

Meeting title:	UHL Public Trust Board	Public Trust Board paper R
Date of the meeting:	12 October 2023	
Title:	CRN East Midlands Quarterly Board Report	
Report presented by:	A Furlong, Medical Director, E Moss, Chief Operating Officer, CRN East Midlands and A Farooqi, Clinical Director, CRN East Midlands	
Report written by:	E Moss, Chief Operating Officer, CRN East Midlands and C Sheppard, Host Project Manager, CRN East Midlands	

Action – this paper is for:	Decision/Approval	X	Assurance	x	Update	
Where this report has been discussed previously	CRN East Midlands Executive Group on 31 August 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
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.

<p>Acronyms used:</p> <ul style="list-style-type: none"> CRNCC - NIHR CRN Coordinating Centre CRN - Clinical Research Network DHSC - Department of Health and Social Care DDT - Direct Delivery Team LCRN - Local Clinical Research Network NIHR - National Institute for Health and Care Research RDN - Research Delivery Network RRDN - Regional Research Delivery Network HLOs - CRN High Level Objectives
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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, LCRN Governance Framework (annual update requiring Trust Board approval) and current 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.

Furthermore, we request that the Board reviews and approves our updated LCRN Governance Framework (Appendix 2). The updates are shown as tracked changes in red text to make them visible.

Summary

This report provides the latest update on the reconfiguration of the Clinical Research Network, commentary on our strong performance and an update on the UK commercial clinical trials landscape. The report also includes information pertaining to our year-to-date financial performance & current forecast, and data for the 2023/24 CRN High Level Objectives.

On the CRN risk register, risk #65 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. The probability of this risk has reduced meaning the overall risk rating is now relatively low.

On the CRN issue register, issue #08 relating to challenges associated with commercial research performance has been closed. A new issue (#09) has been added, which states it is becoming increasingly difficult to recruit to CRN posts. We are working closely with HR and providing feedback nationally to address this issue, with further actions set out on the issues register. A further new issue (#10) has been added, which states there are ongoing delays to payment of all CRN invoices from suppliers and partners, breaching the contractual obligation. We are working with the Host Finance Lead and other UHL Finance colleagues to address this issue and have set out remedial actions on the issues register.

Main report detail

1. Current priorities and progress

i) Reconfiguration of the Network

From October 2024, the NIHR Clinical Research Network will become the NIHR Research Delivery Network (RDN). The RDN is being established to build on the success of the Clinical Research Network, to support the country's world-class research system to deliver high quality research that enables the best care for our population.

The NIHR Research Delivery Network will:

- support the successful delivery of high quality research, as an active partner in the research system;
- increase capacity and capability of the research infrastructure for the future.

Following a competitive process, UHL submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN). The successful applicant has been notified and a formal, public announcement will be made in due course.

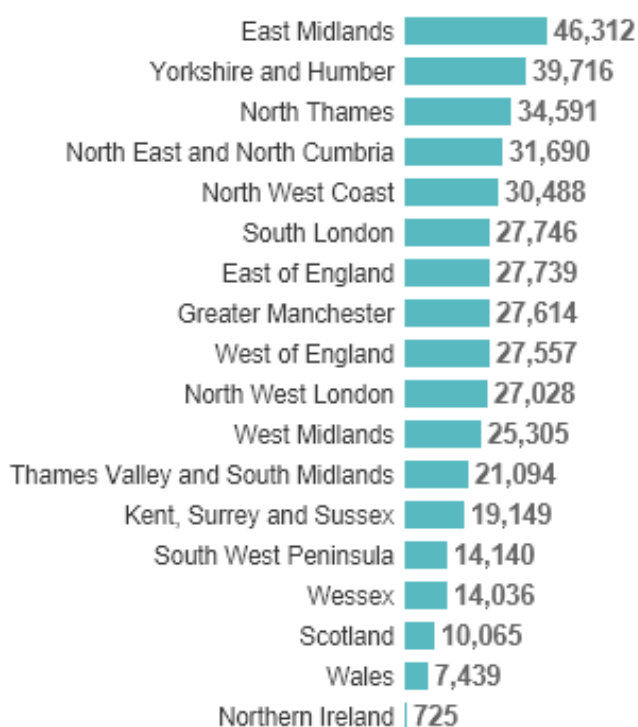
To ensure preparation for the commencement of the new RRDN contract on 1 October 2024, a small group has been convened, led by Andrew Furlong with support from UHL's Head of Strategy and Planning, Simon Pizzey and CRN East Midlands Host Project Manager, Carl Sheppard. In addition, the CRN Coordinating Centre (CRNCC) has appointed an 'RRDN Transition Lead', Kaatje Lomme to support this process.

ii) Performance

CRN East Midlands has made a very strong start to the year with respect to performance. As of 26 September 2023, the East Midlands has recruited 46,312 participants into NIHR CRN Portfolio studies and we are the top recruiting LCRN out of the 15 regional Networks (as shown in Figure 1 below). This is an excellent achievement, particularly when compared to our average position over recent years (CRN East Midlands finished in sixth position in 22/23 and eighth position in 21/22). The improvement this year is reflective of some fantastic work across many of our partner organisations, the targeted placement and hard work of the DDT agile team and work done to develop our regional portfolio with an increase in high recruiting studies. Furthermore, CRN East Midlands Primary care has made a significant contribution and is the top recruiting ‘organisation’ in England with recruitment of 23,834 participants. Overall, this is a fantastic start to the year, and we have communicated this and thanked our partners for their contributions.

Figure 1. Total recruitment by LCRN region (data cut 26.9.23)

RECRUITMENT in 2023/24



As of 26 September 2023, CRN East Midlands has recruited 3,499 participants into commercial studies and is in fourth position out of the 15 regional Networks. This year-to-date recruitment figure exceeds our annual commercial recruitment total over any of the last five years, which is another excellent achievement. This improvement is due to an increase in the number of high recruiting commercial studies and activities undertaken across our partner organisations and primary care. Notably, we wish to recognise the contribution of Lincolnshire Partnership NHS Foundation Trust, who have recruited 1,042 participants into a single commercial mental health study this year.

Recruitment of Global and European ‘first’ participants into commercial contract studies is seen as another important indicator of commercial study performance by the NIHR and DHSC. Recently, CRN East

Midlands has recruited one first Global and one first European participant, which is another great achievement at this stage of the year; both of these were within primary care.

CRN East Midlands’ data for contributing to the national CRN High Level Objectives are set out in section 3 of this report.

iii) Commercial clinical trials landscape

In February 2023, the government 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 has now been published and it outlines 8 problem areas and 27 recommendations, including priority actions to progress in 2023 and longer-term ambitions for UK commercial clinical trials.

The government response welcomes all recommendations from the review, in principle, and makes 5 headline commitments backed by £121 million. An implementation update, setting out progress made against these commitments and a comprehensive response to the remaining recommendations, will be published in the autumn. The NIHR are working closely with DHSC to contribute to this work, and over the coming months we can expect to be asked to ensure our local plans for commercial research delivery are reflective of this direction of travel.

2. Financial Position

Our latest Host finance report is attached at Appendix 1. This report provides an update on CRN East Midlands year to date financial performance and current forecast.

3. Performance (CRN High Level Objectives)

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 have been updated for 2023/24 and 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.

Objective		Measure	National ambition	East Midlands data (data cut: 26/09/23)
Study Delivery (SD)	Support sponsors to deliver their NIHR CRN Portfolio studies to recruitment target	Percentage of <u>open</u> to recruitment commercial contract studies which are predicted to achieve their recruitment target	80%	83%
		Percentage of <u>open</u> to recruitment non-commercial studies which are predicted to achieve their recruitment target	80%	66%

Objective		Measure	National ambition	East Midlands data (data cut: 26/09/23)
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)	1,199
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

With respect to the data in the above table, we can provide the following supporting commentary:

- For the Study Delivery (SD) measures, the national ambition has increased from 60% (for 22/23) to 80% (for 23/24). This objective relates to studies which are locally led. CRN East Midlands is currently meeting the ambition for commercial studies, however, we are currently below the ambition for non-commercial studies. There is an expectation to manage study recruitment throughout the study lifecycle and we are working to improve our systems to achieve this measure as the year progresses.
- For the Participant Experience (PE) objective, CRN East Midlands has made excellent progress to date and we are very close to achieving our target for the number of participants responding to the Participant Research Experience Survey (PRES). A range of innovative approaches are being used across the region to support this.

As highlighted earlier in this report, primary care research activity continues to be an area of great strength in the East Midlands. The 'percentage of general medical practices recruiting into NIHR studies' is no longer a formal High Level Objective and some considerations are being made nationally regarding the best way to measure primary care engagement and contribution. Locally, we will continue to monitor GP recruitment activity closely and support sites. Last year, the national ambition was to achieve 45% of practices recruiting into NIHR studies at year-end, which we exceeded achieving 51%. However, our current performance is 81%, which reflects a huge increase in the number of research active practices in the East Midlands. This is largely due to one study (Quality-of-life in patients with long COVID) that is being delivered at many GP practices (including 223 practices which were previously not research active this year).

4. LCRN Governance Framework

CRN East Midlands Governance Framework (Appendix 2) describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system

and escalation process for the management of the LCRN. This framework is updated on an annual basis in order to reflect any changes in governance, assurance and escalation processes. In this annual update there have been a number of minor governance and administrative changes. The updates are shown as tracked changes in red text to make them visible. This document has been reviewed by CRN East Midlands Executive Group and is provided to the Trust Board for formal approval.

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 #065 - Uncertainty around the future arrangements of the Network (as it transitions to the RRDN) could negatively impact planning and performance of the CRN. The RRDN Transition Lead is now in post and a group has been established to support the requirements for the transition. The probability of this risk has reduced from 'possible' to 'unlikely' meaning the overall risk rating is relatively low.
- Issue #08 - Current challenges associated with commercial research performance nationally. A significant amount of work has taken place over recent months and performance has improved both nationally and regionally (particularly within primary care settings). There is also a strong upcoming pipeline of commercial studies, therefore this issue has been closed.
- Issue #09 (NEW) - It is becoming increasingly difficult to recruit to CRN posts. This is caused by a range of factors, which are described on the issues register. This is resulting in management time being spent on having to re-advertise posts, unpicking issues and not being able to deliver promptly on services and broader aspects of research study delivery. We are working closely with HR and providing feedback nationally to address this issue, with further actions set out on the issues register. This issue is rated as medium priority with moderate severity.
- Issue #10 (NEW) - There are ongoing delays to payment of all CRN invoices from suppliers and partners, breaching the contractual obligation. This could negatively impact the reputation of the CRN & UHL and affect some elements of study and business delivery. We are working with the Host Finance Lead and other UHL Finance colleagues to address this issue and have set out remedial actions on the issues register. This issue is 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
- Professor Azhar Farooqi OBE, Clinical Director
- Professor David Rowbotham, Deputy Clinical Director
- Carl Sheppard, Host Project Manager

Supporting documentation

- Appendix 1 – Finance Update Report
- Appendix 2 – LCRN Governance Framework (annual update requiring Trust Board approval)
- Appendix 3 – Risks & Issues Register

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CRN EM EXECUTIVE GROUP

DATE: 31st August 2023

FROM: MAHENDRA WADHWANA - HOST FINANCE LEAD & PARITA YADAV - FINANCE BUSINESS PARTNER

SUBJECT: CRN EM FINANCE UPDATE: PERIOD 4 23/24 Forecast Outturn Summary

1. Purpose

This report provides an update on the 23/24 year forecast outturn position as at period 4, July 2023, an explanation of any significant variances to the annual plan and an update on any issues for information.

2. Forecast Variance at Period 4

The table below summarises the annual plan to forecast outturn position at period 4 (July 2023). Appendix A provides a more detailed summary by cost centre and actual to date income and expenditure.

	2023/24 Annual Plan	Forecast (Income)/ Expenditure	Variance (Surplus)/Deficit
	£000's	£000's	£000's
Income	-24,849	-24,939	-90
Expenditure			
Pay	3,885	3,775	-110
Non Pay	20,964	21,164	200
Total Expenditure	24,850	24,939	90
Variance	0	0	0

Main points to note:

Overall

The forecast outturn position is balanced to the annual plan. Pay cost variances largely due to vacant posts across service areas. Some of this relates to additional funding in 23/24 where this funding is required to appoint to new roles for which there is a lead in time. In addition, services are reporting that it is increasingly challenging to appoint to research roles from a limited resource pool. Any pay underspend will be re-allocated to ensure funding is

maximised but remain within funding plans. There are no other significant variances to report at this stage.

3. Additional Funding in 23/24

The last report to Executive in May 23 focused on the 22/23 outturn. It is appropriate now to provide an update on the additional funding that has been made available in 23/24.

£586K for NHS Pay award uplift (equating to 2.54%). Announced December 22

£400K additional funding for NHS Pay award, a further 2.46%

£350K for Services Supporting Research

£85K underserved funding

£50K additional investment in Research Community Dental Practice scheme

4. Other Issues/Updates

NIHR Capital Funding Bid

The successful outcome of the UHL capital bid was announced in May 23. This was much later than originally expected – March 23. £4.7m has been awarded to UHL of which £940K is for CRN partner organisations. Contractual formalities are being conducted at present to allow funding to flow to UHL. Regarding the pass through of funding from UHL to partners not part of the existing BRC contractual arrangements, a separate collaboration agreement will be required. This is being progressed.

5. Recommendations

The CRN Executive Committee is asked to:

- Note the 23/24 forecast outturn position

Appendix 1

Summary by cost centre – Annual Plan to Forecast Variance Summary as at Month 4 (July 2023)

	April to July 2023			
	2030/24 Annual Plan	YTD Actual	Forecast Expenditure	Variance (Surplus)/Deficit
	£'000	£'000	£'000	£'000
Income				
NIHR Allocation	-24,849	-6,305	-24,940	(90)
Expenditure				
Network Wider Team	708	130	629	(79)
Host Services	388	103	392	4
Management Team	857	215	830	(27)
SSS Team	612	154	656	44
Direct Delivery Team	530	119	479	(51)
Clinical & SG Leads	204	48	224	19
Non pay for non staff	230	53	230	0
Non Nhs SSC	90	24	93	3
Direct Delivery Team Transformation	712	173	707	(5)
Transformation Non DDT	197	32	119	(78)
Public Health	77	18	77	0
Additional Funding	32	-2	33	1
Underserved communities	461	60	537	76
RSI	1,332	687	1,317	(16)
ETC	0	89	90	90
Partner Organisation Infrastructure	18,419	4,257	18,486	68
To be allocated	0	144	42	42
Total	24,850	6,305	24,940	90
VARIANCE	0	0	0	0

NIHR Clinical Research Network East Midlands

GOVERNANCE FRAMEWORK

Host Organisation:

University Hospitals of Leicester NHS Trust

Change Control

Version	Date	Changes made
1.0	01.04.14	Original document – approved by UHL Executive Strategic Board
1.1	08.04.14	More detail on roles of the Clinical Research Divisional Leads and additions to section 7.1.
1.2	22.09.14	Changes to risk management process (section 10)
2.0	13.03.15	Annual review (2015/16) with the addition of Financial Management section (8)
2.1	02.07.15	Update to Executive Director, removal of Business Delivery Manager post
3.0	29.01.16	Annual Review (2016/17) – added reference to Study Support Service (section 5), Clinical Leadership Group included within Operational Management Group (section 5), listed Working Groups (section 6), updated Executive Group details (section 6), updated reporting assurance to quarterly Board Report (section 7), updated staff responsible for operational management of Service Support budget (section 8), updated table for LCRN financial cost codes and delegated authorisation allowances (section 8), updated resolution to audit findings (section 9).
4.0	07.03.17	Annual review (2017/18) – removed historic reference to transition of Network (section 1), updated Executive Leadership Team (section 4), updated LCRN Leadership Team (section 5), Lead RM&G Manager post removed (section 5), clarified Divisional Clinical Research Leads (section 5), defined details of Clinical Leads Group (section 6), updated Governance Structure (section 6), updated details of Working Groups (section 6), added Senior Leadership Team Meeting which fulfils requirements of OMG (section 6), updated frequency of Executive Group to every 3 months (section 6), removed reference to RM&G and included SSS (section 6), updated Finance Support Structure (section 8), updated financial cost codes and delegated authorisation allowances (section 8), updated details to confirm audit due this year (section 9).
5.0	22.06.18	Annual review (2018/19) – added new Co-Clinical Director post (section 4), new Deputy COO post (section 5), added reference to Financial Operating Procedure (section 8) updated responsibility for operational management of the SSC budget (section 8), reported 2017/18 audit findings (section 9) , updated risk scoring matrix in line with national template (section 11).
6.0	06.09.19	Annual review (2019/20) – added reference to new Portfolio eligibility criteria (section 1), added new Clinical Leads Recruitment SOP (section 5), updated Working Groups, new Chair of Partnership Group and updated number of Operations Managers (section 6), added new Financial SOPs (section 8), added reference to LCRN Contract Compliance Assurance Framework (section 9), and Issue Resolution Procedure (section 12), updated branding.

7.0	22.09.20	Annual review (2020/21) - updated introduction (1.1 & 1.2), updated Trust's Acting Chief Executive Officer (4.1), updated description of Industry Delivery Manager role (5.1), updated list of Working/Steering groups (6.1), clarified title of Communications and Engagement Lead (section 6.3), updated reporting format (section 6.5), updated funding description (8.2), updated LCRN Host Finance Lead role description, (8.8), updated costing and financial management arrangements (8.11 and 8.12), updated CRNEM Finance Support Structure (8.13), updated financial cost codes table (8.15), added reference to issue log (9.9), updated Trust's Acting Chief Executive Officer (12.2).
8.0	02.06.21	Annual review (2021/22) - added DCOO to Exec Leadership team (4.5), added Transformation Lead (5.1 & 5.3), updated governance structure (6.1) updated financial management section (8), added roles for budget authorisation purposes (8.17), updated delegated authorisation table (8.18), added latest audit findings (9.13), removed Contract Compliance Assurance Framework (9.14), added Risk Identification and Escalation process (11.4).
8.1	17.09.21	Updated section 8.18 - changes made to authorisers' delegation to financial cost codes.
9.0	05.08.22	Annual review (2022/23) - update to name of NIHR (1.1), updated post holders for Trust Chief Executive, LCRN Clinical Director, Deputy Clinical Directors and LCRN Deputy COO (section 4), updated title of Industry Operations Manager and description of Transformation Leads (5.1), updated Leadership Structure (5.3), added possibility to split Clinical Lead posts (5.4), added reference to social care (5.7), updated structure (6.1), updated chair of Partnership group (6.2), added Deputy Clinical Directors (6.3), included DCOO (6.5), LCRN Annual Business Plan is no longer required and removed quarterly report on UHL R&D (7.1), added requirement to complete an annual financial declaration (8.6), updated DCOO postholder (8.12), change to responsibility for SSC budget (8.13), (8.17), updated delegated authorisation table and moved to Appendix 1 (8.18), added description of Partner Contract requirements (8.19), other contract types (8.20) and authorised signatories table (8.21), updated table of Internal and External Sources of Assurance (9.8), updated audit arrangements (9.12), updated escalation points of contact (12.2), updated Professor Azhar Farooqi as new Clinical Director (14.1). Minor formatting changes throughout document.
<u>10.0</u>	<u>16.08.23</u>	<u>Annual review (2023/24) - added reference to new NIHR Research Delivery Network (1.5), removed Transformation Leads and added Workforce Development Lead (5.1), updated Figure 1 - CRN East Midlands Leadership Structure (5.3), added Social Care Specialty Lead (5.8), updated working groups (6.1), updated Chair and Deputy Chair of Partnership Group (6.2), added Workforce Development Lead to Leadership Team and update number of Operations managers (6.4), changed group name from 'Clinical' to 'Divisional' (6.6), updated Host Finance Lead (8.10), added Business Operations Manager (8.14), Table 1 updated in line with UHL Scheme of Delegation (8.18), added a request has been made to waive the requirement to conduct an audit during 2023/24 due to the upcoming RRDN transition (9.13).</u>

NIHR CLINICAL RESEARCH NETWORK EAST MIDLANDS

Governance Framework

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1. INTRODUCTION

- 1.1 The National Institute for Health and Care Research Clinical Research Network (NIHR CRN) supports patients, the public and health and care organisations across England to participate in high-quality research, advancing knowledge and improving care. The CRN is comprised of 15 Local Clinical Research Networks (LCRNs) and 30 Specialties who coordinate and support the delivery of high-quality research both by geography and therapy area. National leadership and coordination is provided through the CRN Coordinating Centre. In January 2018 the NIHR CRN Portfolio eligibility criteria were expanded to include research taking place outside traditional NHS settings. This change in policy was introduced to better reflect the environment and services that people access and live in today. This means that the CRN also supports the delivery of funded health and care research taking place in settings such as care homes, hospices, schools, prisons, or other social care and public health environments.
- 1.2 The formal name of the LCRN in the East Midlands is NIHR CRN East Midlands (the LCRN). University Hospitals of Leicester NHS Trust (the Trust) hosts the Network on behalf of the NIHR and partner organisations in the East Midlands (Derbyshire, Nottinghamshire, Lincolnshire, Leicestershire, Rutland and Northamptonshire).
- 1.3 The Trust is committed to providing safe high quality care and has developed a range of policies, systems and processes which together comprise robust and integrated Financial Management, Assurance and Escalation, and Risk Management Frameworks. The principles of which have informed this document to ensure high-level, informed accountability of the Trust Board for the good governance of the LCRN.
- 1.4 The LCRN was launched on 1 April 2014. This document describes the processes and controls established by the LCRN to ensure good governance. This document provides governance assurances for delivery of the Department of Health and Social Care (DHSC) issued Contract and NIHR CRN Performance & Operating Framework.
- 1.5 The current LCRN Host Contract has a completion date of 30 September 2024. From 1 October 2024, the NIHR Clinical Research Network will be changing with the establishment of the new NIHR Research Delivery Network (RDN). The NIHR Research Delivery Network will continue to support the effective and efficient initiation and delivery of funded research across the health and care system in England, with a name that better reflects the scope and purpose of the network (including public health and social care studies). The whole of England will be supported through 12 NIHR Regional Research Delivery Networks (RRDNs). These will work with the national Coordinating Centre to provide a joint RDN leadership function so that the NIHR RDN as a whole functions as a single organisation with a shared vision and purpose across England. Following a competitive process, UHL submitted an application to host the new East Midlands Regional Research Delivery Network (RRDN). The successful applicant has been notified and a formal, public announcement will be made in due course.

2. PURPOSE

- 2.1 This framework describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN.
- 2.2 This framework will be reviewed by the LCRN Executive Group and the Trust Board on an annual basis in order to reflect any changes in governance, assurance and escalation processes.

3. GENERAL PRINCIPLES

- 3.1. The Trust Board is accountable for the good governance of the LCRN. The Board should apply, in a proportionate and appropriate way, the principles of good governance and thereby promote:
 - Robust, transparent and accountable LCRN governance;
 - Effective and supportive LCRN hosting arrangements;
 - Effective and proportionate contracts with Partners and other organisations in receipt of LCRN funding or resources;
 - Responsible financial management including budgetary control and the production of financial reports;
 - A structure that ensures effective local performance management;
 - Partner participation and engagement, research delivery and value for money.
- 3.2. The Trust, along with the LCRN leadership, are responsible for developing governing structures, systems, terms of reference and local working practices for working for the LCRN. The specific governance requirements required are detailed in this framework and in respect of:
 - The Accountable Officer;
 - The nominated Executive Director;
 - Scheme of delegation and Host Board controls and assurances;
 - Financial management;
 - Assurance framework and risk management system;
 - Escalation process;
 - LCRN Leadership and Management Groups.

- 3.3. NHS patients and the public are the key stakeholders in NIHR CRN research, and are to be included in LCRN governance arrangements. Patient or public representatives have been included in the agreed membership of the LCRN Partnership Group.
- 3.4. LCRN governance arrangements are required to be formally signed off by the Trust Board and by the national CRN Coordinating Centre.

4. EXECUTIVE LEADERSHIP TEAM

- 4.1 The **LCRN Accountable Officer** is the Trust's Chief Executive Officer, Richard Mitchell.
- 4.2 The Nominated **Executive Director** for the LCRN is the Trust's Medical Director, Mr Andrew Furlong.
- 4.3 The Trust has appointed Professor Azhar Farooqi OBE as the **LCRN Clinical Director**. The Clinical Director has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre. The Trust has appointed Professor David Rowbotham and Professor Stephen Ryder as **LCRN Deputy Clinical Directors**. The LCRN Clinical Director and Deputy Clinical Directors will lead in the engagement of the regional clinical and research community, promoting research and building clinical research capacity.
- 4.4 The Trust has appointed Elizabeth Moss as the **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network. The Chief Operating Officer reports to the LCRN Clinical Director and the national CRN Coordinating Centre. The Board understands that it is a contractual obligation to ensure that the Chief Operating Officer is a Trust employee.
- 4.5 It is a requirement of the NIHR CRN Performance and Operating Framework that the LCRN Chief Operating Officer has a nominated deputy. This may be by means of either (a) a substantive post of 'Deputy Chief Operating Officer' or (b) another LCRN senior manager who is the nominated deputy. The Trust has appointed Daniel Kumar as the **LCRN Deputy Chief Operating Officer (DCOO)**. The DCOO reports to the Chief Operating Officer, with the capacity to deputise for the COO, as required.
- 4.6 The governance responsibilities of the LCRN Executive Leadership Team are to:
 - Deliver the core activities of the LCRN, in line with the agreed governance requirements within the Host Contract and Performance and Operating Framework;
 - Ensure any activities are carried out as may be necessary for the proper governance of the LCRN;
 - Ensure that a proper and auditable process is developed and executed for the fair and effective distribution of LCRN funding;

- Be available for regular meetings as a core Leadership Team;
- Support scrutiny and transparency, for example by providing any information as required for the internal auditors, and attending the audit committee of the Trust as requested;
- Ensure the timely delivery of performance and other reports;
- Support the Trust by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements;
- Convene regular Partnership Group meetings;
- Make freely available to the Trust and all Partner organisations, as requested, any information that is not commercial and/or in confidence and in line with national NHS policies;
- Manage the LCRN so as not to compromise either the Host Organisation or Partner organisations through reasons of conflicting issues such as competition law or data protection.

5. LCRN LEADERSHIP TEAM

5.1 The Trust has appointed a LCRN Leadership team consisting of:

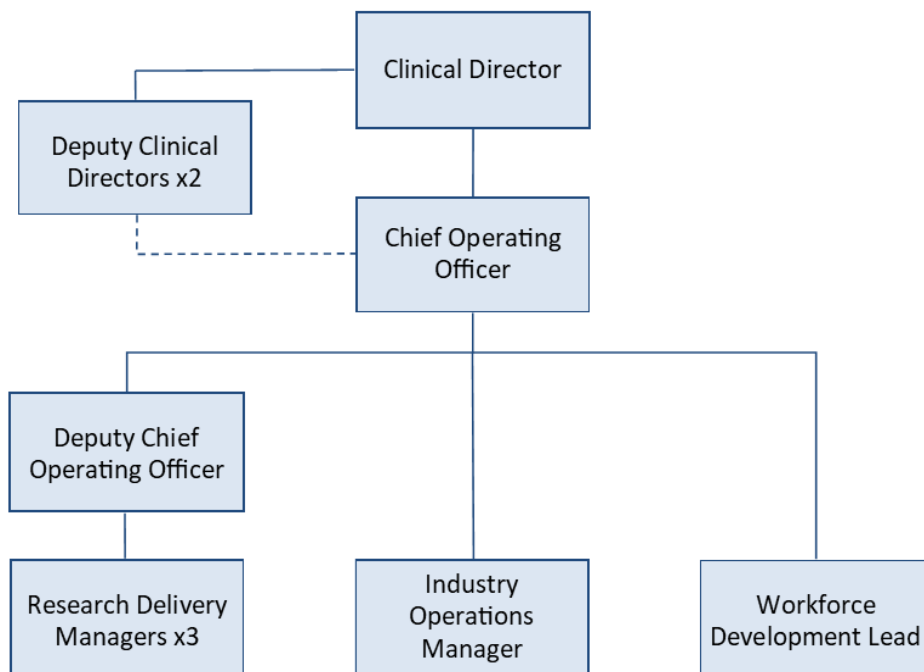
- **LCRN Clinical Director** (supported by the **Deputy Clinical Directors**) has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre;
- **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network;
- **LCRN Deputy Chief Operating Officer** who is responsible for deputising for the Chief Operating Officer and for monitoring budget expenditure and LCRN overall performance;
- **LCRN Divisional Research Delivery Managers** who provide day-to-day operational management of research activity in each of the six operational divisions;
- **Industry Operations Manager** who is responsible for supporting and enabling the effective delivery of commercial research within the LCRN;
- **Workforce Development Lead who is responsible for the delivery of Workforce Learning and Organisational Development within the LCRN, oversight of and implementation of the LCRN Workforce Plan, and ensuring a trained and flexible workforce is available to deliver NIHR CRN Portfolio studies.**

5.2 The governance responsibilities of the LCRN Leadership team are to:

- Deliver the management and operational (i.e. non-clinical) activities of the LCRN, in line with any agreed governance requirements;
- Support the LCRN Executive Leadership team to ensure that activities are carried out as may be necessary for the proper governance of the LCRN;
- Ensure delivery of NIHR CRN Portfolio studies, including life sciences industry research, are delivered in accordance with any agreed governance requirements.

5.3 Figure 1, illustrating the LCRN leadership structure, is included below:

Figure 1 - CRN East Midlands Leadership Structure



LCRN Divisional Clinical Research Leads

5.4 The LCRN has appointed six **LCRN Clinical Research Leads**, one for each research delivery division. It may be decided to split Clinical Research Divisional Lead appointments, with some Divisions having two co-leads. These clinicians represent the clinical activity interests of all specialties within their research delivery division, liaising closely with the Clinical Research Specialty Leads. They work closely with their Divisional Research Delivery Managers (see below).

5.5 The governance responsibilities of the LCRN Divisional Clinical Research Leads are:

- Address resource allocations and the balance of the LCRN portfolio across

specialties, sites, trusts, care settings, patient groups and study composition;

- Provide clinical intelligence and advice to support research delivery within the division, including a view of the clinical implications of national policy locally;
- Support Clinical Research Specialty Leads with the identification and development of research communities within the LCRN area, across all NHS partners.

LCRN Clinical Research Specialties

5.6 The NIHR CRN has adopted a framework of 30 Clinical Research Specialties for the purposes of engagement with clinical research communities and to enable clinical leadership and oversight of the NIHR CRN research portfolio.

5.7 The 30 Clinical Research Specialties* are grouped into six Divisions for operational management purposes:

- Division 1: Cancer
- Division 2: Cardiovascular disease; Diabetes; Metabolic and endocrine disorders; Renal disorders; Stroke;
- Division 3: Children; Genetics; Haematology; Reproductive health & childbirth;
- Division 4: Dementias and neurodegeneration; Mental health; Neurological disorders;
- Division 5: Ageing; Dermatology; Health services and delivery research; Oral and dental health; Musculoskeletal disorders; Primary care; Public health;
- Division 6: Anaesthesia, perioperative medicine and pain management; Critical care; Ear, nose and throat; Gastroenterology; Hepatology; Infectious diseases and microbiology; Injuries and emergencies; Ophthalmology; Respiratory disorders; Surgery.

*The CRN has expanded its remit to support the delivery of social care research. Often social care studies are included in Division 5, however, they may be included in any of the six divisions.

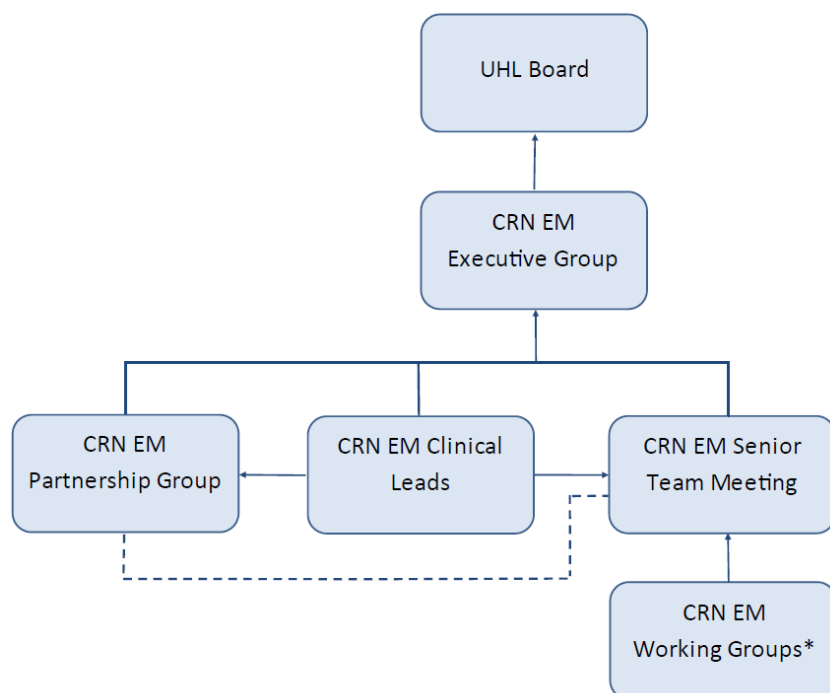
5.8 The LCRN has appointed local Clinical Research Specialty Leads for all 30 specialties. The LCRN Clinical Research Specialty Leads report to the LCRN Divisional Clinical Research Lead responsible for that Specialty. Local Clinical Research Specialty Leads will be responsible for the clinical leadership of their research communities within the LCRN area, development of local Clinical Research Specialty Groups and clinical oversight of the performance of the Specialty portfolio of studies. In addition, a Specialty Lead for Social Care has been appointed.

5.9 The LCRN has produced a Standard Operating Procedure for the recruitment of Clinical Research Divisional Leads, Specialty Leads and Sub-specialty Leads.

6. LCRN GOVERNANCE STRUCTURE

6.1 A diagram of the LCRN governance structure is included as Figure 2.

Figure 2 – CRN East Midlands Governance Structure



* Finance Working Group, ~~R&D/Leads Engagement Group~~, ~~Mental Health and Primary Care Commercial groups~~ (ad hoc groups to be convened as needed, e.g. Public Health/pandemic related, ~~EoI Group~~, ~~Sharing Best Practice Group~~).

6.2 The Trust has established the **LCRN Partnership Group**. The Group is a formal forum of LCRN partners and key stakeholders. Its role is to provide active oversight and constructive mutual challenge on LCRN plans, activities, performance and reports in order to support the LCRN to achieve its objectives and raise the ambitions for clinical research of the LCRN Partners. The Trust has appointed an independent Chair (~~Simon Weldon, Group CEO at Northampton General Hospital and Kettering General Hospital~~ Stephen Posey, Chief Executive, University Hospitals of Derby and Burton NHS Foundation Trust) and Deputy Chair (Andrew Morgan, Chief Executive, United Lincolnshire Hospitals NHS Foundation Trust) and the group will be attended by the Trusts' Nominated Executive Director, LCRN Clinical Director and LCRN Chief Operating Officer. The Group meets three times per year.

6.3 The Trust has established a **LCRN Executive Group** chaired by the Nominated Executive Director reporting to the Trust Board. Membership includes LCRN Clinical Director, Deputy Clinical Directors, LCRN Chief Operating Officer, LCRN Deputy Chief Operating Officer, LCRN Project Manager, LCRN Host Financial Lead, and LCRN Communications and Engagement Lead. Its purpose is to oversee and deliver good governance of the LCRN as defined by the Host contract and LCRN Operating Framework. The Group will meet every 3 months.

6.4 The Trust has established a **Senior Team Meeting** chaired by the Chief Operating Officer and reporting to the LCRN Executive Group. This group fulfils the

expectations of the **LCRN Operational Management Group**. Membership includes Clinical Director, Chief Operating Officer, Deputy Chief Operating Officer, Research Delivery Managers (3), Industry Operations Manager, Workforce Development Lead, with the next management tier of Operations Managers (67), and Senior Nurse to inform business need. Its purpose is to maintain oversight of overall management of the LCRN and be the forum to address cross-divisional and cross-cutting needs for support and intervention. The Group will liaise with the Clinical Leads Group. The Senior Team will meet formally every 4-6 weeks. In addition, the LCRN Leadership Team will convene a weekly teleconference to discuss ongoing operational matters.

- 6.5 A verbal report will be provided at the Regional R&D/I Leads meeting every 8 weeks to provide updates on LCRN business. The Chief Operating Officer, DCOO or a member of the LCRN Senior Team will attend the meeting to discuss LCRN business as required.
- 6.6 The Trust has appointed a Divisional Clinical Leads Group, ~~described as the Clinical Cabinet~~ consisting of the Clinical Director, Co-Clinical Director, Chief Operating Officer, Deputy COO and LCRN Divisional Leads. The Divisional Clinical Leadership Group will work closely with the Senior Leadership Team; its role includes providing: (i) advice on clinical implications of national policy at the local level; (ii) intelligence to determine resource allocations and (iii) clinical intelligence and advice to support LCRN research delivery.

7. HOST BOARD CONTROLS AND ASSURANCES

- 7.1 The Trust Board will agree to review and/or sign off the following LCRN activities:
- Receipt of the LCRN Annual Finance Plan from the Executive Director, for approval;
 - Receipt of an LCRN Annual Report, from the Executive Director, for approval;
 - Submission of the Annual Finance Plan and Annual Report to the national CRN Coordinating Centre for approval.
 - Provision of the approved Annual Report to all the members of the LCRN Partnership Group;
 - Report to Trust Board quarterly on the work of the LCRN;
 - Inclusion of LCRN key performance indicators in the quarterly Trust Board Report.

Note, from 2022/23, all parts of the CRN will work to a single 'CRN Annual Plan' in respect of national priority activities. The LCRN Leadership Team is expected to contribute fully to the development of this (national) CRN Annual Plan and to ensure appropriate local implementation. This means the LCRN Leadership Team is not required to prepare or submit a separate, formal 'LCRN Annual Business Plan' using a template specified by the CRN Coordinating Centre, as has been required in previous years.

- 7.2 The Trust, as Host Organisation, has an obligation to ensure the proper management of the LCRN in terms of compliance with the governance framework and processes of the Host, including human resources, standing financial, audit and standards of business conduct instructions. The Trust shall ensure that internal policies and standing financial instructions, as they affect the LCRN, do not unreasonably diminish the efficient management of the LCRN.
- 7.3 The Trust, as Host Organisation, shall ensure that the LCRN is run in accordance with relevant laws and regulatory requirements, relevant national NHS policies and requirements, and the NHS Constitution.

8. FINANCIAL MANAGEMENT

- 8.1 The Trust, as Host Organisation, receives, manages and distributes the allocated funding with the LCRN via the Department of Health and Social Care (DHSC) approved standard template sub-contracts, or other forms of agreement with DHSC approved text.
- 8.2 The Trust, as Host Organisation, has an obligation to use the funding solely for development and delivery of LCRN activities as set out in the contract between DHSC and the Trust. Along with any other purposes, as described in executed contract variations (e.g. Excess Treatment Cost distribution). A range of measures have been developed to provide assurance that LCRN funding provided to partner organisations is used solely for these purposes.
- 8.3 Such assurance measures are in line with the Minimum Financial Controls, contained within LCRN Contract Support Document CSD007, which is annually updated by the NIHR CRN Coordinating Centre.
- 8.4 The Trust (as Host Organisation), is responsible for the financial reporting of the CRN activities. This responsibility is discharged to the LCRN Executive Leadership team, who will draw up an annual financial plan for the LCRN, as part of the LCRN Annual Plan. This plan will be developed through the Finance Working group, in collaboration with partners. During its development it will be consulted through and shaped by the Partnership Group and LCRN Executive Group. The plan will also require review and approval through the Trust Board.
- 8.5 Through the LCRN Executive Leadership team, the Trust, as Host Organisation, reports to the National CRN Coordinating Centre on financial expenditure including forecast outturn for the financial year, via the NIHR CRN Finance Tool, on a quarterly basis.
- 8.6 Through the Executive Leadership Team, the Trust, as Host Organisation, is required to submit an end-of-year financial return to the National CRN Coordinating Centre in respect of LCRN funding received. The financial return reports on all LCRN funding and expenditure, for all organisations in receipt of that funding and agrees the year-end figures for respective Partner Organisations. In addition, there is a requirement to complete an annual financial declaration which must be signed by the Host Finance Director, alongside the CRN COO.

- 8.7 The LCRN Executive Leadership team has produced a Financial Operating Procedure, which provides guidance to budget holders on the best practice for budget setting and monitoring. This is in line with the Trust's own financial procedures and expectations. This helps to ensure that the Clinical Research Network East Midlands (CRN EM) financial matters are managed to the highest professional standards and in accordance with NHS accounting standards.
- 8.8 In order to meet the NIHR LCRN Minimum Financial Controls, the Executive Leadership team are responsible for the preparation of relevant Standard Operating Procedures for the monitoring of Partner organisations to ensure that LCRN funding provided to Partners is used solely to deliver NIHR portfolio research activities as per the LCRN Partner Organisation contracts.
- 8.9 The Executive Leadership team is also responsible for the provision of guidance in relation to income generated from NIHR CRN portfolio commercial contract research with partner organisations, and will action this via a Standard Operating Procedure and Guidance for CRN Portfolio Commercial Contract Research Income.

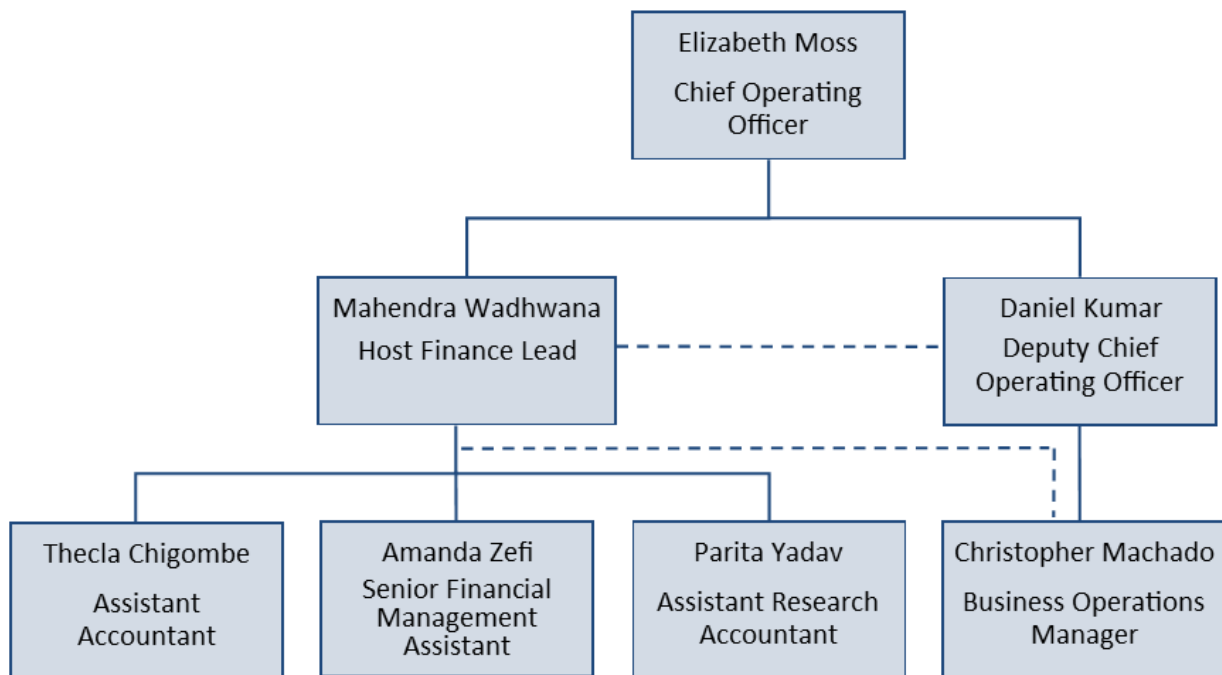
Financial Scheme of Delegation

- 8.10 The Trust, as Host Organisation, has appointed [Mahendra Wadhwana](#) ~~Martin Maynes~~ as **LCRN Host Finance Lead** who is responsible for providing financial support and specialist technical accounting knowledge to the LCRN leadership team. [Mahendra Martin](#) produces LCRN financial reports for review by the LCRN Executive Group, Host Board and LCRN Partnership Group.
- 8.11 Elizabeth Moss, **LCRN Chief Operating Officer**, is responsible for overall LCRN budget oversight and strategic decision making.
- 8.12 The COO and CD have appointed Daniel Kumar as **LCRN Deputy Chief Operating Officer** who is responsible and accountable for operational management for the infrastructure and central budgets
- 8.13 Each Lead LCRN study is assigned a study lead from within the Study Support Service team, who is responsible for the cost attribution for all non-commercial NIHR portfolio studies led in the East Midlands via the Schedule of Events Cost Attribution Template (SoECAT) - these are authorised on behalf of the Network by Divisional Managers and the SSS Compliance and Assurance Manager. Unmet Service Support Costs provided to Primary Care and non-NHS organisations are managed by the Study Support Service team. Harpal Ghattoraya (Research Delivery Manager, Divisions 2&5) is responsible for the operational management of the Service Support Costs budget.
- 8.14 [The COO and DCOO have appointed Christopher Machado as **Business Operations Manager** who is responsible for the effective delivery of a range of critical business operations associated with the LCRN. This includes financial operations, transactional input support and coordination, supporting the Finance team, along with other \(non-financial\) aspects of the role.](#)

8.15 The CRN Executive Leadership Team have appointed a qualified and experienced finance team to monitor the budget on a day to day basis. The finance team work closely with research finance staff within partner organisations. All members of the finance team are line managed by the LCRN Host Finance Lead, with day to day operational management by the Deputy Chief Operating Officer.

8.16 Figure 3, which presents the structure of the finance team, is set out below.

Figure 3 – CRN East Midlands Finance Support Structure



8.17 The scheme of delegation for financial authorisation limits has been set to reflect those of the Host organisation. The roles for CRN authorisation mirror the following roles within UHL for budget purposes only, and are summarised in 8.18, below.

8.18 Table of corresponding CRN and Host roles for budget authorisation purposes, and to reflect approval limits.

Table 1

UHL Role for budget control purposes <u>and Delegated Authority Level</u>	CRN corresponding role for budget control purposes
Other Executive Director <u>CMG Clinical Director/Deputy Director/Director of Operational Finance (Level 3)</u>	Chief Operating Officer
Deputy Head of Operations <u>or Head of</u>	Deputy Chief Operating Officer

<u>Nursing (Level 5)</u>	
<u>General Managers</u> or Deputy Head of Nursing (<u>Level 6</u>)	Business Operations Manager, RDM (Div 2 & 5), Industry Operations Manager
Service Manager <u>or Matron (Level 7)</u>	Budget Holder (Workforce Development Lead, DDT Team Lead, Transformation Lead Communications & Engagement Lead)
<u>Service Manager or</u> Matron (requisition approval) (<u>Level 7</u>)	Project Support Officer

8.19 Appendix 1 provides the LCRN financial cost codes and delegated authorisation allowances.

8.20 The Trust will maintain a fully executed contract with each LCRN Partner organisation using the Category A, Category B, or Category C LCRN Partner form of contract as included within the DHSC / LCRN Host Organisation contract (described in Table 2 below).

Table 2

Partner Contract Type	Description	Authorised signatory
Category A Partner	Organisations that receive LCRN funding totalling £50,000 or more per annum for one or more financial years	Host Chief Executive
Category B Partner	Organisations that receive an allocation of LCRN funding of between £10,000 and £49,999 per annum for one or more financial years	CRN EM Chief Operating Officer
Category C Partner	Organisations that receive an allocation of LCRN funding less than £10,000 per annum for one or more financial years	CRN EM Chief Operating Officer

8.21 CRN East Midlands maintains a log to record details of all the products and services provided by third party suppliers. This includes items such as software for training/events/design and subscriptions to a range of online tools. Table 3 sets out the roles authorised to sign different types of contract. If a contract has a value of £10,000 or greater, this can only be signed by the Chief Operating Officer or Deputy Chief Operating Officer. Advice regarding contract clauses may be sought from the Trust's Corporate and Legal department, however, the final decision to sign a contract will be made by the decision maker (i.e. the relevant budget holder or COO/DCOO).

8.22 Table 3 sets out the roles authorised to sign different types of contract

Table 3

Contract Type	Authorised contract signatories						
	LCRN Chief Operating Officer	LCRN Deputy Chief Operating Officer	Workforce Development Lead	Research Delivery Managers	Business Operations Manager	Comms & Engagement Lead	IOM
LPMS	Y	Y					
Training/e-learning products	Y	Y	Y		Y		
Other IT software & products	Y	Y			Y		Y
Event venues	Y	Y	Y	Y	Y	Y	Y
Communication materials	Y	Y			Y	Y	

9 ASSURANCE FRAMEWORK

- 9.1 The LCRN is committed to supporting safe high quality research and has developed a range of policies, systems and processes to clarify how issues or concerns which may detrimentally impact upon the LCRN are escalated throughout the organisation.
- 9.2 This section describes the structure and systems through which the LCRN Leadership and Management Groups, and the Trust board receive assurance.
- 9.3 The assurance framework describes how the LCRN is able to identify, monitor, escalate and manage issues in a timely fashion and at an appropriate level.

Issue Management and Control

- 9.4 An issue is defined as a relevant event that has happened, was not planned, and requires management action.
- 9.5 The LCRN has an open and learning culture encouraging monitoring and comments and concerns to be communicated relating to issues that impact on LCRN delivery. The table below provides examples of both internal and external sources of identified issues.

Table 4

Internal Sources	External Sources
Staff and management	Patients, carers and the public
Staff surveys	External audit
Risk register	CRN Coordinating Centre
Executive Group	Partner feedback and complaints
Partnership Group	Partner and public surveys
Senior Team Meeting	

- 9.6 It is important that the LCRN has the capability to respond to issues or concerns in a timely fashion. In practice the response required varies considerably according to the

nature of the issue or concern. In some cases, immediate action may be required. In other cases, and particularly with more complex or longstanding issues, the commissioning of a full report may be an appropriate response. However the response must always be:

- timely
- proportionate
- comprehensive
- inclusive
- effective.

9.7 The LCRN will follow a five step procedure for issue management and control (table 5). This procedure will be followed by the LCRN Senior Management who comprises the Operational Management Group.

Table 5

Procedure	Description	Delegation
1. Capture	Determine severity/ priority	
2. Examine	Assess impact on LCRN strategic and operational objectives	Request for advice (Executive or Partnership Groups)
3. Propose	Identify options Evaluate options Create recommended options	
4. Decide	Escalate (if beyond delegated authority) Approve, reject or defer recommended option	Request for advice (Executive or Partnership Groups)
5. Implement	Take corrective action or Continue to monitor	

Internal and External Sources of Assurance

9.8 Internal and external sources of assessment/assurance cover the range of the LCRN's activities and include:

Table 6

Internal Sources of Assurance	External Sources of Assurance
NIHR CRN Annual and mid-year Performance review meetings	Patients, carers and the public
Host Trust Internal audit (review of internal systems and processes)	NIHR CRN External Audit Program
Executive Group	CRN Coordinating Centre - ad hoc reviews and requests for assurance
Partnership Group	Partner feedback and engagement - informal feedback and specific questionnaire responses

Senior Team Meeting	PRES Survey data
Staff surveys and exit interviews	Partnership Group annual questionnaire - Partner survey
UHL Board report and feedback	
LCRN Performance Dashboard	
PRES Dashboard	

9.9 The LCRN has implemented an issues register to record and manage key issues currently impacting on LCRN business. Each issue is assigned an owner and scores based on the severity and priority of the issue to the LCRN. The issues are reviewed regularly in parallel with the risk register, primarily via the Executive Group.

9.10 The LCRN has produced an Issue Resolution Procedure so that stakeholders have a route to raise any matters of concern which may arise in relation to CRN East Midlands business.

LCRN Host Organisation Annual Review

9.11 The Trust may be requested, on an annual basis, to review its role in discharging the Department of Health and Social Care contract for hosting the LCRN and provide a report on this within the LCRN Annual Report. This report must be shared with the LCRN Partnership Group.

LCRN Auditing Arrangements

9.12 The Trust is obliged to ensure that LCRN activity is included in the local internal audit programme of work. The LCRN should be audited at least once every three years. The LCRN Chief Operating Officer instigated these arrangements with the Trust's Chief Financial Officer and PwC UK.

9.13 The LCRN was audited in December 2020 and was provided a low risk rating. There were four findings (3 minor, 1 medium) and the LCRN have implemented an action plan to ensure all findings will be resolved. The next audit will be due in 2023/24, however, due to the upcoming RRDN transition, a request has been made to the NIHR CRN Co-ordinating Centre to waive this requirement.

10 BUSINESS CONTINUITY ARRANGEMENTS

10.1 The Trust has a responsibility to ensure that robust local business continuity arrangements are in place for the LCRN, to ensure continuity of service in the event of an emergency.

10.2 The LCRN has developed a Business Continuity plan. This is to enable the LCRN to respond to a disruptive incident, including a public health outbreak e.g. pandemic or other related event, maintain the delivery of critical activities/services and return to "business as usual". Business continuity arrangements have been developed in line with the guidance set out by the national CRN Coordinating Centre.

10.3 The LCRN has developed an Urgent Public Health Research plan to enable the Trust and the LCRN to support the rapid delivery of urgent public health research, which

may be in a pandemic or related situation. The Urgent Public Health Research plan will be immediately activated in the event that the Department of Health and Social Care requests expedited urgent public health research.

11 RISK MANAGEMENT PROCESS

11.1 The Trust operates within a clear risk management framework which sets out how risk is identified, assimilated into the risk register, reported, monitored and escalated through the Trust’s governance structures. The framework is set out in the Risk Management Policy and is supported by relevant policies, including the Risk Assessment Policy and Policy for reporting and management of incidents including the investigation of Serious Untoward incidents.

11.2 The LCRN has implemented a risk management framework, which includes a risk register. The risk register is updated regularly and reviewed every 3 months by the LCRN Executive Group.

11.3 Both strategic and operational risks are captured within the LCRN risk register. Each risk is assigned a risk owner and a score based on the likelihood of occurrence and the impact to the LCRN. Risk scores take into consideration any mitigating actions and are reviewed regularly. The risk matrix is shown below:

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*	*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
6-11 YELLOW = MEDIUM	
12-19 AMBER = HIGH	
20-25 RED = EXTREME	

11.4 Risk Identification and Escalation

If a member of CRN East Midlands Central team identifies a potential risk which they are concerned about, the following process should be applied:

1. Raise risk with line manager and line manager will decide if the risk should be escalated to the Executive Leadership team.
2. The Executive Leadership team will review the risk and decide if a formal risk assessment is required. If this is the case, the Executive Leadership team will offer

guidance to complete the required Trust risk form.

3. The Executive Leadership team will review risk and mitigations, and subsequently decide if the risk needs to be recorded on the LCRN risk register.

12 ESCALATION PROCESS

12.1 This process describes the escalation route of issues or concerns or risks which could threaten the delivery of the Trust's obligations with regard to the delivery of the Department of Health and Social Care contract and Performance and Operating Framework.

12.2 There are identified points of contact within LCRN management, the Host Organisation, and the national CRN Coordinating Centre for concerns and issues to be escalated. Agreed escalation routes and levels are:

1. LCRN Clinical Director – Professor Azhar Farooqi (or LCRN Deputy Clinical Directors – Professor David Rowbotham / Professor Stephen Ryder)
2. Nominated Executive Director – Mr Andrew Furlong
3. The Trust Chief Executive Officer – Richard Mitchell
4. National CRN Coordinating Centre

12.3 The level of the organisation at which an issue should be addressed also varies considerably. The principle of subsidiarity is generally followed i.e. the lowest level consistent with providing an effective response. If one level finds that it cannot provide an effective response, it has a duty to escalate to the next level. However, escalation should not be used simply to pass on a problem.

13 MONITORING OF ACTION PLANS

13.1 The Trust has developed a common action plan template. Action plans developed by the LCRN that are to be monitored by the LCRN Executive Group are in accordance with this model.

13.2 The LCRN Executive Group will continue to monitor any new action plans created in [2023/24](#) that develop from the Annual Plan or are required as routine or extraordinary plans throughout the year.

14 REVIEW

14.1 The Governance Framework will be reviewed on an annual basis by the LCRN Executive Group and by the Host Organisation Trust Board.

Professor Azhar Farooqi OBE
Clinical Director, CRN East Midlands

LCRN Governance Framework: Appendix 1 - Cost centres and invoice/payment authorisers - updated August 2023

Cost Code	Description	Authorisers									
		LCRN Chief Operating Officer	LCRN Deputy Chief Operating Officer	Workforce Development Lead	Industry Operations Manager	Senior Nurse (NUH)	Business Operations Manager	RDM (Div 2 &5)	Project Support Officer	Comms & Engagement Lead	Transformation Lead
		Up to £500,000	Up to £100,000	Up to £10,000	Up to £50,000	Up to £10,000	Up to £50,000	Up to £50,000	Up to £5,000	Up to £10,000	Up to £10,000
O11	CRN EM Targeted Funding	Y	Y	N	Y	N	Y	N	N	N	Y
S18	CRN EM RSI	Y	Y	N	N	N	N	Y	N	N	Y
S19	CRN EM Clinical and Specialty Leads	Y	Y	N	Y	N	Y	N	N	N	Y
S89	CRN EM Service Support Costs	Y	Y	N	N	N	N	Y	N	N	Y
S90	CRN EM Partner Organisation Budgets	Y	Y	N	Y	N	Y	Y	N	N	Y
S97	Excess Treatment Costs	Y	Y	N	Y	N	Y	N	N	N	Y
S98	CRN EM Non pay Non staff	Y	Y	Y	Y	N	Y	N	Y	Y	Y
U08	CRN EM DDT Central	Y	Y	Y	N	N	N	N	N	N	Y
U62	DDT Transformation	Y	Y	Y	N	N	N	N	N	N	Y
U90	Transformation Non DDT	Y	Y	N	N	N	N	N	N	N	Y
U14	CRN EM SSS	Y	Y	N	N	N	N	N	N	N	Y
U89	CRN EM Senior Team	Y	Y	N	N	N	N	N	N	N	
U96	CRN EM Host Services	Y	Y	N	Y	N	Y	N	Y	N	Y
U97	CRN EM Network Wider Team	Y	Y	N	Y	N	Y	N	N	Y	Y

COR 014	Central Network Funding (NUH)	Y	Y	N	N	Y	Y	N	N	N	N
O17	Under-served Communities	Y	Y	N	N	N	Y	N	N	Y	N
O19	Public Health	Y	Y	N	N	N	N	Y	N	N	N
O49	UHL	Y	Y	N	N	N	N	N	N	N	N

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)
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	<p>Cause: 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.</p> <p>Effect: 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.</p>	3	3	9	April 2024	Communicate regular updates to staff in relation to future Hosting arrangements and RRDN Any concerns from staff to be escalated to leadership team, and discussed directly with staff Transition Lead started 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. Work with Host to support transition to the RRDN	COO Leadership team COO/ Transition Lead COO/HPM	4 4 4 4	2	3	6	Open	Decreased

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: 27.9.2023

Issue ID	Issue Type	Date Raised	Owner	Description	Severity	Priority	Actions	Action Owners	Action status	Issue status
I08	Services	Jan-23	COO / IOM	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 & 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.	Moderate	High	Meet with Partner R&D teams to review performance	STLs	4	Closed 16.8.23
							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	
							Opened Clinical Support Services funding stream - targeted on commercial studies to provide additional support for services (e.g. pharmacy, pathology etc.)	COO	4	
I09	Services	Jul-23	COO	It is becoming increasingly difficult to recruit to CRN funded and other research posts. This is caused by a range of factors including: short period of the current CRN contract, uncertainty around the future Network arrangements, shortage of nurses and wider NHS workforce, difficulties in attracting staff to work in the NHS. Also, admin posts difficult to recruit to for many of these reasons. Also some unnecessary delays with HR at UHL. The impact of this is that management time is being spent on having to re-advertise posts, unpick issues and not being able to deliver promptly on services and broader aspects of research study delivery, where posts are vacant for a longer period of time.	Moderate	Medium	Provide feedback nationally to identify and explore common issues affecting recruitment	WFDL	4	New
							Work with HR to improve appointments process	COO	1	
							Work with HR for opportunities to engage with career fairs	WFDL/ STLs	1	
							Use LinkedIn to advertise roles more widely	Comms Lead	4	
							Explore different ways of promoting DDT roles, and research delivery roles within POs	WFDL/ STLs	1	
							Discussion with Host regarding longer term appointments	COO	1	
I10	Services	Sept-23	HFL	There are ongoing delays to payment of all CRN invoices from suppliers and partners, breaching the contractual obligation, to negatively impact reputation of CRN & UHL and affect some elements of study and business delivery.	Moderate	High	Monthly collation of data points for invoice payments	HFL	1	New
							To report this to CRN Executive Group on a quarterly basis	HFL	4	
							To update the Host Finance Lead on a monthly basis	DCOO	4	
							Ensure appropriate escalation of delays due to management of AP inbox	HFL	3	

						Identification of senior member of the Accounts Payable team to escalate and when possible have regular update meetings	HFL	3
						Management of relationships with suppliers and partners by senior CRN staff	DCCO	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