

CRN East Midlands COVID-19 update and Annual Report 2019/20

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong

Trust Board paper G

Purpose of report:

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

Previous consideration:

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

It has been agreed that it is no longer a requirement for this paper to be presented to the Executive Performance Board (EPB) unless there are any specific issues that require EPB consideration.

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.

Under our normal reporting cycle, we would request that the Trust Board reviews and formally approves our 2019/20 LCRN Annual Report, accompanied by our quarterly performance report. It is recognised that the Board will currently be focussed on priorities pertaining to COVID-19, therefore formal review and approval of our report is not required this year. Accordingly, our Annual Report is submitted to this Board meeting for information and sign-off only.

In addition, for the information of the Board, we have prepared a further update on CRN East Midlands' response to COVID-19 and our progress in supporting the national research effort.

Questions

1. What has been the CRN regional response to COVID-19 and does the Board require any further information or assurance in relation to this?
2. What have been the key achievements of the CRN for 2019/20 and does the report provide sufficient information and assurance in line with the expectations of UHL Trust Board?

Conclusion

1. Following our previous report at the end of April, this paper provides an update on CRN East Midlands' progress in supporting COVID-19 Urgent Public Health research. The paper also includes information on our plans for supporting the national pipeline of COVID-19 vaccine studies, the restarting of paused NIHR Portfolio research, and an update on our collaboration with the Centre for Black and Minority Ethnic Health.
2. Our Annual Report describes the activities delivered by CRN East Midlands across key areas in 2019/20. This includes highlights relating to the delivery of accurate data and effective digital resources, effective partner and stakeholder engagement, and workforce development & wellbeing investment. The report includes a summary of our performance achievements, as well as projects completed in other areas, such as patient and public involvement and engagement (PPIE), targeting local health needs and social care. An infographic displaying some of our highlights is also attached.

Input Sought

Due to the current circumstances relating to COVID-19, it has been agreed nationally that formal review of our Annual Report is not required this year. It is recommended that our Annual Report is submitted to the Board for information and sign-off only.

Moreover, we would be happy to address any comments or queries from the Board in relation to our COVID-19 response.

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

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

CRN East Midlands COVID-19 Response - Update 18 June 2020

For the information of the Board, we have prepared this update on CRN East Midlands' response to COVID-19 and our role in supporting the national research effort.

Urgent Public Health (COVID-19) Research

Since our last update at the end of April, we have been continuing to work very closely with our partner organisations to coordinate a breadth of COVID-19 Urgent Public Health (UPH) research activity across the region. As of 18th June, we are delivering 16 UPH studies, which have in total, recruited over 7,500 participants in the East Midlands, demonstrating a significant regional achievement. Across the UK, around 100,000 participants have been recruited into UPH studies to date. In the East Midlands, there are currently ten studies in set-up across a range of settings and we expect the study portfolio to expand further over the coming months.

The East Midlands has made a notable contribution to the RECOVERY trial, which has had widespread media coverage in recent weeks, particularly since the preliminary findings on the use of dexamethasone were reported. We recognise that UHL has made a significant contribution to this study as the top recruiting site nationally, with Nottingham University Hospitals NHS Trust and Northampton General Hospital NHS Trust also in the top ten recruiting UK sites.

Vaccine studies

A critical component of the global response to COVID-19 is the development of a safe and effective vaccine. The UK government has established a Vaccine Taskforce (which includes NIHR CRN representation) that will drive forward, expedite and co-ordinate efforts to research and then produce a vaccine, and ensure this is made available to the public as quickly as possible. Currently there are c.10 vaccine candidates in the pipeline, with ongoing discussions with government and sponsors. These will move through to clinical trials and we anticipate those trials will be a mix of commercially funded and academic / government supported.

Within the UK there are currently three vaccine studies, COV001 & COV002, led by the University of Oxford and COVAC1 (and to come COVAC2) led by Imperial College London. One of these (COV002) is recruiting within the East Midlands, at Cripps Health Centre, in Nottingham, and it is likely we will look for a regional site for COVAC2 once this is further worked up. This will be followed by further waves of vaccine research, with a significant contribution from the global pharmaceutical industry.

To support and coordinate this work, the NIHR has established a national COVID-19 Vaccine Research Delivery Group. The role of this group is to coordinate resources and intelligence to

deliver COVID-19 vaccine studies across the UK. This will involve establishing a number of regional facilities with sufficient experienced staff to recruit high numbers of research participants from around September time.

In the East Midlands, we have set up a COVID-19 Vaccine Research Delivery Group to consider and plan our approach to best support the regional delivery of COVID-19 vaccine research. The group will work collaboratively to maximise the regional opportunities to deliver vaccine trials. The group is led by the CRN, and includes broad representation from our partners, including the Biomedical Research Centres (BRCs), Clinical Research Facilities (CRFs), Patient Recruitment Centres (PRCs), R&D at Acute, Healthcare and Community NHS Trusts, potential Principal Investigators for vaccine studies, Public Health, Primary care and universities.

NIHR Framework for Restarting Research

As the number of new cases of COVID-19 declines and NHS services gradually re-open, we are working with our partners to discuss when and how other research (outside of UPH studies) might be re-started, in cases where it has paused. This is dependent upon local services, local capacity (including research capacity), whether amendments might be required, any funding concerns, potential impacts of UPH activity and indeed a range of other factors. To guide this work, the NIHR has published a [‘Framework For Restart’](#) to set out the principles and preconditions around the restarting of NIHR research activities. There is a continued emphasis on the need for pragmatic, local decisions through this framework, and to remind all partners that the CRN are able to support this at local sites. Many members of the CRN team have been closely working with partners through panels and in an advisory and supportive capacity.

Each organisation is identifying which areas of research can restart, as the effect of COVID-19 varies across organisations and localities. In general, commercial sponsors are expecting their studies to reopen, indeed for many Trusts it is a huge incentive to do this due to a large part of income coming from these studies. Non-commercial sponsors are also keen to re-establish studies but may need to contact grant awarding bodies to discuss financial and other practical elements of restart.

CRN Performance management and priorities

It has been made clear that the key objectives for the CRN this year are to enable the rapid set up and delivery of the COVID-19 Urgent Public Health studies, including vaccine studies, and to support health and care organisations as they begin to restart paused research. This is a national effort, and we thank all sites involved in COVID-19 research for their significant contribution to the national response to the pandemic. At present there is no significant focus placed upon other metrics, and local performance reports are not regularly being produced or circulated at this time.

Centre for Black and Minority Ethnic Health Collaboration

In response to the finding that those from BAME backgrounds are disproportionately impacted by coronavirus, the CRN East Midlands has established a collaboration project with the Centre for

BME Health and the NIHR CRN Coordinating Centre. This work is focussed on measures to ensure COVID-19 studies are available and accessible widely and equitably, and providing targeted support to researchers. A work programme has been established, which to date has led to the development of a Network of clinical champions to support this work; the identification of different issues acting as a barrier to recruitment, which have been shared so that action can be taken to address these issues; the production of a “call to action” video featuring celebrities; a dedicated web page within the national Be Part of Research website; and close working, through the Centre for BME Health, with community panels for very useful feedback in relation to some of the UPH study documentation. There is further work planned, which we can report on, in due course.

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

- Elizabeth Moss, Chief Operating Officer, elizabeth.moss@nihr.ac.uk or
- Professor David Rowbotham, Clinical Director, david.rowbotham@nihr.ac.uk or
- Carl Sheppard, Host Project Manager, carl.sheppard@nihr.ac.uk

CRN East Midlands 2019/20 Annual Report

a. Three highlights from 2019/20

Accurate Data and Effective Digital resources were key, we delivered....

- Full implementation of the new Integrated Research Intelligence System, we achieved the highest level of RA data completeness - 98% at year end, due to excellent partner engagement.
- A three year [Digital Maturity Proposition](#), for 2019/20 this included: a stocktake survey with published results; a comprehensive workshop with four clear themes emerging; personalised google sites (e.g. [1](#) & [2](#)) for local CIs and further plans for future initiatives.
- The East Midlands contributed 1,851 PRES questionnaires and developed an [easy view dashboard](#) which has been shared and replicated across many other LCRNs.
- Excellent uptake of our responsive & interactive [primary care website](#). Initially developed for GP Practices, it includes information on the RSI scheme, details of studies, searches & training material; it has recently been expanded to include community Pharmacies.

Focussing on effective partner and stakeholder engagement, we delivered...

- A very well received CRN @ 5 event at the Leicester Space Centre to celebrate amazing regional achievements and partnerships enabled through the CRN
- We continue to invest in partner and stakeholder relationships; last year we received further invitations from partner CEOs/MDs to lead work in their organisation to support, review and renew their important R&D functions
- Sustained investment in regional partnerships, particularly with the AHSN and SMEs; the RDS in relation to social care scoping work and the ARC in relation particularly to EDI
- We continue in our supra-network working with Eastern and West Midlands CRNs, particularly in joint CI Leadership and close working on WFD activities

Workforce development & Wellbeing investment is critical, we have supported this by...

- Establishing a Wellbeing working group & developing a full annual programme of wellbeing activities, events and support, including the training of 2 Mental Health First Aiders.
- Holding our second Early Career Researcher Event to promote opportunities to deliver research and build a research career across many different professions and settings.
- Held another incredibly well attended (oversubscribed) Research Forum event, this year with a digital theme, which provided a fantastic opportunity for connecting, networking & learning.

b. HLO Performance

We have met the majority of our measures, or slightly missed (HLO2a, 78%). Many we have well exceeded, with highlights of HLO8 and HLO2b. Exception reporting is provided below/over.

HLO1a Target: 54,000 Outurn: 56,935	HLO1b Target:2,044 Outurn:1,298	HLO2a Target: 80% Outurn: 78%	HLO2b Target: 80% Outurn: 95%	HLO6a Target: 99% Outurn:100%
HLO6b Target: 70% Outurn: 56%	HLO6c Target:45% Outurn: 47%	HLO7 Target: 1,300 Outurn: 1,361	HLO8 Target: 1,000 Outurn: 1,851	HLO9a/b Target:80/60 days Outurn: 72/58 days

HLO1b is a new measure, which we envisaged from the outset would be challenging. Nationally this measure is dominated by a small number (c.20) of high recruiting studies, and despite significant

endeavours it has proved very difficult to get these locally placed. To get these studies there is a need to grow your own, and we have made investments here; over the past year we have seen an increase in the number of new companies approaching the Network and we are engaging to ensure upcoming studies are included on the NIHR Portfolio.

HLO2a, reported at 78%, with considerable work undertaken to attain this, not least a focus on Oncology specifically across the two main acute trusts due to volume and performance. We have also visited the national team in Leeds to support them in understanding the regional drivers for this metric to influence the national process, we are keen to continue to work on ways to better shape this metric.

HLO6b, at 56%, we continue to struggle with this metric, primarily due to the constitution of our trusts, and the paucity of a commercial pipeline which is appropriate for mental health and community trusts. Much focussed work has taken place to identify suitable studies, and to promote our local organisations, along with a targeted approach to EoIs/Site ID forms. We continue to follow up key potential studies with the national team and study sponsors. Our work is beginning to bear fruit, with 3 of the partner organisations that have not recruited into commercial research studies in 2019/20 being selected for a commercial research study due to open in 2020/21, with one being the first ever commercial study for the organisation.

In relation to the new Specialty Objectives, we have met 4 of the 5 specialty objectives, narrowly missing Objective 2. In this regard, we achieved 7 out of 9 specialties with public health and dermatology not reaching the required increase; in both specialties, the available portfolio is quite small and in previous years we have had large recruiting studies which have not been replaced by new studies. Objective 5 (collection of year of birth data) is an area where we would welcome a further conversation in due course, as to future expectations.

c. Response to COVID-19: Our response to the COVID-19 pandemic, can be best summarised across these core areas

- **An East Midlands-wide regional response, with excellent collaboration**

We have seen a fantastic joint response from the R&D/CRN community, this has included the very well attended weekly meetings with all R&D Leads and the CRN with genuine good will and openness, indeed R&D Leads have fed back that they enjoy these meetings and hope they continue like this, post covid. We have seen the sharing of good practice, e.g. around consent in a critical care setting, intelligence sharing around study set-up and overcoming obstacles. Also a lot of collaborative work with partners acting as a regional team through the mobilisation of the research workforce. The best example of this is across Lincolnshire where the CRN funded workforce have come together as a county-wide team, regardless of employment, and been able to collectively respond to delivering the UPH studies, flexing staff to support across all settings. Our peripatetic research delivery team have also been key in this and we have been able to engage this resource to best support UPH studies, to fit with different local delivery models.

- **A strong regional response**

We have delivered a strong regional response and performance into UPH studies. We have swift set-up times for studies and strong recruitment. Most trusts are engaged in undertaking COVID-19 research, either at their own site, or through workforce mobilisation. We have two trusts in the top ten (NGH & UHL) for RECOVERY, when mapped to incidence, with UHL leading the way across the country and working closely with the CRN CC to help promote research opportunities within the Nightingale hospitals. Overall there is a good breadth of COVID-19 research studies being delivered

across the region, in the acute and primary care settings; across the region we are currently (14/05/20) delivering 16 studies, with a further 3 in set up.

- **Focussed and organised teams**

Our central team have also responded incredibly well, with all staff suddenly moving to home-based working. We reviewed the team, workload and working practices early on and developed a [red/blue team approach](#), which has helped to add structure, share out the work and maintain excellent leadership. This allows us to have a clear focus on UPH study delivery, but also maintain a BAU stream, which will best support us as we come out of the pandemic. Within this structure we also have clearly defined routes for the supporting elements of pandemic delivery such as Comms and information sharing - both critical when working in a changing system with multiple stakeholders.

- **Underpinning and wider support**

We have established a range of supporting measures for our teams across the region:

- [Dedicated COVID section](#) within our workforce development website
- Developing virtual versions of all our learning offerings to enable us to upskill wider workforce to support delivery of COVID-19 studies
- Introduced a wide range of Wellbeing activities for the central team who are largely home-based, many examples, such as: mental health first aider support; desk yoga; creation of virtual kitchen; themed team meetings; team quiz; mindfulness support etc.
- Provision of resources, signposting and other support in relation to wellbeing for more delivery focused teams in trusts and sites delivering studies.

- **BAME Research Awareness Collaboration Project**

The East Midlands CRN has acted as Host in relation to a [collaborative project](#) between the NIHR and the Centre of BME Health, in Leicester. This is to improve equity of access and raise awareness of studies across BAME communities through a range of approaches: establishing a national network of LCRN leads and others Champions; developing plans for further involvement of patient/public panels; producing a short COVID-19 specific information video drawing on elements of [The BAME Health Research Toolkit](#) for researchers; developing a short on-line training package and checklist; supporting production of targeted videos; utilising opportunities afforded by social media and supporting work to raise national awareness of the issues affecting the BME communities during the coronavirus epidemic.

d. Targeting Health Needs

In 2019/20 we committed 2% of our funding (£420,000) to support research into the local health needs of the East Midlands. We invited proposals, to specifically focus on areas of poor health outcome, low research opportunities and high incidence of disease burden. During the year, the network supported 30 proposals and drawn out four early examples of impact:

- The East Midlands is very diverse, with a fifth of the population from a non White British background; yet the majority of research participants in the region are White British. Therefore, we have supported a number of projects that begin to address this including supporting the further cascade of a targeted toolkit designed by the Centre for BME Health in Leicester for increasing participation of BAME groups in health and social care research, which we had previously part funded. Also working closely with both the aforementioned Centre, the Leicester BRC and the East Midlands CLAHRC, we supported the delivery of a cardiometabolic screening programme, through local lay Community Health Advocates taking place in community faith centres and workplaces in Leicester City. This was an excellent example of how to engage local communities.

- Our region has one of the highest incidence of alcohol and drug use, with liver disease preventable mortality increased by 37% in the past three years. Despite this, there is little research led by the East Midlands in this area. We supported the development of a project evaluating the use of an alcohol care team in the Emergency Department and the implementation of a screening (Identification), Brief Advice, +/- Fibro scanning and Referral for Specialist Treatment (IBAFIRST) programme for at-risk drinkers in the ED. This has led to the submission of a larger study to a NIHR funding stream, where we will be the Lead CRN.

- We also have supported work to understand the uptake of vaccinations in some migrant groups, which led to the inclusion of an important study onto the NIHR portfolio recruiting 150 participants and may inform some work in relation to COVID-19 vaccination uptake.

- In addition to some very large cities, the East Midlands also contains some very rural areas, such as in parts of Lincolnshire, where rural deprivation and health inequalities are a particular concern. We have supported the development of a virtual rehabilitation programme, adapted from a model used in cardiovascular disease, to support patients with multimorbidity health issues. We are particularly interested in this not only as a tool in rural communities but also the East Midlands has a higher than national average incidence of preventable deaths. A small scale pilot using this tool has been running over the past 9 months with a view to expanding the use for a large scale national trial.

e. Partner Engagement (with reference to the LCRN's 2020 Partner Satisfaction Survey)

The 2020 Partner Survey data was shared with us on 4 March, and although it was circulated immediately, at the Partnership Group on 6 March it was considered that there had not been sufficient time to review this, and it would be discussed in due course. The coronavirus pandemic then followed. The intention was to use the Partnership Group as a vehicle to discuss the survey result, and to review any areas where improvements could be made, or further clarity provided. This will still be the intention, once we move further towards BAU, past the current prioritisation of COVID-19 work for the CRN and our partners.

In addition to the Partner Survey, there are many other ways in which partner engagement and satisfaction can be measured, not least the fantastic regional response we have collectively delivered in relation to the coronavirus pandemic. As detailed in section c (above), partner engagement has been enhanced at this time as we have delivered a regional response.

f. Patient and Public Involvement and Engagement (PPIE)

PRES: We increased the size and scope of the Participant in Research Experience Survey (PRES), surpassing our regional and national targets for responses and introducing it into new settings including Primary Care and hospices. Analysing the results with partners enabled us to identify improvements to be made to research processes and the delivery of PRES itself, such as using participant quotes to promote research.

Research Champions: has been an aspect we have invested in this year, which included a roundtable event as the impetus to reflect and consider how to deliver the programme across the East Midlands. This was followed by an audit of Research Champions and partners to better understand levels of activity and participation. As a result we have developed stronger relationships with partners which has resulted in greater structure, contact and guidance for Research Champions and led to increased engagement with national opportunities linked to the programme. Partnering with our Champions, they have shared their personal stories in order to raise the profile of research, including through attendance at healthcare, community and charity events, by creating case studies around key

priorities such as ICTD. One of our Research Champions, Karen Rockell, spoke at our CRN@5 event and her contribution was exceptionally well received by the audience, showing the unique value that Research Champions add.

Awareness raising: through collaboration with our partners we introduced new materials and approaches designed to raise awareness and increase research participation across public audiences. This included the creation of thank you cards to be given to research participants, customised posters to be displayed across the region that celebrate the impact and potential of research and the use of digital platforms including social media to display videos, graphics and infographics to highlight key achievements; this proved especially effective for the annual statistics campaign in May 2019.

g. Social Care Pump Priming Pilot, including confirmation of any underspend

The funding was spent as planned, we undertook a scoping review of the social care environment in the East Midlands. This has captured social care services commissioned by local authorities and identified key priorities for adult social care in the region. We have also mapped active social care research at East Midlands university research groups. We have identified key contacts within these organisations and used this information to engage with stakeholders to discuss social care research. Of note, we have engaged with the Lead for the East Midlands Association of Directors of Adult Social Services (ADASS) group to discuss opportunities for research and the support we may be able to offer. We have had discussions with several university researchers and partners including NHS Trusts that are involved in research in social care and community settings. We have collaborated with the RDS (regional social care steering group in place) and engaged with colleagues at the ARC to join up our approach towards social care research in the East Midlands.

In the next phase of this work, we will continue to build links with local authorities by attending the regional ADASS meeting and linking in with the Principal Social Worker (PSW) network. This will be key to understanding more about the opportunities and challenges around social care research, as well as informing the next steps. We are also planning further engagement with researchers and care providers, subject to prioritisation, however, currently this has been postponed due to COVID-19.

Annual Report 2019-20

Highlights



98% research activity data completeness at year end



Over 1,850 responses to our Participant in Research Experience Survey



Research Forum with a digital theme and opportunities for networking and learning

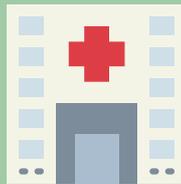
Performance

56,935



people took part in research, surpassing our target

47%



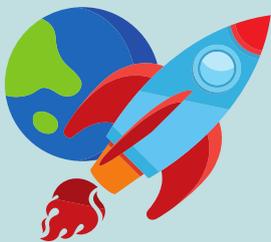
of GP practices recruited patients into research studies

95%



of non-commercial locally led studies recruited to time and target

Key projects



CRN@5 event featuring a Research Champion at the National Space Centre



Coordinated regional response to deliver urgent COVID-19 studies



Funded 30 projects to support research participation across all communities

