board that we are not concerned about this and we anticipate that there will be studies which meet this criteria in due course.

| Objective                          | Measure   | Ambition                                   | East Midlands Performance |
|------------------------------------|---|--|---------------------------|
| Efficient Study Delivery           | (1) Proportion of new commercial contract studies led within the East Midlands achieving or surpassing their recruitment target during their planned recruitment period                             | 80%  | No data to report         |
|                                    | (2) Proportion of commercial contract studies led within the East Midlands in the managed recovery process achieving or surpassing their recruitment target during their planned recruitment period | 70%  | No data to report         |
|                                    | (3) Proportion of non-commercial studies led within the East Midlands in the managed recovery process achieving or surpassing their recruitment target during their planned recruitment period      | 70%  | No data to report         |
| Provider Participation in Research | (1) Proportion of NHS Trusts recruiting into CRN Portfolio studies  | 100%                                       | 100%                      |
|                                    | (2) Proportion of NHS Trusts recruiting into CRN Portfolio commercial contract studies  | 70%  | 69%                       |
|                                    | (3) Proportion of General Medical Practices recruiting into CRN Portfolio studies   | 45%  | 30%                       |
| Research Participant Experience    | Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey, each year   | 1,400 (East Midlands)<br>12,000 (National) | 720                       |

## 5. Risks & Issues

Risks and issues are formally reviewed through the CRN Executive Group chaired by Andrew Furlong. A risks & issues register (Appendix 2) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC).

Risks and issues are recorded on the register as follows:

- Risk #59 - risk of a potential underspend for CRN East Midlands budget for 2021/22 due to a significant uplift in funding. The risk probability remains scored as unlikely as a number of actions have been taken to plan and manage the additional funding. The risk impact is scored as moderate meaning the overall risk score is still relatively low.
- Risk #60 - this has been moved to the Issues Register (see Issue #03 below).
- Risk #61 - The recovery of the CRN portfolio could be negatively impacted in the event of a significant increase in COVID-19 hospitalisations in autumn/winter, along with further winter pressures, flu, RSV, and wider pressures on A&E and Critical Care. The risk probability is currently scored as possible and the risk impact is scored as moderate meaning the overall risk score is medium.
- Risk #62 (new risk) - Research in NHS settings could be negatively impacted due to backlog pressures and challenges linked to restoration of services. The risk probability is currently scored as possible and the risk impact is scored as moderate meaning the overall risk score is medium. Whilst some actions can be set in place, both this risk (62) and the previous one (61) are wide in scope, and may impact upon research capacity and performance measures. We will continue to work with our NHS partners to seek all opportunities to promote and deliver research for patients in challenging circumstances.
- Issue #03 (formerly risk #60) - LCRN finance methodology for 2022/23 LCRN budgets (often linked to performance) is not known (as of 14.09.21). This presents a potential risk to our future regional budget and an inability to influence/maximise this through specific performance focussed work. It is now too late to use the national model to inform the approach to Partner budgets and we intend to feed back to Partner Organisations at the next Partnership Group meeting, and select the best fit regional model. This is now being managed as part of routine business and the issue has been closed on the Issues Register.

If you have any questions 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 David Rowbotham, Clinical Director, [david.rowbotham@nihr.ac.uk](mailto:david.rowbotham@nihr.ac.uk) or
- Carl Sheppard, Host Project Manager, [carl.sheppard@nihr.ac.uk](mailto:carl.sheppard@nihr.ac.uk)

## UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

**REPORT TO: CRN EM EXECUTIVE COMMITTEE**

**DATE: 8th OCTOBER 2021**

**REPORT FROM: MARTIN MAYNES – HOST FINANCE LEAD**

**SUBJECT: CRN EM FINANCE UPDATE**

### 1. Purpose

This report provides an update on the following issues:

- 21/22 financial performance and forecast
- Additional funding 21/22

### 2 2021/22 Financial Position

The table below summarises the 21/22 forecast outturn position and key variances to the opening plan.

|                                     |               | April to July<br>2021 |               |            |
|-------------------------------------|---------------|-----------------------|---------------|------------|
|                                     | Annual Plan   | YTD Actual            | Forecast      | Variance   |
|                                     | £'000         | £'000                 | £'000         | £'000      |
| <b>Income</b>                       |               |                       |               |            |
| NIHR Allocation                     | 22,303        | 7,916                 | 23,375        | -1,072     |
| <b>Expenditure</b>                  |               |                       |               |            |
| Network Wider Team                  | 682           | 212                   | 576           | -106       |
| Host Services                       | 350           | 117                   | 350           | 0          |
| Management Team                     | 797           | 241                   | 851           | 54         |
| Study Support Service (SSS) Team    | 493           | 167                   | 507           | 15         |
| Research Study Team (RST)           | 538           | 159                   | 727           | 188        |
| Clinical & SG Leads                 | 126           | 53                    | 119           | -7         |
| Research Site Initiative            | 795           | 400                   | 790           | -5         |
| Primary Care Service Support Costs  | 100           | 33                    | 100           | 0          |
| CRN EM ADDITIONAL FUNDING           | 740           | 47                    | 1,318         | 578        |
| Partner Organisation Infrastructure | 17,040        | 5,585                 | 16,882        | -159       |
| ETC                                 | 0             | 212                   | 157           | 157        |
| CRN EM Non Pay Non Staff            | 191           | 57                    | 157           | -34        |
| Innovation Fund                     | 450           | 107                   | 469           | 19         |
| <b>To be allocated</b>              |               | <b>525</b>            | <b>371</b>    | <b>371</b> |
| <b>Total</b>                        | <b>22,303</b> | <b>7,916</b>          | <b>23,374</b> | <b>0</b>   |

The remainder of this report will focus on the use of the additional funding streams as these are the key areas of financial risk at the moment. The main points to note are as follows.



## Income

The network is in receipt of a number of new funding streams to support restart and new initiatives. This is summarised in the table below.

| Funding Stream         | Cost Centre   | Income  | Forecast | Variance |
|------------------------|---------------|---------|----------|----------|
|                        |               | £       | £        | £        |
| Public Health          | S90           | 65,922  | 65,922   | 0        |
| Transformation Funding | O11, U08, U89 | 909,091 | 753,942  | 155,149  |
| Targeted Funding       | O11           | 740,479 | 738,709  | 1,770    |
| Managed Recovery       | O11           | 163,000 | 163,222  | -222     |

The network is confident there are sufficient controls over the income coming in and what it is for, have adequate processes in place to monitor and forecast the income and processes for reporting to relevant committees. The new funding streams are summarised below.

### Public health funding (c.60k)

This funding was given last year and this year. Funding is also confirmed for 2022/23. This is DHSC direct funding to fund two specific posts. One is a Public Health (PH) Consultant, linked to local authorities for around 1PA per week, to work regionally. This post is to generate research ideas to develop more PH studies in the region. A preferred candidate for the role has been identified, with a start date of 1 November. This post will be employed through the University of Nottingham. The preferred candidate comes with good knowledge and is a good appointment and will provide good value for money.

The other post is for a 1WTE, Research Fellow to work alongside the PH Consultant, supporting the research and developing networking opportunities and to reinvigorate PH across the region. This post was appointed in March 2021 and is employed via Lincolnshire University.

A planned programme of work has been identified and this was included in the annual plan so we will be required to report back on this. We will be identifying key areas of work for the PH Consultant.

### Cost pressure funding (£551k)

This came as additional funding at the beginning of the year. The network took a view to apportion to partner organisations on a percentage based on what they were already in receipt of in terms of infrastructure funding. This was added to the PO budgets at the beginning of the year (uplift). This funding has been well incorporated into budgets and receiving reports back from POs on spend. This is managed as part of usual monthly allocation, and the network does not have to report on it separately. Most POs have incorporated it into their core budget

As CRN funding is allocated on a year by year basis we are unsure of the recurrence of this funding, however early indications are that this additional funding will be incorporated into our budgets going forward.

### High priority funding (£450k)

Last December, it was thought that the high priority funding would be used to continue pandemic studies and recovery of studies. This is not new money, it is money that was kept aside in the financial planning round. When the budget planning meetings took place at the beginning of the year, this fund was identified. The network allocated funding early in the financial year which gave more confidence of the ability to spend in year. The funding was purposely overcommitted to account for slippage. Currently spent £455k which is a strong position at this point in the year.

Continuous dialogues are taking place between POs and senior team links to monitor the spend and ensure it is being utilised as agreed. If any changes are required these are agreed with the senior team link. This is being reported within our budget.

### **Targeted funding (£740k)**

This funding was made available at the beginning of the year. A call was opened for the recovery of portfolio, innovative ways of working and growing pipeline. The network worked with our partners, academic institutions and also community trusts to look at new sectors. An extra £300k was added from the transformation fund (see below). Again, we overcommitted to this funding, currently we are slightly underspent. We are continuing to receive bids against this funding. This fund is requiring tight monitoring as we are seeing slippage/changes in spend. We are required to report separately in the financial returns.

### **Transformation funding (£909k)**

This funding has been given to ensure our reach can be extended from health arena into social care, local authorities, hospices, care homes, prisons etc. As it came later in the year it was acknowledged that it would not be possible to spend all against transformation this year and therefore we were allowed to apportion some of the funding to other areas. Some money has been moved to transformation (see above), digital and social care activities. We have been instructed by the CC to use the bulk of the remainder of the funding to develop a DDT targeted workforce across the region which will help to deliver across these settings. Two transformation leads have been appointed. Plans to appoint into the DDT team are being developed. We understand that this funding stream will be available to us for three years. Funding will tie in with the CRN contract. DDT will be Host (UHL) employed, which was part of the mandate of the funding.

### **Managed recovery funding**

The network was approached six weeks ago by the CC to say funding is available as there is concern around life sciences research and the recovery of this has been a challenge (post COVID/BREXIT). There is a series of 'deep dives' looking at commercial portfolio studies and how we can turn them around. The network has contacted all our NHS partners who deliver commercial studies. Two levels of requests - one for NHS support costs and we have £163k allocated out to three of our partners (UHDB, UHL, NUH). To date we have not heard anything yet from the second amount - not sure if we will get it. If we do get the funding, partners will require a variation to contract as the funding would support commercial costs. Will need to ensure a contract in place before money is released.

Cost recovery - emphasis on cost recovery for this funding would sit with the partner organisation, not the network. Partners would want to be clear on accountability and responsibility before accepting funding. Further information on the additional LCRN funding for managed recovery was received from the CC via a recent CRN bulletin:

It has now been confirmed that this funding is provided to help alleviate the pressures on staff resources and space to protect UK Life Sciences, and make more rapid progress on the recovery of the multi-site commercial studies on the CRN portfolio. The funding does not need to go directly to commercial research but should support the system in a way that supports commercial research, with a focus on Managed Recovery studies.

The first round of Managed Recovery funding allocations, totalling £8.5m, is for service support costs only and should be spent as specified in the plan submitted by the LCRNs. The funding should be spent before the end of the current financial year, i.e. 31 March 2022.

LCRNs received an email on 25 August requesting additional information relating to the non-service support and deep-dive funding requests. This information is required by 5pm on Friday 10 September. Once the CRNCC has this information this will be drawn up into a detailed bid for DHSC.

For clarity, the commercial income policy is applicable to this funding. Mandatory requirement 10 in the 2021/22 POF states: "Implement and maintain Standard Operating Procedure(s) specifically to ensure NIHR CRN funding is not used to

subsidise commercial contract research delivery in the LCRN Host Organisation or Partners, and that commercial research is supported on a 'full cost recovery' basis. For 2021/22, the UK government priority is the recovery of non-COVID-19 clinical research as we emerge from the COVID-19 pandemic, as articulated in the UK Vision for Clinical Research Delivery and implemented through the Managed Recovery programme. A priority for LCRNs is to support commercial clinical research, and cost recovery arrangements must not be a barrier to this. This does not affect the underlying principle, as set out in AcoRD, that the NHS (rather than the LCRN specifically) is required to recover, from industry, all costs over and above the standard NHS Treatment Cost.

### **Accounting treatment**

It was noted that it is important that the spend is recorded in dedicated cost centres for each significant income stream on the general ledger, as this is more preferable from an accounting point of view. This was agreed in principle by the FWG group as a consideration for the 2022/23 budget however would need to see the future income streams and whether the above funding streams turn into longer term funding. This can be revisited at the 2022/23 budget planning stage.

For now, the CRN has good systems and processes in place to monitor the spend through the general ledger. A summary of the management processes in place to manage the funding streams is being produced.

### **Q4 ETCs**

The CRN operates the national ETC budget on a "pass through" basis. Therefore there is no direct impact to the Network of this allocation.

### **PO Refund re 20/21**

As reported at the last Exec Meeting there is an underspend of £59k relating to 20/21 which we expect will be recouped by NIHR in this financial year.

## **4. Recommendations**

The CRN Executive Committee is asked to:

- Note the 21/22 Financial Forecast
- Note the planned use of new funding received

## 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 | Probability | Impact | Value (PxI) | Risk status (open or closed date) | Trend (since last reviewed) |
| R059                    | Financial        | Mar-21      | COO        | There is a risk of an underspend for CRN East Midlands' budget for 2021/22 due to a significant uplift  | <p><b>Cause:</b> Increased funding of c.£2.2 million (over 10%) to CRN EM annual budget for 2021/22.</p> <p><b>Effect:</b> Budget surplus at end of year, which means funding intended for the region does not get sufficiently well invested to offer more research to our patients. Also this could impact on future funding if there is a perception we do not need the funding provided.</p>   | 3           | 3      | 9           | Mar-22      | Robust financial monitoring and reporting on a monthly basis, with oversight from Finance Working Group   | DCCO/ FWG             | 4             | 2           | 3      | 6           | Open                              | Static                      |
|                         |                  |             |            |   |  |             |        |             |             | Three separate funding streams 2. Targeted funding for UPH/RRG (£740k), call opened to allocate funding promptly, as at 16/07/21 c.85% allocated, thus reducing risk                                  | Leadership Team       | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Three separate funding streams 3. Transforming research (£909k) plans submitted to NIHR CC, approved, intention to re-channel c.£350-400k to stream 2, remainder is well planned against              | COO                   | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Early identification of areas of underspend with timely targeting and redistribution of funding   | COO/ Senior Team      | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Recently awarded additional £163,000 to support Managed Recovery which must also be spent in year. Received feedback of some ability to vary planned spend, currently working with POs on the detail. | COO                   | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | By end Q2 will have undertaken thorough analysis of all new funding streams, and overall position   | COO / Finance Team    | 4             |             |        |             |                                   |                             |
| R061                    | Services         | May-21      | COO        | Recovery of the CRN portfolio could be negatively impacted in the event of a significant increase in COVID-19 hospitalisations in autumn/winter, along with further winter pressures, flu, RSV (peads), and wider pressures on A&E and CC | <p><b>Cause:</b> Increase of COVID-19 cases, and wider winter pressures, leading to hospital admissions, and diversion of research delivery staff, also likely increase in staff unavailability due to isolation requirements, and/or covid-19 positive cases</p> <p><b>Effect:</b> Resource has to be redeployed onto the frontline or to support an increase in UPH research activity, which would see activity on non-UPH studies (RRG) reduce/significantly reduce. The impact for commercial studies is a lack of confidence in the UK research system, with reputational impact for the future. Also for commercial and non-commercial studies, the impact will be for patients not being offered the latest treatments/interventions.</p> | 3           | 4      | 12          | Q2-Q4 21/22 | When setting up studies, communicate to sponsors and study teams the risk of disruption in event of an increase in COVID-19 hospitalisations  | SSS Team              | 4             | 3           | 3      | 9           | Open                              | Static                      |
|                         |                  |             |            |   |  |             |        |             |             | Seek advice from CRNCC and other LCRNs if there is useful information that can be shared  | COO / DCCO            | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Keep in close dialogue with partners regarding best placement of resource, and plans for any redeployment   | STLs / COO            | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Ensure RST placements are maximised, further focus on UPH work, as needed   | WFDL / COO            | 4             |             |        |             |                                   |                             |
| R062                    | Services         | Aug-21      | COO        | Research in NHS settings could be negatively impacted due to backlog pressures and challenges linked to restoration of services   | <p><b>Cause:</b> Backlog of routine clinical care to be delivered by NHS services due to impact of COVID-19</p> <p><b>Effect:</b> Priority is to address backlog of routine care cases, which could result in reduced workforce capacity (e.g. PIs) and infrastructure, including reduced access to space to deliver research</p>  | 3           | 3      | 9           | Q3-Q4 21/22 | Early identification of disruption to studies so that issues can be addressed promptly, supported and resourced.  | STLs with POs         | 4             | 3           | 3      | 9           | Open                              | New                         |
|                         |                  |             |            |   |  |             |        |             |             | Keep in close dialogue with partners regarding best placement of resource, and plans for any redeployment   | STLs / COO            | 4             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Seek all opportunities for innovative approaches such as remote patient "visits" and use of technology  | IOM/TL (KL)           | 1             |             |        |             |                                   |                             |
|                         |                  |             |            |   |  |             |        |             |             | Ensuring any new funding opportunities are pursued to help increase capacity  | COO/ R&D Leads in POs | 4             |             |        |             |                                   |                             |

**SCORING:**

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

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

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

**Action RAG Status Key:**

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

**CRN East Midlands Issues Register**

Date Last Reviewed : 08.10.2021

| Issue ID          | Issue Type | Date Raised | Owner | Description   | Severity | Priority | Actions  | Action Owners | Action status | Issue status   |
|-------------------|------------|-------------|-------|---|----------|----------|--|---------------|---------------|----------------|
| I03<br>(was R060) | Financial  | 25.08.2021  | COO   | LCRN finance methodology for 2022/23 LCRN budgets (often linked to performance) is not known (as of 14.09.21). This presents a potential risk to future regional budget and an inability to influence/maximise this through specific performance focussed work. It is now too late to use the national model to inform approach to Partner budgets, intention to feedback to POs at next Partnership Group meeting, and select best fit regional model. | Moderate | Medium   | Seek further guidance and assurance from CRNCC   | COO           | 5             | Closed 8.10.21 |
|                   |            |             |       |   |          |          | Intention is for the East Midlands plan for budget distribution to be based upon how to incentivise and support partners to deliver the CRN contractual priorities, likely to no longer be linked to the national funding model to the regions. Budget planning to commence in Sept 2021 e.g. survey/working group | COO           | 4             |                |
|                   |            |             |       |   |          |          | Advise POs we will not be using the national model to inform Partner budgets   | COO           | 1             |                |

| 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 |