

Clinical Research Network: East Midlands

Annual Report 2014-15

Author: Elizabeth Moss Sponsor: Mr A Furlong – Acting Medical Director Date: 4 June 2015

Executive Summary

Paper T

Context

This document comprises the Clinical Research Network East Midlands (CRN: East Midlands) Annual Report for 2014-15. This has been written in line with the NIHR CRN Performance and Operating Framework, and Performance Management and Reporting Framework 2014.

The NIHR CRN: East Midlands is one of 15 regional research delivery arms of the NHS England, tasked with supporting the rapid set up and effective conduct of clinical research studies so that researchers can gather robust evidence needed to improve treatment for NHS patients. The CRN: East Midlands is hosted by the University Hospitals of Leicester NHS Trust and as such the Board is required to have sight of this report, comment as necessary and sign off prior to submission.

This report details the Network's performance against various objectives, both nationally set (High Level Objectives - HLOs) and locally agreed, together with an overview summarising the network's performance for the operational year.

Questions

1. Has the Network achieved its aspiration goal of 50,000 patients to be recruited into portfolio studies across 2014-15?
2. Has the number of new commercial contract studies entering the NIHR CRN Portfolio increased across the year?
3. Has the Network delivered on the government's dementia challenge?

Conclusion

1. We have exceeded our aspirational target, with 50,549 participants recruited into clinical research studies across the East Midlands of which we are immensely pleased.
2. We can report increased activity year-on-year with 191 studies reporting recruitment in 2014/15, against 166 actively recruiting commercial studies in 2013/14.
3. Recruitment of patients into dementia studies in 2014-15 was 1,050, which is 100% in excess of our target recruitment, and represents significant local effort, hard work and co-ordination. Additionally, we have increased the number of trained raters in the region,

Board Intelligence Hub template

attracted a high level of interest from Care Homes, through establishing an ENRICH office and embraced the opportunities provided through Joint Dementia Research.

Input Sought

The CRN: East Midlands is hosted by the University Hospitals of Leicester NHS Trust and as such the Board is required to have sight of this report, comment as necessary and sign off prior to submission.

For Reference

1. The following [objectives](#) were considered when preparing this report:

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

2. This matter relates to the following [governance](#) initiatives:

Organisational Risk Register	[Not applicable]
Board Assurance Framework	[Not applicable]

3. Related [Patient and Public Involvement](#) actions taken, or to be taken: [Input from lay members through the CRN Partnership group]

4. Results of any [Equality Impact Assessment](#), relating to this matter: [Not applicable]

5. Scheduled date for the [next paper](#) on this topic: [TBC]

6. Executive Summaries should not exceed [1 page](#). [My paper does not comply]

7. Papers should not exceed [7 pages](#). [My paper does not comply]



**National Institute for
Health Research**

Clinical Research Network
East Midlands

Annual Report 2014/15

Clinical Research Network: East Midlands



Delivering research to make patients,
and the NHS, better



***National Institute for
Health Research***

Clinical Research Network
East Midlands

Page left intentionally blank

NIHR CRN: East Midlands Annual Report 2014/15

Host Organisation	University Hospitals of Leicester NHS Trust
Partner Organisations – Members of the Partnership Group	<ol style="list-style-type: none"> 1. Chesterfield Royal Hospital NHS Foundation Trust 2. Derby Hospitals NHS Foundation Trust 3. Derbyshire Community Health Services NHS Trust 4. Derbyshire Healthcare NHS Foundation Trust 5. East Midlands Ambulance Service NHS Trust 6. Kettering General Hospital NHS Foundation Trust 7. Leicestershire Partnership NHS Trust 8. Lincolnshire Community Health Services NHS Trust 9. Lincolnshire Partnership NHS Foundation Trust 10. Northampton General Hospital NHS Trust 11. Northamptonshire Healthcare NHS Foundation Trust 12. Nottingham University Hospitals NHS Trust 13. Nottinghamshire Healthcare Foundation NHS Trust 14. Sherwood Forest Hospitals NHS Foundation Trust 15. United Lincolnshire Hospitals NHS Trust 16. University Hospitals of Leicester NHS Trust
Other affiliated partners (eg CCGs/Social enterprises)	<p>19 CCGs</p> <p>NHS Corby CCG NHS East Leicestershire & Rutland CCG NHS Erewash CCG NHS Hardwick CCG NHS Leicester City CCG NHS Lincolnshire East CCG NHS Lincolnshire West CCG NHS Mansfield and Ashfield CCG NHS Nene CCG NHS Newark and Sherwood CCG NHS North Derbyshire CCG NHS Nottingham City CCG NHS Nottingham North and East CCG NHS Nottingham West CCG NHS Rushcliffe CCG NHS South Lincolnshire CCG NHS South West Lincolnshire CCG NHS Southern Derbyshire CCG NHS West Leicestershire CCG</p> <p>2 Area Teams</p>

	<p>NHS England Leicestershire, Lincolnshire, Hertfordshire and South Midlands Area Team NHS England Nottinghamshire, Derbyshire Staffordshire and Shropshire Area Team</p> <p>1 Social Enterprise</p> <p>Nottingham CityCare Partnership</p> <p>10 Other Partners</p> <p>East Midlands Academic Health Science Network Leicester Cardiovascular Biomedical Research Unit Leicester Clinical Trials Unit Leicester Experimental Cancer Medicine Centre Leicester-Loughborough Diet, Lifestyle and Physical Activity Leicester Respiratory Biomedical Research Unit Biomedical Research Unit NIHR CLAHRC East Midlands Nottingham Clinical Trials Unit Nottingham Digestive Diseases Biomedical Research Unit Nottingham Hearing Biomedical Research Unit</p>
--	---

Host organisation Accountable Officer for CRN: East Midlands		
Name:	Mr John Adler	<i>Contact details</i> Email: john.adler@uhl-tr.nhs.uk Tel: 0116 258 8940
Host nominated Executive Director for CRN: East Midlands		
Name:	Andrew Furlong	<i>Contact details</i>
Job title:	Interim Medical Director	<p>Andrew Furlong Interim Medical Director University Hospitals of Leicester NHS Trust Trust HQ University Hospitals of Leicester Level 3 Balmoral Building Leicester Royal Infirmary Leicester, LE1 5WW</p> <p>Email: andrew.furlong@uhl-tr.nhs.uk mailto:andrew.furlong@uhl-tr.nhs.uk</p>

		Tel: 0116 258 5829
CRN: East Midlands Clinical Director		
Name:	Professor David Rowbotham	<i>Contact details</i> Email: david.rowbotham@nihr.ac.uk o:david.rowbotham@nihr.ac.uk Tel: 0116 258 5291
CRN: East Midlands Chief Operating Officer		
Name:	Elizabeth Moss	<i>Contact details</i> Email: elizabeth.moss@nihr.ac.uk elizabeth.moss@nihr.ac.uk Tel: 0116 258 6185

To be completed by the Host organisation

Please briefly outline the involvement of the LCRN Partnership Group in reviewing and agreeing the submitted Clinical Research Network: East Midlands Annual Report 2014-15, including the financial report			
This report was prepared by the CRN Senior team, with input from partners and clinical specialty leads. A draft version of this report, along with a financial summary taken from the NIHR Finance Tool was circulated to the Partnership Group, OMG, R&D Leads and Clinical Specialty Leads with an opportunity to input and comment. All comments received to be reviewed and incorporated prior to submission.			
Confirmation of approval of the Annual Report by the Host organisation Board			
Name:		<i>Email:</i>	
		<i>Tel:</i>	
Role:			
Signature:		Date:	04/06/2015
Contact for any communication regarding the CRN: East Midlands Annual Report			

Name:	Elizabeth Moss	Email: elizabeth.moss@nih.ac.uk elizabeth.moss@nih.ac.uk Tel: 0116 258 6185
Role:	Chief Operating Officer, CRN: East Midlands	

Contents

Item:	Page:
Clinical Research Network: East Midlands 2014/15 Performance Overview	7
Clinical Research Network: East Midlands contribution to the national High Level Objectives	13
Clinical Research Network: East Midlands contribution to the 2014/15 Specialty Objectives	23
Clinical Research Network: East Midlands achievements against the Operating Framework Compliance indicators	42
Report on the conduct of the organisation: University Hospitals Of Leicester NHS Trust	47
Appendix:	
Clinical Research Network: East Midlands Risk Register example	50

2014/15 Performance Overview

Successes & Challenges

On reflection, 2014/15 is perhaps best described as a challenging year, with a successful outcome. The key challenge has been managing the transition to form and develop the CRN; the main success measure has been exceeding our aspirational goal to recruit 50,000 patients. All specialities played a key part in contributing to this target; however, primary care contributed 43% of the total recruitment, recruiting over 21,000 patients across the East Midlands into portfolio studies. This is phenomenal achievement and an area of continuing growth.

The CRN was formerly established in April 2014, with most of the senior management roles in place by June; in reality it took some months for systems, processes and staff to be established and structures to bed-in. Whilst the senior staff were in post fairly promptly, it has taken considerable time to fully understand the research support and delivery workforce across the region. Some teams have been transitioned across from former CLRN and P/TCRNs, however there remains some work to complete in early 2015/16. Alignment of staff and services across this wider region has taken, and continues to take, a considerable amount of time, however this is a critical investment to ensure effective teams are established to support the region in the years ahead. Specific challenges relate to the RM&G workforce where we have seen significant staff turn-over, however we have been reluctant to re-appoint due to a lack of concrete information on both scope and timelines from the HRA regarding their processes. Additionally, throughout 2014/15 there has not been a high level of clarity in relation to the specific local deliverables of the Study Support Service. In light of this, East Midlands has done very well to continue to deliver on the key NIHR metrics for RM&G, however some concerns remain regarding workforce.

Moving towards a national financial model with an increasing focus on activity, with the main proxy recruitment, has been a significant challenge. The East Midlands has seen high levels of budget cuts across both 2014/15 and into 2015/16. In some ways this has given us an opportunity to openly discuss and debate the best approach, however much funding is in effect “locked-in” to staff in posts. A budget model driven by recruitment, was however a key driver in setting our 50,000 aspirational target. This target was exceeded with 50,549 participants recruited in 2014/15; considering the pressures of transition we are delighted with this achievement. We are also hopeful that this level of recruitment will have an upward influence on the East Midlands 2016/17 budget.

An important area of work this year has been the programme of partner communication and involvement. In the early stages of transition, 2013/14, it was clear that involving partners enabled a more collective and genuine approach to achieving goals. All of the established working groups are open and have membership across organisations; the OMG has representation from partners across the health economy (acute, mental health, teaching/university and primary care/community). In addition to this we have held various events to facilitate partner engagement. A particular focus for this engagement work has been in relation to financial planning. In September 2014 we outlined our intention to change the approach to Network budgets through our Finance engagement event. In October, the Partnership group had agreed a set of principles and initial plan, and by December we had modelled and shared draft partner budgets for 2015/16. The key to this was transparency throughout the modelling and planning stages with all partners having sight of the full workings and final proposed budget envelopes for all organisations. Whilst we

were clearly disappointed to receive a significant budget cut, which does pose some challenges for 2015/16, we have every confidence that the approach taken has been fair and open. We are

actively seeking feedback from all of our partners on the budget approach and process taken during 2014/15 and hope to draw on lessons learnt to inform future practice.

As part of the budget process we also established “Senior Team Links”, whereby a member of the senior management team is allocated several partner organisations to build a long term, in depth relationship. The intention is to provide support to partner organisations during annual planning and throughout the year; to agree and sign-off budget plans and to support organisations through CRN changes or new developments. Whilst this is quite a new initiative, early feedback suggests this has been largely successful and we are keen to further develop this. We intend to continue to meet with partners, both through regular, individual meetings and as a larger group when debate and discussion can be fostered; lessons learn from this year can inform our service offering across subsequent years.

One of the challenges, with the increase in geography, is how to best work effectively and efficiently across a range of sites, spanning a number of counties. In the East Midlands the use of the Google platform has been embraced, yet not without its challenges! From 1 January all of staff providing central services committed to using NIHR Google exclusively for calendar, emails and meeting planning, many are using other features such as Google drive and hangouts. We have established Google Hub Champions and there are frequent requests for training, which we provide, along with informal “lunch and learn” sessions. In deploying the Google platform, we learnt from previous tools, such as SharePoint, and were clear that for partners the use of this technology was optional, with support where necessary. The approach taken has been an inclusive one, rather than mandating use, we have invited partners to join this new way of working through the available technology.

The Dementia Challenge has also been a challenge in our region, with no former DeNDRoN located in the patch, although some coverage to the south. As such the achievements through this programme have been phenomenal. The target of 510 recruits into DeNDRoN studies was far exceeded, with the final reported figure of 1,050. There has been an investment in time and resource to ensure there is a sufficiently trained, skilled and experienced workforce to support these studies. Running parallel to this is the establishment of an ENRICH office to engage care homes, with strong interest particularly in Nottinghamshire & Lincolnshire. To embrace the opportunity offered by Join Dementia Research we also hosted an event in March which gave staff, patients and members of the public first-hand experience of 'Living well with Dementia'. Guest speakers included a patient and carer who gave their personal perspective of managing health issues associated with the disease.

Impact & Innovation

One area where portfolio research has helped shaped service is following the PARADES study. The first impact relates to the PARADES Group Psychoeducation versus Group Support, randomised controlled trial. This recruited 304 participants with bipolar disorder, a serious mental illness characterised by periods of mania (elated mood, over-activity, disinhibited behaviour and depression), with 132 from the East Midlands. This study showed benefits of group psychoeducation over group support, which is quite commonly provided in the UK. The study resulted in the set-up of group psychoeducation as a service in Nottingham and Mansfield, running four groups for 72 patients per year. It is now a key recommendation in the 2014 NICE Guideline

and is also one of the new Bipolar Disorder Quality Standards. The same programme examined the Mental Capacity Act through a survey of 549 service users and 660 psychiatrists nationally with

qualitative interviews in 30 participants. The study showed that only 36% of participants had heard of the 2005 Mental Capacity Act, only 11% had used it, yet 95% considered the protection of their rights and ability to express preferences in treatment, in advance of losing their capacity to express themselves because of illness, as important or very important. The study team were asked to give evidence to the House of Lords Select Committee on the failure of implementation of the Mental Capacity Act. The team produced a booklet with service users in the study, in partnership with AHSN East Midlands and CLAHRC East Midlands. So far, the booklet has been downloaded 23,000 times. It has led to two Recovery College courses in Nottinghamshire that are being rolled out to other parts of the East Midlands and the booklet is now part of the SCIE (the social care arm of NICE) website of useful interventions in social care.

The East Midlands has a strong track record of delivering Hepatology research, especially in relation to commercial research delivery. Hepatitis C treatments are a major area of new drug development with the prospect of very high cure rates. Two specific studies, BOSON and TURQUOISE 2 offered new drug treatments to people with high clinical need - advanced liver disease with a real risk of liver failure. The CRN ensured that patients were able to enter these studies from all over the East Midlands with the clinicians locally identifying patients and allowing them to enter the study at the trial centres. Every part of the East Midlands contributed and cure rates were between 80 and 100% in the 2 studies, a major improvement on previous therapies. This has huge health benefits to those individuals and a saving the NHS budget of around £30k per patient treated. The trials allowed access some 2 years before NHS approval are likely. As a network we are keen to further consider this East Midlands wide model for the delivery of commercial studies across a range of clinical disciplines.

Another study which has significantly contributed to local, national and international approaches to patient care is the CvLPRIT (Complete versus culprit Lesion only PRImary PCI Trial) study. This British Heart Foundation funded a Leicester led multi-centre trial (n=296) to assess the value of treating either the occluded 'culprit' artery alone, or the occluded artery plus any additional narrowed ones in patients with a heart attack. Results from the study showed that for most routine patients, treatment of the non-infarct related artery during the acute admission resulted in a greater than 50% reduction in future events. MACE composite end point (J Am Coll Cardiol 2015;65:963-72). CvLPRIT has since reversed the USA Guideline on "do not treat" and without doubt these results will also influence and be reflected in updated international STEMI guidelines when next revised. This study only achieved the target recruitment with support from the CRN, allowing expansion of the study to both Kettering and Derby. These units made a substantial contribution to the study and the CMR sub-study funded by the NIHR EME programme.

Key challenges & associated actions

An area of underperformance this year has been time and target data for both commercial (53%) and to a lesser degree non-commercial (77%) studies; additionally our first participant in data sits at 28% and 22% respectively for commercial and non-commercial research. Much work has been undertaken to understand and unpick this, specifically an action plan has been developed and presented at the Executive Group, in relation to commercial studies to ensure this is kept as high priority. We are confident that our time and target data will improve due to the measures established and engagement of all CRN teams in this activity, led by the Research Delivery

Managers across all Divisions. In relation to the first patient data, much time has been invested in establishing a LPMS which should assist us in tracking this data at an early stage to flag and

follow-up early, as presently there is a lag in the receipt of data locally, which results in incorrect targeting and chasing of teams.

In 2014/15 the CRN East Midlands COO and CD requested that the network be added to the Host internal audit programme and an audit was undertaken by PriceWaterhouseCoopers. Overall the audit considered six elements, five relating to the NIHR minimum controls and an additional (requested) element in relation to the hosting function. The findings were five at a low level and one medium, giving an overall medium rating. The area rated as medium is in relation to use of NIHR commercial income by the host and partners. As a result of these findings a comprehensive action plan was drawn up to ensure all findings are addressed. We have also begun a process of discussion and engagement with our partners and will be presenting a guidance document for further discussion at the Finance Engagement event in June, and to which several of the partners have expressed a particular interest.

CRN Integration activities

In 2014/15 the working relationship between the CRN and Academic Health Science Network (AHSN) for the East Midlands was formalised through the signing of a regional partnership agreement. This led to the identification of a management lead (Louise Young RDM Division 5) between both organisations to drive forward shared partnership priorities and in doing so, position East Midlands as the forefront of clinical research delivery and accessible solutions for patients engaging in research.

Also due to close working with the AHSN, the CRN Business Delivery Manger was an active member of the AHSN-led [Research Engaging Patients and the Public \(REPP\) Group](#). REPP brings together patients and the public who are interested in health research with researchers and health staff to talk about how to work together to make research stronger and more useful. The REPP Group held a collaboration event in 2014/15, a further event, co-hosted by the CRN is planned for 2015/16.

During 2014/15 CRN: East Midlands Division 1 has been working in close partnership with NHS England East Midlands Senate and Strategic Clinical Network to raise the profile of cancer research and its delivery across the East Midlands. We have been successful in organising that the RDM and Specialty Leads become members of and present at their Expert Clinical Advisory Group (ECAG) Meetings and the Specialty Leads are appointed as their ECAG Clinical Trials Leads, which cover all tumour sites. Awareness of research & targets has successfully been increased by providing research reports, research summaries and presentations, where performance is critically reviewed and benchmarked plus referral pathways discussed to ensure a balanced portfolio and equity of access for cancer patients across the East Midlands. Into 2015/16 we intend to further develop this with the Specialty Leads to be the key link at these meetings providing clinical research leadership.

East Midlands Contribution to the National picture

The network has contributed to a range of national developments and initiatives through representation on various groups. Dan Kumar, Industry Delivery Manager, has been involved in

facilitating sessions at the 'Network Expert Event' for CRO's, the National Industry Event and specific pharma to embed the Network processes and service offering. Excellent feedback was received for Dan's input to this work.

Locally we are establishing a Business Intelligence Service, Led by Kathryn Fairbrother, BI Lead. Some of the scoping work for this has been undertaken by Paul Maslowksi, Information Manager, as part of the first cohort of staff to attend Lean 6 sigma training, working towards greenbelt. Additionally, Paul also attends the vBIU - virtual Business Intelligence Unit meetings. The vBIU remit extends to support all Information Professionals in the networks which includes a very useful Google Community. As a result of this national link, locally we have been able to increase staff development opportunities with three members of staff supported to attend ODP training.

In relation to the emerging Study Support Service, Sheila O'Malley, Lead RM&G Manager, has taken the lead in providing RM&G responses to NIHR requests for reviews and surveys, including collating and providing feedback on HRA Policy Framework. Sheila is one of our Accord Specialists and is a project member of the Expression of Interest SSS Programme.

Elizabeth Moss, Chief Operating Officer, is a member of the NIHR Research Delivery Steering Group, contributing to that agenda from a COO perspective. Beth is also the LCRN Project lead for the Study Support Service, taking an interest to ensure local systems are established in line with national expectations.

Locally we have two GCP Programme leads, Michele Eve & Penny Scardifield, who regularly attend the required Programme Leads meetings. Through this they have been involved in developing a Quality Assurance Framework which will be used nationally as well as overseeing local delivery of the programme. Michele led a session at the national GCP Facilitator meeting in Birmingham (12 March) and supported delivery of a Facilitator Development Programme in London (25 November). Both have also contributed to the PI Masterclass, each developing one of the bite-sized sessions which will be rolled out nationally. Additionally, Michele is a trainer for the R&D Forum and has been involved in updating and delivering their training programmes.

One of our primary care locality managers, Debbie Jeffrey, is a member of the national Clinical Practice Research Database (CPRD) Group. The group was established to embed this work locally and assess regional uptake. Debbie has contacted all practices in the region to raise awareness and data extraction is expected to commence in SystemOne practices April 2015.



***National Institute for
Health Research***

Clinical Research Network
East Midlands

Table 1: Clinical Research Network: East Midlands contribution to the national High Level Objectives

Objective	Measure	CRN Target	LCRN Goal-Target	LCRN actions-activities for 2014-15	Performance against plan
1	Increase the number of participants recruited into NIHR CRN Portfolio studies	650,000	Locally set target: 50,000 NIHR set aspirational goal for 2014-15: 47,066	<p><u>Strategic:</u></p> <ul style="list-style-type: none"> • In all activities ensure the CRN: East Midlands works to and maintains clear intent and value added purpose (see Executive summary mission and vision). • Engage with CRN: East Midlands partners, stakeholders and affiliated organisations, industry and business partners to support research activity planning (short, mid, long term) that offers a balanced portfolio and opportunities for growth, informed by Divisional Clinical Leads and Clinical Specialty Groups. • Local actions to support national specialty objectives can be found in Table 2. • Build upon and establish new mutually beneficial connections that bring added value to each party and support the strategic objectives of the CRN: East Midlands allowing for innovation and improvement. This will include taking forward East Midland wide initiatives with existing and new partners. • Enable growth, strategic development and equity of access to clinical research without restriction (geography, skills, people, facilities, resources). • Maximise opportunities to secure external financial investment and reinvestment locally • Maintain regional expertise in both strategic and operational leadership, clinical, managerial and delivery aspects. • Ensure effective engagement with specialty leads and partners in the development of realistic but ambitious recruitment targets. • Engage with experts in the marketing field to positively promote the EM region as a place to do research, sell ourselves and our successes. • Continue to use the Partnership Group, Clinical Leadership Group, OMG and Working Groups for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. Ensure that the Clinical Division Leads work closely with the Division Managers and OMG to ensure effective operational and strategic decision making. • Develop and implement Divisional annual budget and action plans with Divisional Clinical Leads, Specialty Leads and Divisional Managers with continuity of local leadership and a strong managerial and clinical focus on operational strategies. • Develop and implement annual action plans in each of the workstreams that support both strategic and operational goals. • Establish robust and transparent finance and activity reporting and performance management mechanisms to support openness and encourage partnership working. • Prioritise engagement opportunities to enable partners to be involved in strategic planning and delivery (particularly in the early stages of divisional planning with Clinical Leads). • Contribute to national initiatives/working groups • Build confidence and understanding amongst all network staff that they are part of the NIHR family and an integrated team supporting a common goal. 	<p>2014/15 has been a challenging, but rewarding, year in terms of recruitment, with much work focussed towards our nationally set goal of 47,066 and locally, our aspirational target of 50,000. The final recruitment figure for CRN: East Midlands is 50,549 which has surpassed both national and locally set targets, and of which we are immensely pleased.</p> <p>We have achieved this through implementing a number of strategic priorities, in addition to specific operational actions, as detailed below and in line with our 2014/15 annual plan:</p> <p><u>Strategic:</u></p> <ul style="list-style-type: none"> • An ongoing and productive programme of partner engagement has been undertaken in 2014/15; regular meetings on all aspects of CRN business and extended invitations to the series of working groups established for all workstreams. This is the most critical part of our approach, and is expected to continue in 2015/16. • Refined and streamlined meetings, and ensure focused agendas; OMG is now openly extended to all Clinical Leads, which has reduced the frequency of Clinical meetings, as all critical business can happen through OMG. • Established a programme of senior team “Link”, with each Partner Organisation assigned a member of the senior team to build a productive relationship with. The senior link role is essentially to support their POs, help them develop and use resource efficiently and to support budget discussions. • Dedicated finance support team, working very closely with partners. We moved from an opening position of £1.9M over-committed to a final year end break-even position, a fantastic achievement. • Implemented an open and transparent approach to funding for partner organisations, based on activity, so as to incentivise, yet capped, in order to prevent de-stabilisation. • Streamlined the approach to service support costs across the region, through a harmonised, consistent approach with funding paid in arrears, based on costs incurred due to activity. • In addition to the senior team outlined in our 2014/15 plan, we have appointed a Business Intelligence Lead to provide effective strategic direction to the intelligent use of data and information to better support the various operational aspects of CRN business. • Procured the best-fit LPMS system for the region following a comprehensive and transparent process. • Begun work to promote and market the East Midlands more widely as the place to do research, some of this work in partnership with the AHSN. • Maintained stability in RM&G metrics, despite significant changes to the team due to loss of staff <p><u>Operational:</u></p>

				<ul style="list-style-type: none"> • Ensure a stable infrastructure exists to support delivery through planning with partners and a flexible research ready workforce. • Work closely with other partners on common goals, e.g. AHSN, BRU's, CLAHRC, RDS to establish opportunities to grow our own CI's with effective training, funding and support, exploring new CI's from other clinical professions. • Develop areas with low coverage and establish expertise in underdeveloped areas through effective workforce development, supervision and training for research teams. • Engage with supporting services across the region to maximise opportunities for clinical research participation and delivery (e.g. exploring service leads, community resources, community sites, community Champions). • Explore incentive schemes with partners to maximise engagement and participation (reward and recognition/job planning/awards/protected time). • Review infrastructure and resources at midyear point. <p><u>Operational:</u></p> <ul style="list-style-type: none"> • Local actions to support national specialty objectives can be found in Table 2. • Ensure sustainable strong performance and delivery across the CRN: East Midlands during the continuing transitional period informed by robust action planning and review. • Maintain a highly skilled, professional workforce, research taskforce, delivery staff and support staff across the region, supported by a robust T&E strategy and programme that offers personal development and opportunities. • Utilise mapping and existing good practices to support this HLO. • Develop and implement consistent approaches to scanning the portfolio, sharing study opportunities and pipeline knowledge. • Ensure effective and regular communication with partners (comms strategy/review of distribution lists). • Embed new organisational delivery structures swiftly. • Establish effective performance management mechanisms. • Provide active collaborative study and data management, supported by an effective LPMS. 	<ul style="list-style-type: none"> • Through the Business Intelligence service we produce a suite of reports for partners to aid performance management through the provision of accurate data and the identification of trends, concerns and successes. • Monthly summary reports are also key to providing high level data on specialty and divisional performance and balance, along with performance against CRN objectives; these are reviewed at the OMG and Executive Group meetings, with action plans prepared where performance is dipping. • Streamlined industry service introduced to offer a consistent approach locally and to aid in developing the industry portfolio. • Significant change in the approach to performance management of commercial studies across the whole NIHR portfolio, with a much closer consideration of targets and ongoing performance; a challenge especially in some of the former topic areas which has impacted our performance in RTT, however we are very hopeful that these new processes will see an improvement in 2015/16 data. • Full review of the various working groups established as part of transition, with many groups remaining, although with membership enhanced and updated terms of reference; these groups lead on the various CRN workstreams, all groups have wide representation. Key achievements include: the new budget approach; SSC harmonisation; LPMS procurement; ENRICH Care home programme plan; commercial support arrangements clarified; establishment of three Study Support Service groups; established programme of reporting; reviewed & planned approach to network Communication, including regional newsletter etc. • Attendance by both COO and CD at the monthly, East Midlands R&D Leads meetings in the region - very useful information gathering and sharing opportunity, seen as critical to engagement, and regularly held thus able to engage and update recent developments very promptly. • A focus on the detail of recruitment upload, much work has been undertaken to engage all Partner Organisations in identifying where recruitment reported nationally does not reflect local activity to ensure that all study teams are recognised for their contribution to the East Midlands. This has been achieved by working with R&D managers, as well as local study teams, particularly where previously the importance of ensuring activity is uploaded centrally has not been an issue before. • Workforce review encompassing two "taskforce" peripatetic research teams established in former CLRN's, resulting in the development of one smaller regional Research Support Team of research experienced professionals available to support short term need in partner organisations, and deployed in partnership with Divisional Delivery Managers.
--	--	--	--	--	---

2	Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time	A: Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites	80%	80%	<p>Strategic: actions cover both 2a and 2b</p> <ul style="list-style-type: none"> Continue to use the Partnership Group, Clinical Leadership Group, OMG and Working Groups for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. CD and Divisional Clinical Leads will play a key role in strategic initiatives to support this HLO with strong operational implementation led by Divisional Delivery Managers, Business Delivery Manager and industry Operations Manager. Work with Divisional and Clinical Specialty Leads, and senior management team (Delivery, Business, Industry managers) to support the strategic development of industry and non-industry activity. Develop and implement an Industry Action Plan with continuity of local leadership and a strong managerial focus on operational strategies that addresses T&T and performance management and active study management throughout the pathway. Adopt industry good practices in non-industry performance and delivery where relevant. Continue to build on the expert, professional workforce to provide maximum delivery and performance. Strengthen relationships with industry partners to support effective working together. Develop and agree reporting mechanisms and tools, ensuring delivery and performance reports reach Partner CEO's and are reported at trust Board level. Review infrastructure and resources at midyear point. <p>Operational: actions cover both 2a and 2b</p> <ul style="list-style-type: none"> The Industry Delivery Manager will work closely with Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. The Business Delivery Manager will work closely with Divisional Delivery Managers and the RM&G Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. Ensure a single point of contact for industry is identified and communicated effectively. Effective communication of T&T metrics: explore T&T champions – forward planning and readiness. Ensure delivery and support teams are “research ready” through effective communication, training and strategic planning. Review and refine systems and process by analysing, amalgamating and coalescing processes adopting lean working principles. Implement an LPMS that meets the needs of the CRN: East Midlands to support performance and data management and effective reporting. Review and refine escalation processes that offer consistency across the region where relevant. Standardise feasibility and Site Identification returns across the region. Each division to identify a nominated person for liaising with the 	53%	<p>Strategic & Operational: actions 2a</p> <p>143 studies recorded as closed to recruitment, of these just 11 have a network reference in the new format (since April 2014), thus 132 studies were open prior to the establishment of the CRN: East Midlands, during which time this HLO was not applicable for the majority of these studies. On further investigation, there is little flexibility locally for us to alter some of the unrealistic historic targets sets, which has had an impact on our performance.</p> <p>During 2014/15 we have made significant progress which we can see is improving our overall performance (local data shows RTT of 62%, as opposed to the nationally reported 53%). However much of this will have an impact in future years, as we are now responsible for both the target setting and ongoing performance management of all NIHR commercial studies in the East Midlands, and indeed relish the challenge. Actions and progress made can be summarised as:</p> <ul style="list-style-type: none"> Through the Partnership Group, Clinical Leadership Group, OMG and specifically the Industry Working Group we have formed a strategic and operational Industry Action Plan <ul style="list-style-type: none"> Industry Working Group including representation from Partner Organisations for true partnership working to focus on RTT <ul style="list-style-type: none"> Change from previous structure and how RTT was managed to one central team supporting all POs and all healthcare sectors. Migration of the commercial performance data across the region onto one internet based LPMS, and implemented processes to keep this up-to-date. Various key operational areas escalated for action to NIHR CRN CC: <ul style="list-style-type: none"> Variation in how the original targets are set for a study, and mechanism when it is appropriate to alter them. CC Currently putting in place a process to escalate requests Commercial Activity Report (CAR) inconsistencies. The CC will now be monitoring the monthly returns of the RAG information from the 6 divisions at the CC to improve the quality of the data in the CAR We have seen an increased volume of studies entering the system for site intelligence and site identification and have focussed on this process as this will have a long term impact on RTT Some inconsistencies in the service offered in the north and south of the region, have moved to streamline the approach to costing & contracts, this will have an impact by reducing the workload in one area to allow increased focus on RTT. Emphasis on RTT through regular performance meetings with Divisional Research Delivery Managers & Industry Delivery Manager, identifying and addressing
---	--	---	-----	-----	--	-----	--

				<p>IOM and allowing clinicians/sponsors to have one person to liaise with.</p> <ul style="list-style-type: none"> • Effective study management: ensure every study has a recruitment plan with regular review by a nominated lead and “contingency” plans to address study changes, recruitment blocks, red and amber performance: “recruitment toolkit”. • Monthly industry performance reviews and RAG data led by the Industry Delivery Manager in close collaboration with study teams and Divisional Research Delivery Managers. 	<p>key themes across the divisions to ensure recruitment plans in place, with appropriate involvement of the partner organisations</p> <ul style="list-style-type: none"> • Single point of contact mailbox operational since the 1st April 2014 and web based LPMS tracking system for all site intelligence/site identification activity • Escalation and roles defined with the Senior Management Team • Released Industry Process defining the flow of studies into the system giving consistency across the region
	<p>B: Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period</p>	<p>80%</p>	<p>80%</p>		<p>77%</p> <p>Strategic & Operational: actions 2b</p> <p>Based on the studies falling within this HLO marker, our data shows 77% of studies (109 of 142) reported recruitment to time and target for closed studies in 2014/15. This is just below our goal of 80%, but overall represents a strong achievement considering this transition year, and set against our overall recruitment through HLO 1. Key achievements in this area:</p> <ul style="list-style-type: none"> • We have established an effective feedback loop with partners, through the provision of monthly reports and then receiving regular feedback for any data inconsistencies • Research Delivery Managers are key to managing ongoing study performance and have played a key role: <ul style="list-style-type: none"> ○ Working with local study teams to regularly review portfolio performance by specialty ○ Working with partners and sharing good practice across sites ○ Effective use of Divisional Reports which have been very recently developed to enable RDMS to manage the portfolio of studies within each division ○ A review of RDM support arrangements has allowed us to establish two Portfolio Support manager roles to assist in effective portfolio study management • Strategic use of the Research Taskforce, now known as Research Support Team (RST), to place additional resource where required to improve time to target data • Also use of RST team leads for advice and support with recruitment plans and supporting PIs/Study teams in thinking through best recruitment routes. • LPMS procurement has been undertaken and a system of choice is in place; data migration will soon commence to enable ‘real time’ monitoring of study performance. During the procurement process there was a considered approach to ensuring we have the correct data-points available for reporting this HLO in due course. • Much work has been done to establish good

						relationships with RDCs and support them with timely data upload.
3	Increase the number of commercial contract studies delivered through the NIHR CRN	A: Number of new commercial contract studies entering the NIHR CRN Portfolio	600	n/a	<p><u>Strategic: actions cover both 3a and 3b</u></p> <ul style="list-style-type: none"> Engage with experts in the marketing field to positively promote the EM region as a place to do research, sell ourselves and our successes. Continue to develop the infrastructure across the region with outside investment to enhance visibility with external stakeholders, maximising the potential to provide an attractive environment to do research. Continue to use the Life Sciences Industry Working Group for strategic and operational planning incorporating mapping of opportunities, expertise, resources, facilities and good practice. 	<p>Although there is no regional target for this, we can report increased activity year-on-year with 191 studies reporting recruitment in 2014/15, against 166 actively recruiting commercial studies in 2013/14.</p> <p><u>Strategic and Operational actions cover both 3a and 3b</u></p> <ul style="list-style-type: none"> Education and signposting for Investigators to direct sponsors/CRO's via the NIHR portfolio through presentations, meetings and use of the central point of contact Mapping of opportunities in key areas to map expertise,

				<ul style="list-style-type: none"> • Work with Divisional and Clinical Specialty Leads to support the strategic development of industry activity and growth. • Develop and implement an Industry Action Plan that addresses ensuring the percentage of commercial contract studies as per HLO 3 is 75% minimum. • Build upon industry relationships to support study pipeline and access to industry studies that offer a balanced portfolio. • Operational: actions cover both 3a and 3b • Operational plan can be found in APPENDIX 15. Supplementary guidance papers are also available. • The Industry Delivery Manager will work closely with Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. • Support the development of marketing and comms material. • Review site identification processes to ensure consistency and speed. • Seek and share feedback on site selection rejections and explore learning opportunities. • Develop knowledge regarding site promotion, accurate feasibility and delivery to time and target across the region. 	<p>resources, facilities with appropriate commercial sponsors</p> <ul style="list-style-type: none"> • Work with Divisional and Clinical Specialty Leads to support the strategic development of industry activity and growth through involvement in the Site Intelligence/Site Identification process • The Industry Delivery Manager has worked closely with Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational actions to support this HLO • Marketing and comms material has been standardised for the Site Identification Forms and further promotional material is in development for the website and a local postcard of information • Communication around the first global recruits in the region and raising the profile of the importance via newsletter and presentations • Feedback on site selection rejections discussed during IOM facilitation of a session at Network Experts event and during IOM teleconferences, due to the importance in building engagement and areas of capacity. No mechanism at a National level to incorporate this as a process highlighted as a shortcoming but rationale that this cannot be changed until CPMS is in place • Review of site identification processes to ensure consistency and speed and interim process implemented to flag forms not returned on a weekly basis • Development of document with intelligence on research teams past performance and capabilities • Commenced working relationship with private provider of early phase research, with an aim to increase the number of portfolio studies as no NHS organisations in the region have the necessary facilities, to give increased research opportunities to NHS patients.
	<p>B: Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II-IV studies</p>	75%	n/a		<p>Data shows the number of Phase II-IV studies reporting recruitment in East Midlands is 145; overall for England, the number of Phase II-IV studies reporting recruitment is 602. We do not have a local target for this, however the East Midlands is clearly a significant contributor to the national data. All of the above reported achievements and actions are relevant to this HLO.</p>
<p>4 Reduce the time taken for eligible studies to achieve NHS Permission through CSP</p>	<p>Proportion of eligible studies obtaining all NHS Permissions within 40 calendar days (from receipt of a valid complete application by NIHR CRN)</p>	80%	n/a	<ul style="list-style-type: none"> • Continue to use the RM&G Working Group for strategic and operational planning incorporating mapping of opportunities expertise, resources, facilities and good practice. • The Lead RM&G Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the Study Support Service teams to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. 	<p>88%</p> <p>The East Midlands have continued to work hard to meet this target, which has been a considerable challenge in light of the reduction in the RM&G workforce during the course of the year.</p> <p>No. of Studies: 83 Median Time to Complete Study-Wide Processes: 13 days</p> <p>The metric was successfully achieved through:</p> <ul style="list-style-type: none"> • Active performance management and monitoring of study progress through local and national systems (RM&G Tracker, CSP and ODP) Problem solving and escalation at Trust, CCG or colleague Network level, depending on where Researchers were experiencing

							<p>difficulties in studies being progressed.</p> <ul style="list-style-type: none"> • Access to Business Intelligence systems for obtaining the necessary management data <p>Leveraging the close relationship with POs to ensure good communications with researchers and understanding of information requirements</p>
5	Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies	A: Proportion of commercial contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued or First Network Site Initiation Visit, at confirmed Network sites	80%	80%	<ul style="list-style-type: none"> • The Industry Delivery Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the Life Sciences Industry Working Group to develop operational and performance management actions to support this HLO and will utilise the mapping and existing good practices to support delivery. • The Business Delivery Manager will work closely with the Partner Organisations, Divisional Delivery Managers and the RM&G Working Group to develop operational actions to support this HLO and will utilise the mapping and existing good practices to support delivery. • Develop and implement Industry and RM&G action plans that address reducing the time taken to recruit the first participant into studies. • Ensure delivery and support teams are “research ready and research responsive” through effective communication, training and strategic planning in close collaboration with R&D teams giving NHS permission for the study to start and study sponsor (e.g. agree SIV dates collaboratively). • Review and refine systems and process by analysing, amalgamating and coalescing processes adopting lean working principles. • Review and refine escalation processes to support a consistent approach. • Ensure every study has a recruitment plan with regular review by a nominated lead and “contingency” plans to address study changes and recruitment blocks: “recruitment toolkit”. • Monthly performance reviews led by the Industry Delivery Manager in close collaboration with study teams and Divisional Research Delivery Managers. 	28%	<ul style="list-style-type: none"> • In 2014/15 the performance for commercial first patient recruited within 30 days was 28%, which is below the national target. We believe this is in line with performance of other CRNs, but would welcome feedback and further discussion. We have, however developed plans to improve this for 2015/16 and are confident our performance will improve. • In 2014/15 the performance for non-commercial first patient recruited within 30 days was 22%, which is also below the national target. • All NHS Trusts in the region are required to comply with the 70 day Clinical Trials Performance target and we have worked with Partner Organisations to enable reporting of this via the Industry, RM&G service and the Business Intelligence Service. This has in turn enabled the performance management of commercial studies to recruit first participant within 30 days. The use of a local portfolio management system, once fully operational, will enable ‘real time’ reporting of this metric and enable new processes to be in place to alert researchers when the deadline for recruitment is arising. • The Industry and RM&G team have also been working with researchers across the region to ensure that robust feasibility is undertaken at the outset of a study and to ensure that all study staff are aware of the metrics. • As reported above. we have instigated regular meetings between all Divisional Research Delivery Managers & the Industry Delivery Manager to ensure this metric is monitored on a more frequent basis.
		B: Proportion of non-commercial studies achieving first participant recruited within 30 calendar days of NHS Permission being issued	80%	80%		22%	
6	Increase NHS participation in NIHR CRN Portfolio Studies	A: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies	99%	99%		94%	In the East Midlands there are 16 Trusts in total, the only trust not reporting recruitment in 2014/15 was the East Midlands Ambulance Service (EMAS). This trust are a fully engaged partner and do contribute well to NIHR studies, however they are very dependent on study availability. EMAS have been working on the development of studies in 2014/15 that will start recruiting in 2015/16, and thus recruitment is expected to be reported.

	<p>B: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio commercial contract studies</p>	70%	70%		56%	<p>Nine out of 16 of our NHS partner Trusts currently report commercial recruitment, In addition to EMAS (as above), the reasons for a lack of commercial recruitment in our other partners is as described, along with related actions:</p> <ul style="list-style-type: none"> • EMAS: Currently no open commercial studies nationally run by ambulance services on the NIHR portfolio. Reviewed studies previously run at other ambulance services across the country to gain insight. Met and sent potential examples to review • Derbyshire Community Health Services NHS Trust: There are few commercial studies open which could potentially run within the community provider services offered by this trust, the CRN: East Midlands Industry support team have met with this Trust and a preliminary plan is in place to take this forward. • Lincolnshire Community Health Services NHS Trust: As above, due to the nature of the community services provided by this trust opportunities for commercial research are very low, again the Industry Delivery Manager has met with the trust and a preliminary plan is in place. • Leicestershire Partnership NHS Trust: the trust provides both mental health and community services, with some opportunity for commercial studies. This trust was selected for one study, logistics were being explored, however the study has now been suspended globally. • Lincolnshire Partnership NHS Trust: provide mental health services and have been involved in commercial research in the past. The site is actively seeking commercial opportunities with one sponsor in touch looking to take a study forward. • Nottingham Healthcare NHS Foundation Trust: provide primarily mental health and forensic medicine services. There was a commercial study initiated at the end of November 2014, which was the 2nd UK site to open, although there were recruits lined up, there has been no reported recruitment due to global suspension of the study. One further site selection visit completed in March 2015 and site now selected. • Derbyshire Healthcare NHS Foundation Trust: provide largely mental health services, some community services. There are two potential studies in the pipeline; one which had a site selection visit in February 2015, currently awaiting confirmation, re. selection.
	<p>C: Proportion of General Medical Practices recruiting each year into NIHR CRN Portfolio studies</p>	25%	25%		64%	<p>In the East Midlands there are 598 GPs, Surgeries & Health care sites, with 380 currently reporting recruitment. This represents 64% of sites across the five counties within East Midlands delivering on NIHR studies. This is a fantastic achievement largely due to continued strong and effective engagement with GP sites, high performing sites across the RSI scheme and speciality lead engagement. The delivery model in place across the</p>

						region fosters a consistent yet locally based approach to supporting sites, which enables good relationships to develop between key CRN staff and GP sites at each of the 5 counties. See table 2 primary care section for further details	
7	Increase the number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	13,500	510 (final target agreed with national CRN Coordinating Centre)	<ul style="list-style-type: none"> • Provide project management support to contribute to national programme and implement local delivery of RAFT • Suitably resource all RAFT related activities and identify an implementation lead • Using local intelligence identify current and projected studies that would benefit from a register approach • Gain researcher agreement to recruit from RAFT and support them with information • Target RAFT information to key PIs and trust R&D depts. • Implement governance policies and recruitment processes defined by RAFT to support implementation • Communicate key study requirements to the researcher community • Oversee studies using RAFT at study launch • Identify changes required for ways of working and use continuous improvement model to agree new processes with stakeholders • In conjunction with R&D departments and RDM, agree and implement local training plan for research support staff • Incorporate training in induction for new staff • Proactively engage with Memory Assessment Services (MAS) (including MSNAP** services) to agree ways to promote research participation and RAFT to their patients as standard practice • Contact memory services, provide RAFT information and encourage its use • Provide support where appropriate to NHS dementia services to access and make use of the implementation and communications toolkit • Identify senior leader in LCRN to take overall responsibility in delivering the dementia plan • Identify regional ENRICH leads to ensure local ENRICH development & to participate in national monthly ENRICH Delivery Team meetings • Provide project management support to contribute to national programme and implement local delivery of ENRICH • Develop and implement an engagement strategy to raise awareness • Provide continued research support proactively to engage care home owners/managers and other fora, assisting growth of local and national research ready network • Identify and appoint clinical research lead in each of the 4 disease areas (Dementia, HD, MND, PD) • Include time and costs for post holders to attend monthly teleconferences and national biannual meetings • Identify staff to attend CRN rater training programme • Identify psychometric/global practice lead(s) • Conduct skills audit and training needs analysis of staff supporting DeNDRoN portfolio 	1,050	<p>The final recruitment figure for DenDRoN studies is 1,050, which is in excess of our target recruitment, and represents significant local effort, hard work and co-ordination. The following are key to the success seen as part of the Dementia challenge:</p> <ul style="list-style-type: none"> • Dementia Project Manager appointed with responsibility to lead on developing and delivering the dementia challenge plan for the region. • Making the Dementia challenge a network-wide goal, rather than sitting within Division 4 only • Living with Dementia event held in March 2015 for members of the public both the to learn about living with Dementia and to raise awareness of research • Working closely with primary care (Division 5) to raise awareness of dementia research: <ul style="list-style-type: none"> ○ RDM for Division 5 has established links, as part of engagement strategy, with CCG dementia leads to raise awareness of JDR . ○ RSI scheme performance criteria revised to incorporate dementia study delivery and increasing awareness amongst patient and carer population • Increasing use of Join Dementia research tool and local promotion: <ul style="list-style-type: none"> ○ All CRN East Midlands staff supporting dementia studies are trained to use JDR. ○ JDR training sessions have been held in all 5 counties. • Regional ENRICH lead identified. Regional EnRICH Advisory group established. East Midlands has achieved 46 care homes signed up to the Enrich programme • 12 delivery staff currently on national Rater register • 3 practice leads identified and trained • Regional Dementia steering group established and chaired by speciality lead • For more detailed information please refer to Table 2 under the specific specialty contribution to the 2014/15 objectives.

				<ul style="list-style-type: none"> • Provide financial support (cost of training £450 plus travel and accommodation) for minimum of 7 DeNDRoN delivery staff to attend national psychometric and global rater training in 14/15 • Support LCRN and trust staff to capture areas of best practice and upload case studies to patients in research website: www.patientsinresearch.org/http://www.patientsinresearch.org/ • Identify / appoint lead research nurse(s) (or other allied health professional(s) / clinical trials officer(s) to provide professional leadership • Include time and budget to facilitate attendance at monthly teleconferences and bi-annual meetings • Develop strategies to increase number of new PI's • Develop mentorship schemes to increase new PIs to support commercial research 		
--	--	--	--	---	--	--

Table 2: Clinical Research Network: East Midlands contribution to the 2014/15 Specialty Objectives

Unless stated otherwise, the following are national targets for 2014-15.

Specialty	Ref	Objective	Measure	National Target	LCRN actions to achieve objective(s)	Performance against plan
Ageing	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	Establish mechanisms by which the age profile of NIHR CRN Portfolio study participants can be recorded	See note ^{1*}	<p>This is a national level objective. Local support provided through contributing where required to relevant work group planning and activity.</p> <ul style="list-style-type: none"> Work with SG lead locally to determine capacity and any local planning 	<ul style="list-style-type: none"> Progress has been made to include sites which have traditionally not recruited, or not significantly, to this portfolio of activity locally. Colleagues have been identified and approached regarding Ageing studies in the East Midlands. National Specialty meetings have been attended by both Specialty leads. A monthly teleconference is undertaken to co-ordinate activity across the whole of the East Midlands, with overall achievement of planned recruitment in this specialty, see below.
		Local Recruitment Target	Local Recruitment Target	310		
Anaesthesia, Perioperative Medicine and Pain Management	1	Increase the number of Anaesthesia, Perioperative Medicine and Pain Management commercial contract studies on the NIHR CRN Portfolio	Number of new Anaesthesia, Perioperative Medicine and Pain Management commercial contract studies entered onto the NIHR CRN Portfolio	4	<ul style="list-style-type: none"> As currently low numbers of commercial contract studies available, aim to take part in 1-2 studies maximum across CRN: East Midlands. Further exploration of RCoA SpR network required at a local level – as an interim aim, increase numbers of NHS Trusts engaged with the NIHR and recruiting to Portfolio studies 	<ul style="list-style-type: none"> Across the region 3 Trusts took part in 3 commercial studies, thus exceeding the aim for 1 - 2 studies and increasing the number of Trusts engaged with the network.
		Establish links with the Royal College of Anaesthetists' Specialist Registrar networks to support recruitment into NIHR CRN Portfolio studies	Number of LCRNs where Specialist Registrar networks are recruiting into NIHR CRN Portfolio studies	4		
	Local Recruitment Target	Local Recruitment Target	145	<ul style="list-style-type: none"> 943 recruits against 145 Year End Goal, representing 650% recruitment against target. 		
Cancer	1	Maintain a minimum level of participation in interventional Cancer studies on the NIHR CRN Portfolio	Recruitment to interventional Cancer studies as a proportion of LCRN cancer incidence	7.5%	<p>In order to meet the cancer specific objectives, working with cancer research leaders in partner organisations, East Midlands Strategic Clinical Network (SCN) for Cancer Expert Advisory Groups (EAGs), research teams and individual principal investigators, CRN: East Midlands will:</p> <p>Objectives 1 & 2</p> <ul style="list-style-type: none"> CRN: East Midlands aims to maintain 2014/15 recruitment and will work towards achieving the recruitment targets set but this is ambitious given 2013/14 recruitment. In order to achieve this goal CRN: East Midlands will: Set targets for individual studies in partner organisation and flag any shortfalls in recruitment that prevent the Network meeting objectives 1&2 Support partner organisations to accurately monitor individual study and organisation level recruitment and adjust portfolio to meet objectives Support partner organisations to make portfolio decisions that enable Network to meet objectives 	<p>Cancer Specific Objective 1</p> <p>CRN: East Midlands did not meet our 7.5% recruitment to interventional cancer studies as a proportion of LCRN cancer incidence target. However we have increased our national position from last to 9th over the last 3 years, for the same geography, by recruiting 5.2% against a target of 7.5%.</p> <p>Cancer Specific Objective 2</p> <p>CRN: East Midlands has increased the number of cancer patients recruited into trials over the last 3 years, for the same geography, entering 2792 cancer patients in 2014/15. We did not achieve our 20% recruitment to cancer studies as a proportion of LCRN cancer incidence target. However, we have increased our national position from 13th to 10th over the last 3 years by recruiting 11.9% against a target of 20%.</p> <p>These were achieved by working closely and in partnership with the Specialty Leads, partner organisations, cancer research leaders, East Midlands Strategic Clinical Networks Expert Clinical Advisory Groups (ECAG), Multi-Disciplinary Teams (MDT), research teams and individual principal investigators within the new geography to:</p> <ul style="list-style-type: none"> Accurately monitor the portfolio and recruitment at the organisational, Clinical
		Increase recruitment into Cancer studies on the NIHR CRN Portfolio overall	Recruitment to Cancer studies as a proportion of LCRN cancer incidence	20%		

^{1*} No target as this is a qualitative objective assessed by a descriptive text from each LCRN

					<ul style="list-style-type: none"> Map and monitor resources to deliver the objectives 	<p>Study Group and individual study level</p> <ul style="list-style-type: none"> Make portfolio decisions that will fill gaps and plan for the closure of high recruiting trials by opening new trials Benchmark against others and adjusting the portfolio accordingly Identify and escalate any barriers to the portfolio and recruitment Set realistic targets for studies and flag any shortfalls in recruitment Review progress and performance through Trusts Performance Review Meetings and Research Delivery Managers (RDM) regular 1-2-1's with representatives from Trusts to identify where and why recruitment has fallen and plan to stop this continuing by providing timeline maps to identify what is opening, closing and gaps Closely monitoring national study performance and share best practice via regular Division 1 RDM Forums and Division 1 RDM Meetings. Develop an appropriate skill mix of research staff (e.g. clinical staff coordinating complex trials and non-clinical staff coordinating follow up and straight forward trials) Provide efficiencies through research staff working in teams and providing across team, hospital and in some cases Trust cover during staff shortages Continually mapping, monitoring and adjusting resources to deliver these objectives and escalate shortfalls. Support requests for replacement posts and CRN: East Midlands RST assistance, plus find other income sources to support the continuation of some posts in the short term Increasing the awareness of research & targets by providing research reports/summaries and presentation at ECAG Meetings, research update presentations for research teams and recruitment targets for Trust Oncology Strategies.
3	NIHR CRN Portfolio of Cancer studies serves the full range of cancer types in adults and children	Proportion of adult and child cancer types on the NIHR CRN Portfolio	100%	<p>CRN: East Midlands has a comprehensive disease specific portfolio with recruitment in all disease site Clinical Studies Group (CSG) portfolios.</p> <p>In order to achieve this goal CRN: East Midlands will:</p> <ul style="list-style-type: none"> Identify gaps in the portfolio by mapping the disease profile of the population of CRN: East Midlands against the current adult, TYA and child portfolio Map local to national portfolio of adult, TYA and children's portfolio to ensure representative distribution of studies by type, treatment modality and disease stage etc. Work flexibly with partners across divisions to maximise recruitment Develop and implement an East Midlands Trial Directory to maximise patient referral pathways Use the portfolio maps to identify studies to fill the gaps (http://csg.ncri.org.uk/portfolio-maps) Map and monitor current resources against adult, TYA and child recruitment and disease profiles to identify areas requiring additional resources Maximise referral to centres of expertise 	<p>Although this is a national goal, the CRN: East Midlands has achieved this at a local level as our regional portfolio of cancer studies serves the full range of cancer types in adult, TYA and children.</p> <p>This has been achieved by:</p> <ul style="list-style-type: none"> Developing a large, broad portfolio of trials that covers all stages of disease, tumour types and treatment modalities. These include challenging trials in support of national priorities e.g. cancer surgery, radiotherapy and rare cancer trials Appointing 13 Specialty Leads to increase clinical leadership and developing these new roles both locally and nationally Working in close partnership with NHS England East Midlands Senate and Strategic Clinical Network to raise the profile of research across the East Midlands. We have been successful in organising that the RDM and Specialty Leads becoming members of and present at their Expert Clinical Advisory Group (ECAG) Meetings and the Specialty Leads are appointed as their ECAG Clinical Trials Leads. Research presentations have been given, performance critically reviewed and benchmarked plus referral pathways discussed to ensure a balanced portfolio and equity of access for cancer patients across the East Midlands Co-ordinating and achieving compliance with Peer Review research measures in all cancer types The RDM regularly meeting with the 13 Specialty Leads to develop the 	

					<p>portfolio and monitor performance by reviewing recruitment, timelines and portfolio maps</p> <ul style="list-style-type: none"> • A full portfolio review of >880 adult, TYA and children's trials was performed and potential new trials identified. These are being circulated for interest and opening/referral into as appropriate across the East Midlands. This will ensure all tumour types have an appropriate portfolio of trials, fill gaps in the portfolio and horizon scan to replace trials as they close • Specialty Leads attending the newly formed 3 monthly CRN: East Midlands Division 1 Joint Specialty Lead Meetings and the National Specialty Lead Meetings held annually.
4	Cancer patients across England can participate in Cancer studies on the NIHR CRN Portfolio	Shared care arrangements between NHS providers within LCRN geographies	See note*	<p>CRN: East Midlands has a Children's Cancer Principal Treatment Centre based between Leicester and Nottingham and Paediatric Oncology Shared Care Units at Northampton, Lincolnshire and Derby. In addition, adult MDTs and Specialist MDTs continue to refer patient within and external to CRN East Midlands. Shared Care arrangements for clinical trials are embedded into standard of care within the child, TYA and adult setting.</p> <p>In order to achieve this goal and build on the existing work already underway across the East Midlands, the CRN: East Midlands will:</p> <ul style="list-style-type: none"> • Maintain close working relationship with CYPICS partner Organisations Continue to maintain and develop the current care pathways, which already include trial participation, ensuring that referring Trusts are made aware when their patients do take up the opportunity to participate • Ensure that individual member organisation portfolios are widely available to individual clinicians to enable easy referral for participation • Ensure patients are referred out of region, as required, for appropriate trial participation • Where possible support partner organisations to receive patients back for follow up activities closer to home • Obtain agreement from all partner organisations for a written shared care agreement or memorandum of understanding (as appropriate) for management of trial patients and data flows • Where participants are required to flow across multiple organisations ensure that trial pathway planning is robust and successful 	<p>Appropriate shared care arrangements exist between East Midlands NHS providers. These include:</p> <ul style="list-style-type: none"> • Adult, TYA and paediatric patients being referred for trial participation within the local hospital via the clinic, MDT and Specialist MDT in accordance with NICE Improving Outcome Guidance. This service is reconfigured depending on the trial requirement with some patients being referred from other hospitals within and outside the East Midlands to ensure access to appropriate trials and new treatment options, especially those with rare cancers. This required the development of strong lines of communication and patient pathways. • We had planned to develop and implement a Trial Directory. This was started but won't be completed until 2015/16. This has been identified as a key document needed to aid referrals across the East Midlands • EMCYPICS shared care arrangements. The EMCYPICS Joint Principal Treatment Centre between Leicester and Nottingham provides services for diagnosis and management of cancer in children and young people living in the East Midlands <ul style="list-style-type: none"> - Shared care arrangements have successfully been implemented with Paediatric Oncology Shared Care Units (Lincoln and Boston level 1 and Northampton level 3). These arrangements were reviewed by an NIHR Coordinating Centre visit on 4.12.14 - Patient pathways dictate that some patients will receive investigations and/or treatments in more than one trust. Therefore, a Clinical Trial Collaborative Agreement has been developed to describe the information gathering and sharing requirements between parties for the purpose of clinical trials - Study set up support was identified as needed during the NIHR Coordinating Centre visit. Support for Nottingham has been arranged via the adult NCCTT research team and for Leicester via the Hope Unit team.
5	Increase the proportion of NHS cancer care providers recruiting into NIHR CRN Portfolio Cancer studies	Percentage of NHS cancer care providers recruiting into Cancer studies on the NIHR CRN Portfolio	100%	<p>CRN: East Midlands already has 100% NHS Acute Trust level participation in research. In order to maximise other opportunities CRN East Midlands will widen involvement in community partners, Hospices and any other (appropriate) qualified providers. In order to achieve this goal CRN: East Midlands will:</p> <ul style="list-style-type: none"> • Develop existing and create new links with community partners, Hospices and any other (appropriate) qualified providers • Develop existing and new links around workforce development and research awareness in these communities 	<ul style="list-style-type: none"> • In the East Midlands 100% of NHS Cancer Care Providers recruit into NIHR cancer studies. • We have been widening involvement in Community Partners, hospices and other qualified providers by developing existing and creating new links and awareness in these communities and across divisions.

					<ul style="list-style-type: none"> • Develop existing and new links across other divisions as appropriate • Map and monitor resources to support this portfolio development 	
	6	Increase the proportion of cancer patients offered participation in research	Percentage of patients reporting being offered participation in research through National Cancer Patient Experience Survey	> 32%	<p>There is an overlap between objectives 3 & 6 so actions taken will boost both areas). In order to achieve this goal and increase the proportion of patients being offered participation: CRN East Midlands will:</p> <ul style="list-style-type: none"> • Involve PCPIE members with portfolio planning particularly targeting under represented populations (using data from mapping exercise in objective 3 and results from 2011/12 and 2012/13 National Cancer Patient Experience Survey (NCPES)) • Annually cascade results of NCPES to PCPIE members and their access to user groups • Annually cascade results of NCPES to EAGs, Clinicians, CNSs, AHPs, Trust R&D and cancer management, etc. • Continue to engage with EAGs through the research lead for the group by providing recruitment reports, current and future trials portfolios • Include PCPI and NCPES in research staff's induction • Where possible use media to report on research opportunities and results • Develop PCPIE through appropriate channels locally <ul style="list-style-type: none"> • Where appropriate conduct local patient experience surveys 	<p>Results from the 2014 National Cancer Patient Experience Survey show that more patients in the East Midlands reported being offered participation in cancer research than the national average (achieving 31% against >32% target)</p> <ul style="list-style-type: none"> • 63% then went on to take part in cancer research, placing us joint 4/15 and equalling the national average • 86% reported having seen information about cancer research in their hospital, placing us joint 6/15. <p>These results are strong, however much work has been, and continue to be, done to improve this. During 2014/15 the opportunity for cancer patients to access studies in each subspecialty was increased by:</p> <ul style="list-style-type: none"> • The discussion and cascading of previous Patient Experience Survey results across ECAGs, MDTs, Cancer Managers/Lead Clinicians and research teams. This helped support local conversations about how research is communicated and how accessible research is to patients by cancer, Trust and Network • Conducting Local Patient Experience Surveys • The development of PPI within CRN: East Midlands via the Business Delivery Manager role and her involvement in national PPI meetings • The involvement of PPI representatives on each ECAG Group. This has helped to ensure each tumour type has an appropriate portfolio of trials and resources are mapped and monitored to support this portfolio. • A CRN: East Midlands Division 1 Steering Group is being established and PPI involvement will be embedded to complement this.
		Local Recruitment Target	Local Recruitment Target	3,917		<ul style="list-style-type: none"> • CRN: East Midlands achieved 80% of the Division 1 target with 3,125 individuals recruited against a year end goal of 3,917. Placing us 8/15 nationally. • In light of transition and loss of staff, including senior management, this an improved performance for the region • In should be noted that many good recruiting trials have closed and most new studies have smaller numbers. There are a large number of patients on follow up and a large industry portfolio with an increased input needed for smaller numbers of patients.
Cardiovascular Disease	1	Increase the number of Cardiovascular Disease commercial contract studies on the NIHR CRN Portfolio	Number of new Cardiovascular Disease commercial contract studies entered onto the NIHR CRN Portfolio	42	<ul style="list-style-type: none"> • Continue to work with Industry to develop and extend existing relationships, and to work together with the CRN: East Midlands Industry Delivery Manager, Division 2 Manager and other stakeholders to maximise links with Industry. Also to explore commonalities across all specialities within Division 2 and other Divisions. This will facilitate a more cohesive management structure, be attractive to Industry, generate more interest and generate more studies. • Enabling links with the 2 Biomedical Research Units within the Division to all sites across the East Midlands will provide an 'access corridor' to facilitate the conduct of studies that have resulted from research proposals being generated from the original BRU contracts. • Facilitate and support identified research leads across all 	<ul style="list-style-type: none"> • A region-wide group of CV research leads in all acute Trusts in East Midlands has been established which meets face-to-face twice a year to discuss the portfolio (local and national), review performance, and discuss any individual issues. The meeting is attended by the Divisional Manager who prepares minutes and action points which are then acted on. Engagement across the region is now much stronger. • We have seen a 28% increase in the number of Cardiovascular studies being undertaken in the East Midlands since 2013/2014 (2013/2014 = 25 studies , 2014/2015 = 32 studies). • In relation to the six sub-specialties of Heart Failure, Atherosclerosis and Thrombosis, Heart Rhythm, Heart Valves, Preventive Cardiology and Congenital Heart Disease, we have recruited to all of these in 2014/15 in the East Midlands.

					Acute Trusts in the East Midlands in anticipation of increased research activity. This has already commenced with the setting of bi-annual meetings. <ul style="list-style-type: none"> To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators. 	<ul style="list-style-type: none"> All EM Researchers now Faculty members of the Cardiovascular BRU.
	2	Increase access for patients to Cardiovascular Disease studies	Number of LCRNs contributing to multi-centre studies in the 6 Cardiovascular Disease sub-specialties	15		
		Local Recruitment Target	Local Recruitment Target	3,950		<ul style="list-style-type: none"> Year end recruitment was 2876, against 3950 Year End Goal To note: this performance target was set on the basis that at some or all of the recruitment (> 5000 in this year) into the GENVASC Study (UKCRN 12698) would count towards the return for Division 2 rather than solely into Primary Care. Similarly the UK Aneurysm Growth Study (UKCRN 10470) which accounted for 957 recruits in the East Midlands has been moved to the Surgery specialty. Taking these two studies into account, we are pleased with the recruitment performance this year for this specialty.
Children	1	Increase the number of Children's commercial contract studies within the NIHR CRN Portfolio in each LCRN	Number of Children's commercial contract studies on the NIHR CRN Portfolio	10%	The Children's theme is composed of the MCRN and paediatric non-medicines portfolios. The national MCRN portfolio has approximately 60% commercial studies and the non-medicines portfolio has <1%. It is expected that 10% is achievable in terms of number of studies with current local activity.	<ul style="list-style-type: none"> During the period of this report we maintained the level of commercial contract studies at 22% of the local Children's portfolio in terms of number of studies.
	2	All relevant sites that provide services to children are involved in research	Proportion of relevant sites recruiting to Children's studies on the NIHR CRN portfolio	95%	<ul style="list-style-type: none"> All acute care Trusts in the CRN: EM region are currently active in supporting children's studies. This will be maintained. We will actively promote and seek to involve primary care sites within the region as both active research sites and patient identification centres. Where appropriate we will seek to develop collaboration between acute and primary care sites. 	<ul style="list-style-type: none"> At year end we have studies in 56% of the Trusts described as partner organisations. We have 100% of acute Trusts actively involved with Children's portfolio research. This level of involvement has been maintained from the start of the new NIHR structure. Those sites not participating at year end are unable to do so because of the lack of suitable studies on the Children's portfolio.
	3	Recruitment of children to NIHR CRN Portfolio studies is undertaken by individuals with appropriate paediatric training and experience, or who are appropriately	Proportion of staff consenting children to NIHR CRN Portfolio studies who are paediatric trained and/or experienced, or who are appropriately supervised	100%	<ul style="list-style-type: none"> All staff involved in recruitment and the consent process will be comprehensively trained in generic research skills to ensure delivery of high quality research. Where specific specialist clinical or administrative skills or knowledge are required for an individual study or trial, appropriate staff will be selected, where possible, according to their clinical training and background and this will be enhanced by study-specific training and supervision. Where suitably trained individual are not available, appropriate training and initial supervision will be provided for all newly recruited staff. 	<ul style="list-style-type: none"> Achieved. 100% of staff supporting Children portfolio studies are experienced and/or trained to do so.
		Local Recruitment Target	Local Recruitment Target	937		<ul style="list-style-type: none"> Achieved. 1049 study participants were recruited against the local target (112%). This was achieved through robust feasibility work before a site agreed to a recruitment target and opening new studies throughout the year; these would not have been included in the initial work to develop the specialty target. Another factor in this success is the engagement and motivation of paediatricians across the region.
Critical Care	1	Increase the number of intensive care units participating in research	Proportion of intensive care units recruiting into studies on	80%	<ul style="list-style-type: none"> Adopt a proven model – identify enthusiastic and capable clinicians in smaller non-research active units. Support them 	<ul style="list-style-type: none"> 9 out of 13 Critical Care Units participating in research (69%) national position is currently 10/15

			the NIHR CRN Portfolio		<p>in the administrative, financial and practical aspects of opening studies.</p> <ul style="list-style-type: none"> • Explore potential for sharing staffing support e.g. research nurse time for specific projects. • Increase the number of NHS Trusts recruiting to Critical Care studies on the NIHR CRN Portfolio (target >95%). • Increase the number of Critical Care units in CRN: East Midlands recruiting to Critical Care studies (target >80%). • Increase the proportion of eligible patients recruited into critical care studies (target >30%). <ul style="list-style-type: none"> • Aim for critical care units with CRN: East Midlands to be within the top ten recruiting centres nationally for NIHR Portfolio Studies (target = 2 studies). 	<ul style="list-style-type: none"> • Regional engagement event held within the Critical Care and Anaesthesia specialties, as a result 2 new Critical Care units opened and took part in commercial studies 2014/15 • Three trusts actively share staffing support / resource across specialties within Division 6, for example, Anaesthetics + Emergency + Critical care
		Local Recruitment Target	Local Recruitment Target	519		<ul style="list-style-type: none"> • 140 recruits against 519 Year End Goal = 27% • The performance against target is much less than was anticipated, however, during 2014/15 there has been a decline in the pipeline of multi-centre commercial and non-commercial studies for this specialty.
Dementias and Neurodegeneration (DeNDRoN)	1	Implement arrangements for local use of the "Join Dementia Research" system to support study recruitment	A: Proportion of NHS Trusts which provide dementia services, which have put in place generic arrangements for access to medical records, with consent, for the "Join Dementia Research" system users	50%	<ul style="list-style-type: none"> • Resourced Project Manager/implementation lead identified/appointed • Local project plan in place to implement RAFT to recruit to studies • Work with Research Design Service and individuals submitting bids and Research Specialty Groups to use database • Work with R&D and IG in Trusts to agree their sign up to Join Dementia Research • Local studies eligible for Join Dementia Research regularly identified and linked to website • Gain researcher agreement to recruit from Join Dementia Research and support them with information • Proactively engage with Memory Assessment Services (MAS) to agree ways to promote research participation and Join Dementia Research to their patients as standard practice • Provide support where appropriate to NHS dementia services to access and make use of the implementation and communications toolkit 	<ul style="list-style-type: none"> • Appointed designated Dementia Challenge Project Manager • JDR being used by all mental health trusts as a tool to recruit participants and raise awareness • Insufficient volunteers yet registered to use as a tool for bid applications, although hopeful for future studies. • All eligible local studies are registered on JDR, with participants now recruited using this tool • All eligible studies have researcher agreement to be promoted on JDR • Ongoing work with MAS Services but all on board and work has begun with commissioners to include JDR as part of patient pathway
			B: Proportion of LCRN staff working on Dementias and Neurodegeneration (DeNDRoN) studies trained to use the "Join Dementia Research" system	60%	<ul style="list-style-type: none"> • Nominate a minimum of 2 staff per LCRN for JOIN DEMENTIA RESEARCH training • JOIN DEMENTIA RESEARCH accounts created for staff supporting DeNDRoN studies • Training delivered to staff supporting DeNDRoN studies • Staff are trained and equipped to use JOIN DEMENTIA RESEARCH 	<ul style="list-style-type: none"> • All LCRN staff working on JDR trained in all counties • All staff supporting Dendron studies have JDR accounts • Training delivered to staff supporting Dendron studies • All staff using JDR have been appropriately trained to the required level
	2	Increase the global and psychometric rating skills and capacity of LCRN staff supporting Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio	A: Percentage of research sites covered by at least 2 trained raters who are registered on the national rater database	80%	<ul style="list-style-type: none"> • Work towards at least 7 DeNDRoN delivery staff on national rater register • Work towards LCRN having at least 3 practice leads for both global and psychometric rating 	<ul style="list-style-type: none"> • Much work has taken place, with 12 delivery staff in the region on the national rater register • At present there are 3 Practice leads trained, as planned
			B: Proportion of LCRN staff who support Dementias and Neurodegeneration (DeNDRoN) studies who	35%	<ul style="list-style-type: none"> • Conduct skills audit and training needs analysis of staff supporting DeNDRoN portfolio • Identify staff to attend CRN rater training programme • Identify psychometric/global practice lead(s) 	<ul style="list-style-type: none"> • Training needs identified via R&D and staff trained as appropriate with support offered via Neuropsychologist. Neuropsychologist and Band 7 establishing Rater Club

			have successfully completed rater training and joined the national rater database		<ul style="list-style-type: none"> Provide financial support (cost of training £450 plus travel and accommodation) for minimum of 7 DeNDRoN delivery staff to attend national psychometric and global rater training in 14/15 	<ul style="list-style-type: none"> Staff identified and attended Rater training programme Practice Leads identified and trained, as above.
	3	Improve access to research for people living in care homes	Proportion of registered care homes participating in NIHR CRN Portfolio studies	20%	<ul style="list-style-type: none"> Identify regional ENRICH leads to ensure local ENRICH development & to participate in national monthly ENRICH Delivery Team meetings Provide project management support to contribute to national programme and implement local delivery of ENRICH Develop and implement an engagement strategy to raise awareness Provide continued research support proactively to engage care home owners/managers and other fora, assisting growth of local and national research ready network 	<ul style="list-style-type: none"> Prof Tom Denning and Prof Adam Gordon identified as local leads. Clare Litherland, CSO, participates in Enrich national meetings Regional Enrich Advisory group established to bring together leads and share good practice of care home research Also a series of local/county forums being set up with particular strength in Nottinghamshire and Lincolnshire East Midlands Enrich Office established with email and telephone support plus advice and study facilitation. Awareness raised via R&D, local events and Primary Care. Care Home owners engaged in all counties and registered via Enrich. Attend local fora. Engaged in appropriate research studies.
	4	Increase clinical leadership capacity and engagement in each of the main disease areas in the Dementias and Neurodegeneration (DeNDRoN) specialty	Number of LCRNs with local clinical leads in each of the main disease areas (dementias, Parkinson's disease, Huntington's disease and motor neurone disease)	15	<ul style="list-style-type: none"> Identify senior leader in LCRN to take overall responsibility in delivering the dementia plan Identify and appoint clinical research lead in each of the 4 disease areas (Dementia, HD, MND, PD) Include time and costs for post holders to attend monthly teleconferences and national bi-annual meetings Identify / appoint lead research nurse(s) (or other allied health professional(s) / clinical trials officer(s) to provide professional leadership 	<ul style="list-style-type: none"> Prof Tom Denning appointed as Dementia Lead for the region, Tom chairs the dementia steering group which provide a focus for this activity Dr Nin Bajaj appointed as Parkinsons Lead No plan to appoint to the HD or MND lead at this time due to a very limited portfolio of studies available.
		Local Recruitment Target	Local Recruitment Target	510		<ul style="list-style-type: none"> We significantly over recruited against target, exceeding by over 100%, with 1050 recruits against a target of 510.
Dermatology	1	Increase the opportunities for patients to participate in Dermatology studies on the NIHR CRN Portfolio	A:Proportion of health care providers of dermatology services recruiting into Dermatology studies	50%	<ul style="list-style-type: none"> Work with SG lead and CCGs to identify local providers and new care pathway following service transformation. Scope current number of research active providers, provide an outline plan for achieving target. Work with SG lead and CCGs to identify emergency department/minor injury units. Scope current number of research active providers, provide an outline plan for achieving target. 	<ul style="list-style-type: none"> More than 50% of Hospital Trusts are recruiting into at least one portfolio study. There remains a good proportion of healthcare providers involved in dermatology research. Nottingham University Hospital NHS Trust has traditionally been a strong recruiter in both interventional and observational studies. However, there has been a decline in recruitment following the commissioning of two separate services in Nottingham, at NUH and at the Nottingham NHS Treatment Centre. This has led to the most active PI being unable to take on new studies, particularly commercial studies. Due to a change in circumstances we are exploring the best option for ongoing PI oversight of existing studies, as well as identifying possible new PIs for new studies. The commissioning process has unfortunately had a detrimental impact on research in the northern part of the region. The HI-Light Vitiligo Trial is about to start recruiting, with Derby and Leicester as recruiting sites. There is a substantial local cohort of patients with vitiligo who have already expressed interest in being recruited. The University Hospitals of Leicester NHS Trust (UHL) have managed to recruit new research staff to replace recent leavers. This will enable UHL to begin to return to its previous levels of activity, particularly in commercial trials. A regional dermatology research meeting is being mooted for the second half of 2015. This should be a positive opportunity to consolidate and build on

						research activity in the region following the considerable changes over the last year.	
			B: Number of 'wounds' treatment centres recruiting into wounds trials	30		Nationally, it has been agreed that this objective will be measured in terms of the number of NHS Trusts recruiting to the following studies: Pressure 1, PCRN2667 Wound, A Randomised, double-blind, placebo-controlled study of Accel-Heal in the treatment of recalcitrant venous leg ulcers (VLUs), Development of a pressure ulcer PROM, Burns wound dressing volatile compounds pilot study (DRESSVOCS) We have no sites across East Midlands involved with delivering the above studies	
		Local Recruitment Target	Local Recruitment Target	665		<ul style="list-style-type: none"> 296 patients were recruited into studies across 2014-15, against a target of 665. This represents 41% achievement against target Recruitment numbers are lower than target, mainly because the target was based upon a particularly high-recruiting year in 2013-14, in which there were a large number of patients recruited into an observational acne study. Recruitment for 2014-15 is likely to reflect expected future recruitment levels. 	
Diabetes	1	Achieve a minimum level of participation in diabetes studies	Proportion of people with diabetes (prevalence rates) recruited into Diabetes studies on the NIHR CRN Portfolio	0.5%	<ul style="list-style-type: none"> A focus on sites who have recruited less than 50 patients per annum over the previous 2 years to understand their barriers to recruitment, will help to develop a recruitment strategy for these sites to increase recruitment to a level that is circa 50% better than their previous annual recruitment numbers. Through a wider and more inclusive engagement with CCGs and primary care organisations across the CRN: East Midlands geography will result in greater recruitment activity in primary care and diabetes recruitment overall. This will be achieved by: <ul style="list-style-type: none"> Establish a working relationship with Division 5 with a view to initiatives such as joint posts, increasing patient access, shared resources, shared education and training events, a joint publicity and communication strategy, joint industry working where possible and exploring how diabetes registries and IS systems are managed and access and how this could be harnessed together for research purposes. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators 	<ul style="list-style-type: none"> Increased focus on improving performance in Commercial Trials along with Industry Team. One large recruiting study still awaiting adoption which would have made a significant recruitment contribution (Girls Active; 1600 recruits) and allowed us to reach target set. Clinical lead is also the Acting Speciality Lead 	
	2	Increase the number of newly diagnosed people with type 1 diabetes in research	Proportion of patients identified via ADDRESS 2 recruited into Diabetes studies on the NIHR CRN Portfolio	5%			<ul style="list-style-type: none"> ADDRESS 2 continues to recruit at both UHL and NUH Trust in EM and ongoing maintenance and liaison with these recruits for new studies.
	3	Increase the proportion of NHS providers recruiting into Diabetes studies on the NIHR CRN Portfolio	A: Proportion of primary care providers recruiting participants into Diabetes studies on the NIHR CRN Portfolio	4%			<ul style="list-style-type: none"> Regular liaison with Division 5 Locality Managers leading to effective joint working around new commercial study recruitment. Piloting new 'recruitment team' model where nurses / HCAs visit GP surgeries to search and recruit patients to Diabetes studies Continuing to support specialist RN posts based in Primary Care
			B: Proportion of secondary care providers recruiting participants into Diabetes studies on the NIHR CRN Portfolio	83%			<ul style="list-style-type: none"> Focus on increasing foot clinic trials with new studies opened recruitment will be realised in 2015/2016. Increase in Investigator Led Pharma Trials (Lydia) with 2 more to come in 2015/2016 (Janssen and BI).
	4	Improve the referral systems in place for newly diagnosed people with type 1 diabetes	Proportion of secondary care trusts with referral systems in place for newly diagnosed people with type 1 diabetes	80%			<ul style="list-style-type: none"> This relates to Address 2 above. Both UHL and NUH operate a hub and spoke method of referral for these patients enabling a referral pathway for smaller trusts within the East Midlands.
			Local Recruitment Target	Local Recruitment Target			3078
Ear, Nose and Throat (ENT)	1	Increase the number of ENT commercial contract studies on the NIHR CRN Portfolio	Number of new ENT commercial contract studies entered onto the NIHR CRN Portfolio	2	<ul style="list-style-type: none"> Currently discussions being undertaken concerning a potential study led by University of Nottingham in collaboration with industry. Nottingham will be a leading site and will engage with partners on the provision of potential 	<ul style="list-style-type: none"> QUIET1 study opened, led by Nottingham in collaboration with Industry First commercial ENT study opened in UHL in 2014/15 this study met recruitment to time and target CL & SL engaged with NUH ENT department to re-energise research within 	

					participants.	<p>this area, i.e. Talking with trainees re: undertaking GCP training, becoming involved in research at an early stage of their career pathway</p> <ul style="list-style-type: none"> 667 recruits against 1613 Year End Goal = 41% The performance against target is not what was anticipated, however during 2014/15 there has been a decline in both commercial and non-commercial multi centre site studies available on the portfolio.
		Local Recruitment Target	Local Recruitment Target	1613		
Gastroenterology	1	Increase the proportion of patients recruited into Gastroenterology studies on the NIHR CRN Portfolio	Number of participants (per 100,000 population), recruited into Gastroenterology studies on the NIHR CRN Portfolio	10	<ul style="list-style-type: none"> Objective 1 – achieving 10/100,000 will be dependent on the studies that are available; some are easy to recruit to, others are more challenging. All objectives – closer collaboration between regional partners; propose a half-day meeting open to all GI researchers in the network to encourage them to become more research active, especially newly appointed consultants. Objective 2 – closer collaboration and build on the track record across the region 	<ul style="list-style-type: none"> Despite an overall decline in multi centre site studies in Gastroenterology CRN East Midlands has achieved 10/100,000 current position 8th out of 15 LCRN (based on national statistics) Work has begun to introduce closer and more joint working across the two main centres for gastroenterology research in 2014/15, further work is anticipated in 2015/16
	2	Increase the number of NHS Trusts actively participating in Gastroenterology studies on the NIHR CRN Portfolio	A: Proportion of NHS Trusts participating in Gastroenterology studies on the NIHR CRN Portfolio	90%		<ul style="list-style-type: none"> 100% of Trusts within East Midlands are taking part in Gastroenterology studies on the NIHR CRN Portfolio (according to national stats)
			B: Proportion of NHS Trusts participating in Gastroenterology commercial contract studies on the NIHR CRN Portfolio	35%		<ul style="list-style-type: none"> 38% of Trusts are participating in Gastroenterology commercial contract studies on the NIHR CRN Portfolio. Current position 5/15 LCRN (based on national stats)
		Local Recruitment Target	Local Recruitment Target	823		<ul style="list-style-type: none"> 318 recruits against 823 Year End Goal = 39% This was in part due to the suspension of a large recruiting study in the East Midlands - SEAFOOD. This was reopened in late November /Dec and it was hoped that it would put the the Specialty back on track however the recruitment was not as much as anticipated in 14/15. In addition during 2014/15 the number of pipeline studies open to multi-centre sites was small in comparison to the previous year.
Genetics	1	Increase access for patients with rare diseases to participate in Genetics studies in the NIHR CRN Portfolio	Number of LCRNs participating in multi-centre genetics studies through the NIHR UK Rare Genetic Disease Research Consortium	14	<ul style="list-style-type: none"> CRN: East Midlands has two partner Trusts who are already part of this consortium – Nottingham University Hospitals NHS Trust and University of Leicester Hospitals NHS Trust. Plans are already in place to participate in studies that have become available via this consortium and will be explored for wider regional input from Trusts providing genetics services 	<ul style="list-style-type: none"> The two sites in the CRN: East Midlands region providing regional genetics services are participating in rare genetic disease research studies. During the period of this report we have increased the number of open rare genetic diseases studies in the region from 7 to 16. This has been achieved through the genetics service lead's desire to ensure their patients have access to all relevant studies. We have also been able to increase support in the delivery team for the Leicester genetics team as a result of investment by the Trust using their own funds.
		Local Recruitment Target	Local Recruitment Target	464		<ul style="list-style-type: none"> This target has been over-achieved. 789 study participants were recruited against the local targets (170%)
Haematology	1	Increase the participation of NHS organisations in Haematology studies on the NIHR CRN Portfolio	A: Number of open Haematology studies in each LCRN	4	<ul style="list-style-type: none"> Current activity in the CRN: East Midlands will be explored and the region is not supporting a minimum of four studies efforts will be made to achieve this target. From data currently available the level of activity is not known. Through collaborative working with the Industry Operations Manager and relevant clinicians we will seek to attract 	<ul style="list-style-type: none"> Achieved. As of March 2015 CRN East Midlands has 15 Haematology portfolio studies open. The portfolio contributed 298 study participants against a target of 62 (481%)
			B: Number of open Haematology commercial	1		<ul style="list-style-type: none"> Achieved. As of March 2015 CRN East Midlands has 7 commercial studies open.

			contract studies in each LCRN		commercial studies of this nature to the CRN: East Midlands.	<ul style="list-style-type: none"> This activity has come about because one of the Trusts (Leicester) has built good working relationships with companies over the years and is seen as a 'go-to' Trust who deliver.
	2	Increase the involvement of haemophilia centres in supporting Haematology studies on the NIHR CRN Portfolio	A: Proportion of haemophilia centres recruiting patients into Haematology studies on the NIHR CRN Portfolio (comprehensive care)	90%	<ul style="list-style-type: none"> The CRN: East Midlands region will be explored to identify what level of activity currently exists and how these map onto the two types of care settings described. This data will be used to explore options for meeting these objectives. 	<ul style="list-style-type: none"> CRN East Midlands has 2 Comprehensive care Haemophilia Centres in the region and both are supporting portfolio studies.
			B: Proportion of haemophilia centres recruiting patients into Haematology studies on the NIHR CRN Portfolio (large centres)	50%		<ul style="list-style-type: none"> There are five haemophilia centres in the East Midlands, two of which are large centres. Both large centres are actively recruiting patients to portfolio studies.
		Local Recruitment Target	Local Recruitment Target	62		<ul style="list-style-type: none"> This target was significantly surpassed, with 298 patients recruited.
Hepatology	1	Increase access for patients to Hepatology studies on the NIHR CRN Portfolio	Number of LCRNs contributing to a multi-centre study in all of the six major study areas (viral hepatitis, NAFLD, autoimmune liver disease, metabolic liver disease).	15	<ul style="list-style-type: none"> CRN: East Midlands wide monthly virtual teleconference has been established with minutes circulated. Explore ways in which to replicate the establishing of a network Wide database similar to the one established at Nottingham University Hospitals to be ready to make applicable research studies available to patients when they come online: Nottingham has a growing database of autoimmune patients with an expectation that studies will come into the pipeline. A number of studies are in the pipeline with potential for all sites to take part in and, hence, access for patients increased. Large number of industry studies in set up that cover a number of different disease areas: viral, metabolic, immunological disease plus links with critical care. 	<ul style="list-style-type: none"> Although the overall specialty target was not achieved CRN East Midlands is one of 6 LCRN's out of the total of 15, contributing to the three major study areas highlighted below. CRN East Midlands is contributing to both commercial and non-commercial multi-centre studies in the following areas: <ul style="list-style-type: none"> Viral hepatitis total of 5 studies NAFLD total of 2 studies Autoimmune related total of 3 studies Currently no studies mapped to the metabolic liver disease
		Local Recruitment Target	Local Recruitment Target	528		<ul style="list-style-type: none"> 323 recruits against 528 Year End Goal = 61% Opened a large number of commercial studies in year but with relatively small recruitment targets set and achieved
Infectious Diseases and Microbiology	1	Increase awareness of the Infectious Diseases and Microbiology specialty through the identification of a local champion	Number of LCRNs with an identified clinical local champion for infectious disease public health emergencies	15	In development with SG Leads	<ul style="list-style-type: none"> The CRN East Midlands has successfully appointed Dr Martin Wiselka based at UHL as the Public Health Champion
	2	Increase access for patients to Infectious Diseases and Microbiology studies on the NIHR CRN Portfolio	Number of LCRNs recruiting into antimicrobial resistance research studies on the NIHR CRN Portfolio	15		<ul style="list-style-type: none"> CRN East Midlands is actively recruiting into the PREDICT study which is identified as an antimicrobial resistance research study Seeking to appoint a new SL in this area, potential area for growth over 2015/16
		Local Recruitment Target	Local Recruitment Target	278		<ul style="list-style-type: none"> 321 recruits against 278 Year End Goal = 115%

Injuries and Emergencies	1	All NHS major trauma centres to support recruitment into NIHR CRN Portfolio studies	Proportion of NHS major trauma centres recruiting participants into NIHR CRN Portfolio studies	100%	<ul style="list-style-type: none"> Ensuring that the number of EDs supporting recruitment into NIHR CRN Portfolio studies increases to nearly a third will involve the continuation and acceleration of work that we have already been doing in identifying and engaging research active and research interested clinicians in units outside the two major centres. We have already visited a number of EDs and had face to face meetings with ED clinicians, managers and representatives of R&D from the respective Trusts. Translating good will into recruitment in these centres will require a combination of support and the diversion of some resource for research nurse and potentially consultant time. The CRN can facilitate this by creating an environment where research expertise can be shared and also by helping clinicians in their negotiations with R&D Departments for resources. Set up and recruitment within the Emergency Setting is a specialised area and one strategy we will be considering will be the sharing of expertise from the bigger centres with units that are at earlier stages in their research infrastructure evolution. We also plan to set up a support system for researchers that will involve regular communication and also the development of a virtual communication platform for meetings, backed up by a few face to face meetings. We have a meeting planned for the 11th June at the Attenborough Centre to which research interested clinicians from EDs across the East Midlands will be invited, where these ideas can be explored further and the development of a definitive plan furthered. We have also already had one meeting with critical care colleagues in the East Midlands region who are natural allies in Division 6 around trials in the Injuries and Emergencies portfolio. More meetings are planned to develop this relationship going forward. A major barrier to recruitment is the lack of GCP trained clinicians. Another key component of the CRN strategy over the coming year will be the encouragement of and support for delivery of GCP training to emergency medicine trainees who are rotating within the East Midlands region and to as many consultants, advanced practitioners, nurses etc. as possible. As well as GCP training we will develop strategies to increase awareness amongst trainees, consultants and nursing staff across the region about trials. 	<ul style="list-style-type: none"> The 1 identified Major Trauma Centre within the CRN East Midlands is actively recruiting participants into NIHR CRN Portfolio studies and has recruited 472 participants during 2014/15 CL/SL engaged with Major Trauma Centre Director -in progress and ongoing Regional meeting held in June 2014 increased awareness of Emergency studies on the NIHR CRN Portfolio, direct result two new sites engaged SL in discussion with deanery to get GCP training as part of the induction package for all future Emergency Department trainees CRN has proved the necessary support to clinicians in their negotiations with a number of the R&D departments across the region. The nurse manager of the DREEAM team (NUH) Phil Millar has shared his knowledge and expertise with a smaller DGH within the region and this support aided in the set up a new study in the Emergency Department within this hospital.
	2	Increase the number of NHS emergency departments supporting recruitment into NIHR CRN Portfolio studies	Proportion of NHS emergency departments recruiting into NIHR CRN Portfolio studies	30%	<ul style="list-style-type: none"> 100% of Major Trauma Centres (MTCs) supporting recruitment into NIHR CRN Portfolio studies: - In the East Midlands, NUH as the Major Trauma Centre will be recruiting participants into Portfolio studies and ED will be undertaking any suitable trials focused on our component of the pathway. A major challenge over the coming year will be a development of an understanding that trauma research will necessarily cross departmental and institutional boundaries. This will require close collaboration between all those involved in research across 	<ul style="list-style-type: none"> 78% of NHS Emergency Departments across the East Midlands are actively supporting recruitment into NIHR CRN Portfolio studies. New research naive PI within NUH successfully met time to target on their first commercial study CAMEO (INJU3343) involving an emergency treatment in angioedema and got recognition for recruiting the first patient in Europe. Chesterfield Hospital NHS Foundation Trust Emergency department has just opened and recruited into the HALT IT study which is quite an achievement for an area that has had little research activity in the past and has not previously undertaken a Randomised Controlled Trial

		Local Recruitment Target	Local Recruitment Target	294	<p>the trauma pathway within the MTC and communication between EMAS, the Trauma Units and the MTC.</p> <ul style="list-style-type: none"> The CRN: East Midlands will need to support the fledgling Trauma Research Group in the process of being set up at NUH and facilitate communication within NUH and between NUH and stakeholders in the network. Tim has previously circulated a document that identified levels at which communication systems need to be in place for trauma research (most are applicable to all research) including. <ul style="list-style-type: none"> a) Between researchers – The CRN: East Midlands will need to be able to identify PIs and researchers with in ED and in other specialities involved in Trauma research and to support communication between them. A robust system will need to be in place to disseminate information about studies on the Portfolio. b) Between research nurses and CROs – A component of this, as well as developing the platform for communication to take place, will be the sharing of expertise, whether by support in person or at a distance. The development of standardised working practices and efficient exchange of information will be also be vital. c) Between Trust R&D Departments - The CRN can encourage a common approach to key trauma research questions (such as consent for incapacitated patients). This will requires a system to identify common issues in trauma care research and a mechanism by which those involved in granting research permission at a Trust level can meet together, discuss the issues, and come to a common understanding, which can then be communicated to researchers. 	<ul style="list-style-type: none"> 636 recruits against 294 Year End Goal = 216%, a significantly enhanced performance.
Mental Health	1	Increase the number of principal investigators supporting Mental Health commercial contract studies	Number of principal investigators working on open Mental Health commercial contract studies on the NIHR CRN Portfolio	95	<ul style="list-style-type: none"> Aim to increase to 25 PIs over the next year. Produce report on the barriers and drivers re: increasing PIs in MH commercial studies Engage with Trusts, AHSN, PPI and CCGs to take this forward Liaise with NIHR to include partnership (with commercial companies) studies to be classed as commercial research as many MH tech studies are partnerships with small commercial companies Industry Lead to act as mentor for new PIs Division 4 to continue to organise and support clinician training via WFD Lead Survey clinicians for special interests and try to match new studies to interest Continue to open new sites when clinician expresses an interest in a portfolio study Continue to work with R&D departments to build infrastructure for studies particularly industry Map for potential growth areas and offer mentoring, training and support. 	<ul style="list-style-type: none"> Some progress is reported, however there has not been a high level of commercial studies within this specialty, and we have experienced some studies set-up and then being put on hold, which has impacted on performance to commercial mental health activity. Overall, we feel that most trusts are engaged in seeking solutions, CRN Industry Delivery Manager has been exploring good practice in other areas to overcome barriers and explore model of whole of the East Midlands acting as one site for commercial studies. Attempted to reclassify some studies, new MTech studies will be sponsored by industry Clinician training in GCP training is undertaken on a case by case basis, with relevant support provided Ongoing work with local R&D teams, with support to match studies to relevant clinician interest New sites opened when available, with local team member work to approach all new studies on the portfolio to offer EM Trusts as sites Potential growth areas in substance misuse and self harm but no suitable studies currently available.

	2	Maintain the skills and capacity of staff supporting Mental Health Portfolio studies in frequently used Mental Health study eligibility assessments (e.g. PANSS)	Number of staff trained in frequently used Mental Health study eligibility assessments	139	<ul style="list-style-type: none"> Continue to put staff forward for PANSS and other assessments training working in the longer term towards the target. Identify an CRN: East Midlands WFD Co-ordinator to ensure staff and clinician training occurs and is kept up to date 	<ul style="list-style-type: none"> 1 additional member of staff trained in PANNS CRN WFD co-ordinator identified
		Local Recruitment Target	Local Recruitment Target	3801		<ul style="list-style-type: none"> 2591 participants were recruited against a goal of 3801 = 68% Overall we feel there has been a decline in mental health and multi site studies available to be run regionally, thus the decline in local recruitment has been affected by this national issue. Other barriers to recruitment include access to imaging and on occasion phlebotomy, however work is being done to overcome this.
Metabolic and Endocrine Disorders	1	Support patient access to Metabolic and Endocrine Disorders studies on the NIHR CRN Portfolio	Number of LCRNs supporting established studies of rare diseases in metabolic and endocrine disorders	15	<ul style="list-style-type: none"> Establishing greater links with Industry through the Industry Delivery Manager to maximise access to studies undertaking trials in complex and rare diseases. To establish links with theme leads from other CRN's and ensuring that the M&E theme of the CRN: East Midlands is fully engaged with any CRN CC National groups or meetings etc. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators. 	<ul style="list-style-type: none"> The Speciality Lead role is currently undertaken by the Division 2 Clinical Lead acting into this position and fulfilling national attendance at meetings to engage with other CRNs.
	2	Increase the number of Metabolic and Endocrine Disorders studies on the NIHR CRN Portfolio	Number of new Metabolic and Endocrine Disorders studies on rare diseases entering the NIHR CRN Portfolio	4		<ul style="list-style-type: none"> Small number of studies on portfolio with very little recruitment (1 per annum in some cases) Revised target for 2015/2016 takes this into account. 5 new studies sent out for feasibility during 2014/2015 Acromegaly and Sleep Apnoea (UKCRN: 17203) added to portfolio in 2014/2015.
		Local Recruitment Target	Local Recruitment Target	120		<ul style="list-style-type: none"> 73 Recruits against at a target of 120 (61%)
Musculoskeletal	1	Increase the opportunities for patients to participate in Musculoskeletal studies on the NIHR CRN Portfolio	Proportion of Musculoskeletal service providers recruiting into NIHR CRN Portfolio studies	75%	<ul style="list-style-type: none"> SG lead to determine numbers of providers. Scope current providers and provide outline plan for achieving target. Undertake a mapping of current MSK studies and work with SG lead to ensure capacity to support commercial contract studies. 	<ul style="list-style-type: none"> 16 sites across the East Midlands host studies. Of these, across 2014-15, 9 of the 16 sites recruited patients. For the region, the Specialty Lead has met up with all the stakeholders [mainly rheumatologists]. Previously Lincoln was not a delivery site for MSK but, are now engaged and working collaboratively, and keen to participate in further studies. The number of studies that local centres are participating in has remained at 16, the same across 2013/14 and this year, . Clinical Specialty Lead has attended all the National MSK LCRN meetings and raised awareness of MSK LCRN to the regional audit meetings. A limiting factor in Leicester has been the availability of workforce to support delivery. The support staff at LRI are not able to accommodate due to a reduction in capacity, which we are addressing in early 2015/16
	2	Increase the number of Musculoskeletal commercial contract studies on the NIHR CRN Portfolio	Number of new Musculoskeletal commercial contract studies entered on to the NIHR CRN Portfolio	30		<ul style="list-style-type: none"> 3 new commercial contract studies entered onto the portfolio. This represents 10% of national target
		Local Recruitment Target	Local Recruitment Target	1175		<ul style="list-style-type: none"> MSK has recruited 1109 patients into studies. This represents 94% achievement against target.
Neurological Disorders	1	Increase the number of NHS Trusts recruiting into Neurological Disorders studies on the NIHR CRN Portfolio	Number of previously inactive NHS Trusts which now are recruiting into Neurological Disorders studies on the NIHR CRN Portfolio	15	<ul style="list-style-type: none"> Work with AHSN, PPI to engage Acute Trusts Extend visits by Industry Lead and Managers to Acute Trusts/Clinical Leads/Medical Directors to support Trusts with recruitment Extend processes, pipeline and staff support to Neurology studies as above Work with CCGs to recruit to appropriate studies 	<ul style="list-style-type: none"> Our two large centres, NUH and UHL and both engaged well with this portfolio, some studies are run in other Trusts including DGHs, many areas keen to extend involvement, where the service commitments see the patient flows Clinical Lead has work to further engage some of the local acute trusts - ongoing and in progress We have worked hard to review the workforce available to support this

					<ul style="list-style-type: none"> Work with Trusts to build infrastructure to conduct studies particularly commercial studies. 	<p>portfolio, with some staff from NHCT and the Research Support Team (formerly research taskforce) provided to under resourced areas where appropriate</p> <ul style="list-style-type: none"> Ongoing work with Div-5 to engage CCGs Commercial studies in this area performing well
	2	Increase the number of principal investigators supporting Neurological Disorders commercial contract studies	Number of principal investigators working on open Neurological Disorders commercial contract studies on the NIHR CRN Portfolio	58	<ul style="list-style-type: none"> Aim to increase to 5 PIs over the next year. Produce report on the barriers and drivers re: increasing PIs in Neurology commercial studies Engage with Trusts, AHSN, PPI and CCGs to take this forward Liaise with NIHR to include partnership (with commercial companies) studies to be classed as commercial research as many MH tech studies are partnerships with small commercial companies? 	<ul style="list-style-type: none"> We have achieved the increase in PIs to over 5 Number of commercial studies significantly increased - barriers are staff capacity Trusts engaged in this specialty CD provides support along with Specialty Lead Potential growth areas in headache, and epilepsy
		Local Recruitment Target	Local Recruitment Target	313	<ul style="list-style-type: none"> Industry Lead to act as mentor for new PIs Division 4 to continue to organise and support clinician training via WFD Lead Survey clinicians for special interests and try to match new studies to interest Continue to open new sites when clinician expresses an interest in a portfolio study Continue to work with R&D departments to build infrastructure for studies particularly industry Map for potential growth areas and offer mentoring, training and support 	<ul style="list-style-type: none"> 995 recruits against 313 Year End Goal = 318%
Ophthalmology	1	Increase the number of Ophthalmology commercial contract studies on the NIHR CRN Portfolio	Number of new Ophthalmology commercial contract studies entered onto the NIHR CRN Portfolio	4	<ul style="list-style-type: none"> Objective 1 – engaging more NHS Trusts may have a positive impact on the number of commercial studies on the Portfolio. This must be supported by access to dedicated research staff who can support studies (e.g. one day per week) and less research experienced clinical staff. Promotion of CRN: East Midlands to clinicians across the EM area, including infrastructure support and increased opportunities for networking. 	<ul style="list-style-type: none"> In the East Midlands there are four commercial Ophthalmology studies recruiting, and one currently in setup
	2	Increase the number of NHS Trusts participating in Ophthalmology research	Number of NHS Trusts recruiting patients into Ophthalmology studies on the NIHR CRN Portfolio	100		<ul style="list-style-type: none"> 30 % of NHS Trusts across the East Midlands are participating in Ophthalmology research Potential growth area for the region within the 2 large acute trusts, current resource allocation being reviewed
		Local Recruitment Target	Local Recruitment Target	807		<ul style="list-style-type: none"> 552 recruits against 807 Year End Goal = 68% The small number of pipeline commercial and non-commercial studies available has been the key issue preventing us from achieving our target this year.
Oral and Dental	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	Number of Oral and Dental studies on the NIHR CRN portfolio recruiting in each LCRN	1	<ul style="list-style-type: none"> This is dependent on local portfolio requirements. Work with Oral and Dental SG lead and Coordinating Centre to determine opportunities for study roll out in LCRN. To scope and develop capacity to support these studies as required. As East Midlands has no dental school it may be problematic to attract and run studies into the region. However, this will be an area of growth for East Midlands LCRN. Develop capacity locally to support commercial contract studies. Work with SG lead and CC to contribute and ensure a national network of capability. Work with SG lead to determine where studies can be delivered in primary care. Identify and support sites to recruit 	<ul style="list-style-type: none"> Currently 1 study recruiting
	2	Increase the number of Oral and Dental commercial contract studies on the NIHR CRN Portfolio	Number of open Oral and Dental commercial contract studies on the NIHR CRN Portfolio	2		<ul style="list-style-type: none"> There currently are no commercial contract studies on the portfolio.
	3	Offer a balanced portfolio of studies to practitioners and participants	A: Proportion of Oral and Dental studies on the NIHR CRN Portfolio recruiting	20%		<ul style="list-style-type: none"> 1 study on the portfolio recruiting from primary care Although the targets set have not been achieved, we aim to build on our current recruitment performance. This is clearly dependent upon the number of

			from a primary care setting		patients.	dentistry studies available within the East Midlands region. We have allocated a nominal primary care lead to oversee recruitment and capacity development for oral and dentistry studies. The role of the lead is to engage with the dentistry national meetings and with allied healthcare professionals within this setting as the number of eligible portfolio studies increases.
			B: Proportion of participants recruited from a primary care setting into Oral and Dental studies on the NIHR CRN Portfolio	50%		13 participants recruited primary care setting into oral and dental studies
		Local Recruitment Target	Local Recruitment Target	26		<ul style="list-style-type: none"> 13 patients recruited against 26 Year End Goal. This represents 50% performance against target.
Primary Care	1	Increase the opportunities for patients to participate in NIHR CRN Portfolio studies	A: Proportion of GP sites registered as research capable ²	35%	<ul style="list-style-type: none"> LCRN to contribute to national definition of 'registered research capable site' and determine additional local criteria that may apply. Establish % benchmark of current RGCP Research Ready accredited sites and forecast target for year end, together with an outline plan for achieving target. Map current geographical spread of registered research capable sites across CCGs. Forecast target for year end, together with an outline plan for achieving target. For geographical areas rag rated red, work in collaboration with CCGs to establish engagement of member practices and delivery to target. Work to establish a community pharmacy champion, with clear role outline. Draw on existing community pharmacy representation from across East Midlands pharmacy research group. 	<ul style="list-style-type: none"> Primary care has exceeded its recruitment target of 12,522 by 178%, achieving 21,567 recruits across 2014-15. This represents 43% of the total recruitment for CRN: East Midlands. This has been achieved through continued active engagement with individual practices and, continuing good working relationships with sites, together with close performance management and delivery of the RSI scheme . Research capable sites are defined as those either accredited as research ready or, those delivering on NIHR CRN portfolio research. In 2014/15, 379 sites delivered on portfolio studies across East Midlands, from a total of 598 sites. This represents 63% of sites research capable. In the East Midlands we have a high level of engagement with the Research Ready scheme with 106 accredited practices and 63 more in the process of accreditation. This compares well with other regions putting us in third place nationally. There is an intention to build upon the success of the RSI scheme and develop leadership sites as part of the scheme and in line with our strategy. To achieve this we have amended the criteria for RSI and leadership sites to ensure performance is in line with requirements and continues to offer good value for money. The scheme is a successful initiative and one that is supported and encouraged by our primary care colleagues. Furthermore, we are conducting a survey of practices within the East Midlands – both research active and non-RSI practices. For RSI practices we aim to identify any barriers to continued engagement and ascertain the potential for expansion of current research activity. We also hope to offer some support during any planned organisational changes.
			B: Proportion of GP sites within any individual CCG registered as research capable	5%		<ul style="list-style-type: none"> The proportion of research capable sites across each of the 19 CCGs is greater than 5%. The percentage range varies from 34.8% at Nene CCG, to 100% recruiting sites Rushcliffe CCG. This reflects a mixture of sites research ready accredited and those non accredited sites but delivering NIHR CRN portfolio studies. However, We intend to promote an even distribution of activity across CCGs within the East Midlands region, increase research ready accredited sites and reduce inequalities in access to research where possible.

² Registered Research Capable Sites are those sites working with the LCRN which have the capacity and capability to support NIHR CRN activities

	2	Improve research engagement with community pharmacy	Number of LCRNs with a community pharmacy Research Champion	15		<ul style="list-style-type: none"> Community pharmacy regional champion for Division 5 appointed October 2014 Nine sites in CRN: East Midlands which have completed the Royal Pharmaceutical Society 'Research Ready' accreditation. Of those, all pharmacies have to complete the NIHR GCP training (currently being developed for community pharmacy). Community Pharmacy Research strategy produced for 2015/16 East Midlands CRN Pharmacy Research group has been established with Terms of Reference. Group has wide representation and will meet quarterly. Awareness of the research ready initiative has been raised at LPCs and associated pharmacy bodies in Leicestershire and Nottinghamshire, with further meetings planned in Derbyshire and Lincolnshire. To date progress has been slow in making suitable contacts with research personnel in Lincolnshire and Northamptonshire. Awareness of community pharmacy 'Research Ready' programme has been raised in Nottingham University, DeMontfort University and CLAHRC East Midlands. Research Champion has made suitable contacts for Lincolnshire School of Pharmacy. Further contacts will also be made with other non-pharmacy HEIs (University of Leicester and Loughborough University) and the RDS to raise the profile of community pharmacy as potential research recruitment sites and involvement for health related studies in primary care. Direct links have been made with the Royal Pharmaceutical Society Research Leads to operationalize Research Ready Initiatives Two Regional Pharmacy Champion meetings have taken place to ascertain support documents and processes to be used for community pharmacy engagement. Common problems include engagement strategies with multiples and RSI schemes/research support costs There is a lack of community pharmacy specific portfolio studies making it difficult to address the importance for getting sites interested in studies: solution will be to 'horizon scan' existing and forthcoming studies for community pharmacy engagement RSI: consideration for service support costs and incentives needs to be discussed at regional level The NIHR Four Fold asthma study team have shown interest in recruitment through community pharmacy (Nottinghamshire and Leicestershire) and discussions for engagement underway, including suitable service support costs. GCP training for community pharmacy: NIHR regional trainers are leading to produce training suitable for community pharmacy. Suggestions include face to face training as online training could prove difficult without suitable studies to engage with. A detailed quarterly activity report is produced for Division 5 steering group.
		Local Recruitment Target	Local Recruitment Target	12,522		<ul style="list-style-type: none"> Year-end recruitment reported of 21,567 against a goal of 12,522, which is a phenomenal achievement and sets the East Midlands as top national performer for this specialty.
Renal Disorders	1	Increase the proportion of Renal Disorders commercial contract studies on the NIHR	Proportion of commercial contract studies in relation to the total number of Renal	20%	<ul style="list-style-type: none"> N.B. The national objective (1) is intrinsically linked to non-academic recruitment in a step-wise fashion, therefore the more non-commercial studies that are undertaken the greater 	<ul style="list-style-type: none"> Increased the total number of studies recruiting in the East Midlands from 24 to 28 from 2013/14 to 2014/15 and have increased the number of commercial studies running in the East Midlands by 33%. We have opened 15 new studies

		CRN Portfolio	Disorders studies on the NIHR CRN Portfolio		the number of Industry trials that need to be conducted. It should be noted that in the East Midlands only a few select sites undertake Industry trials due to the areas of specialism in renal research	in 2014/15.
	2	Improve the promotion of research to patients with Renal Disorders	Proportion of renal units actively promoting research to patients	50%	<ul style="list-style-type: none"> To ensure that all experimental or lab based studies that consent patients are considered for their eligibility onto the NIHR CRN portfolio to maximise recruitment numbers into commercial and non-commercial trials Develop a communications and PPI strategy that will see at least 60% of patients receiving a quarterly newsletter and other promotional material. This material will also be distributed to units that provide a renal service but are not actively conducting research themselves. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators. 	<ul style="list-style-type: none"> We now have our first study running in Lincolnshire and have provided them with the protocol for a second study. We now have renal studies running in all parts of the East Midlands. The Leicester research group successfully recruited a first global patient to the SIGN trial in IgA nephropathy.
		Local Recruitment Target	Local Recruitment Target	1,645		<ul style="list-style-type: none"> Renal CRN lead has met with representatives of all the local Kidney Patient Groups, the East Midlands & East of England National Kidney Federation Advocacy Officer and the Patient Involvement Co-ordinator for Kidney Research UK. We have distributed our first research update newsletter and will be organising a joint meeting of all PPI groups across the East Midlands later in the year.
						<ul style="list-style-type: none"> Recruitment of 1,407, thus not quite reaching the target of 1,645, this was an aspirational target and took into account that the satellite renal sites would be ready to recruit into studies. These sites have been delayed operationally and will come on board in 2015/16.
Reproductive Health and Childbirth	1	Increase the number of Reproductive Health and Childbirth commercial contract studies on the NIHR CRN Portfolio	Number of Reproductive Health and Childbirth commercial contract studies on the NIHR CRN Portfolio	4	<ul style="list-style-type: none"> Through collaborative working with the Industry Operations Manager and relevant clinicians we will seek to attract commercial studies of this nature to the CRN: East Midlands. 	<ul style="list-style-type: none"> During the period of this report we have increased the number of commercial contract studies from 4 to 5. This equates to 14% and 16% of the local specialty portfolio respectively.
	2	Increase engagement and awareness of the Reproductive Health and Childbirth Specialty	Number of LCRNs with an identified midwifery champion to increase engagement and awareness	15	<ul style="list-style-type: none"> We will identify and appoint a Midwifery Champion for the CRN: East Midlands. 	<ul style="list-style-type: none"> Achieved. Yvette Davis is our Research Midwife Champion. She has attended national meetings and is engaged with the Research Delivery Manager and Specialty Lead to help direct strategic plans and review performance across the region.
		Local Recruitment Target	Local Recruitment Target	4,500		<ul style="list-style-type: none"> Overall recruitment of 1,707 study participants, 38% of target. The target was set against the backdrop of high recruitment numbers achieved in 2013/14. Since then the studies providing the majority of these recruits have closed nationally. During the period of this report energy has been invested in developing the specialty portfolio and improving performance.
Respiratory Disorders	1	Increase access for patients to participate in Respiratory Disorders studies on the NIHR CRN Portfolio	Number of LCRNs recruiting participants into studies in the Respiratory Disorders main disease areas of asthma, COPD and pneumonia	15	<ul style="list-style-type: none"> Maintain infrastructure required to increase recruitment to research databases for asthma, COPD and other respiratory disorders centred across the East Midlands area including Primary, Secondary, Tertiary Care areas, supported by the large Teaching Hospitals. Maintain a pool of respiratory specialist staff with the skill set required to carry out asthma and COPD studies in carefully phenotyped patients which facilitates both commercial and investigator driven studies and also a stratified medicine approach which is increasingly being used for new therapies. 	<ul style="list-style-type: none"> CRN East Midlands have participated in 14 Asthma studies and 10 COPD studies. We have not contributed to any pneumonia studies, however only 5 LCRNs are recruiting to pneumonia research, as currently there is only 1 study open.
	2	Increase the number of participants recruited into COPD and Asthma studies on the NIHR CRN Portfolio	Percentage of COPD and Asthma participants recruited into Respiratory Disorders studies on the NIHR CRN Portfolio	10%		<ul style="list-style-type: none"> We have good engagement with the respiratory specialist staff across the region This is a potential growth area for two acute trusts within the region, Divisional Clinical Lead is engaged with both Trusts to re-energise the identified teams.
		Local Recruitment Target	Local Recruitment Target	1021		<ul style="list-style-type: none"> 811 recruits, against a target of 1,021, this is in line with the national trend with recruitment 24% lower in 2014/15 than the previous year
Stroke	1	Increase the proportion of patients recruited into Stroke randomised controlled trials	Number of patients (per 100,000 population) recruited into Stroke randomised	8	<ul style="list-style-type: none"> Build on previous success by maintaining the expertise and current level of resource within the specialty at successful sites – in particular, maintain research staffing levels at 	<ul style="list-style-type: none"> This is a national goal

		on the NIHR CRN Portfolio	controlled trials on the NIHR CRN Portfolio		LRCN sites and continue to provide support to clinicians to act as PIs.	
	2	Increase the number of commercial Stroke studies on the NIHR CRN Portfolio	A: Number of new commercial contract Stroke studies on the NIHR CRN Portfolio	5	<ul style="list-style-type: none"> By continuing to build on the success seen by the current topic specific stroke research network with regards to recruiting patients into the hyperacute stroke studies through continued investment and capacity building in providing and building a quality provision for the HSRC in Nottingham. Focus on recruitment to complex studies, with a number of commercial medical technical studies about to open. The experience of the HSRC staff could eventually extend beyond stroke to other specialties where emergency recruitment is desirable and/ or required. Explore areas for working across specialties within the Division (cardiovascular in particular) and across division (Injuries and Emergency) for more efficient working, whilst recognising that some stroke studies (in particular acute recruitment with capacity and communication issues) require specialist skills. Focus and review sites where recruitment has previously been low, (recruited less than 40 patients per annum per 1.0WTE research practitioner) to understand their barriers to recruitment, and develop a recruitment strategy for these sites to increase recruitment to a level that is circa 50% better than their previous annual recruitment numbers. Explore areas for working across specialties within these sites. If recruitment barriers cannot be overcome, review investment opportunities for building capacity at stroke sites elsewhere in LRCN. However, to maintain >80% of sites involved in stroke research within the CRN: East Midlands. To develop a management structure within the division that will enable performance and delivery of these objectives in line with NIHR Time and Target Indicators. <p>*The 2 med tech studies are part of the overall target of 5</p>	<ul style="list-style-type: none"> Achieved. There were seven studies commercial studies open for recruitment across the East Midlands, with recruitment reported in six of these.
			B: Number of new medical technical studies in Stroke on the NIHR CRN Portfolio	2		<ul style="list-style-type: none"> Achieved. In the East Midlands, Nottingham recruited to 3 med tech commercial studies: CLOTBUSTER, REDUCE and RENEURON. Nationally there is a reduction in the number of new med tech studies on the portfolio and this target has been removed from National HLO for 2015/16 as it is beyond the sites control.
	3	Increase the proportion of NHS Trusts, providing acute Stroke care, recruiting to Stroke studies on the NIHR CRN Portfolio	Proportion of NHS Trusts, providing acute Stroke care, recruiting participants into Stroke studies on the NIHR CRN Portfolio	80%		<ul style="list-style-type: none"> All 8 acute sites in the region have recruited to the portfolio. However, staffing has been affected by transition and loss of staff (Chesterfield, Northampton, Lincoln) has adversely impacted on recruitment at a number of sites. Clear line management structure was not in place for some CRN staff, which did not allow performance management. Furthermore new staff are now in place but opportunity for training has been limited since the Senior Stroke Research post became vacant (Feb 2015). All these issues have impacted on recruitment.
	4	Increase activity in NIHR CRN Hyperacute Stroke Research Centres	A: Number of patients recruited to hyperacute Stroke studies on the NIHR CRN Portfolio in each NIHR CRN Hyperacute Stroke Research Centre (HSRC)	50		<ul style="list-style-type: none"> Nottingham HSRC achieved 49 out of 50 recruits – which is a fantastic achievement – given that staffing levels have been sub-optimal – impacting on the ability for out of hours recruitment. Target was only narrowly missed – when the staffing vacancies were resolved recruitment was able to get back on track.
			B: Number of patients recruited to complex hyperacute Stroke studies on the NIHR CRN Portfolio in each NIHR CRN HSRC	15	<ul style="list-style-type: none"> Nottingham HSRC recruited 18 to complex HSRC portfolio studies –exceeding the target of 15. 	
			C: Number of HSRCs recruiting to Stroke commercial contract studies on the NIHR CRN Portfolio	8	<ul style="list-style-type: none"> Nottingham HSRC is the only HSRC in the EM – one of 8 within the UK. Nottingham's status as HSRC is reviewed annually and we have been successfully awarded HSRC status for 2015/16. 	
		Local Recruitment Target	Local Recruitment Target	1041	<ul style="list-style-type: none"> Recruitment achieved was 596, which is short of the target There are however two particular studies where the recruitment has been attributed to other Specialties, which impacts on this recruitment level, Gloria AF (n=1) and ROSE (n=129) recruitment attributed to Haematology (Division 6). If this was added to the actual recruitment the figure of 726 is much closer to the target set 	
Surgery	1	Increase the number of NHS Trusts supporting Surgery studies on the NIHR CRN Portfolio	Proportion of acute NHS Trusts recruiting patients into Surgery studies on the NIHR CRN Portfolio	75%	<p>Objectives 1 & 2:</p> <ul style="list-style-type: none"> 100% of acute Trusts admitting patients for elective surgery participating in Portfolio research. To have at least one surgeon in each specialty in each Trust trained in GCP. To increase the proportion of surgical patients involved in 	<ul style="list-style-type: none"> CRN East Midlands has achieved 100% of acute Trusts recruiting patients to surgery studies on the NIHR CRN Portfolio SL still to identify nominated surgical lead in each Trust SL to set up cross-regional groups and explore the feasibility of establishing links with the surgical trainees across the East Midlands to ensure they are encouraged and offered GCP training early in their training pathway

	2	Increase the proportion of surgery patients recruited into Surgery studies on the NIHR CRN Portfolio	Number of participants (per 100,000 surgical admissions) recruited into Surgery studies on the NIHR CRN Portfolio	50	<p>clinical trials by 20%.</p> <p>Generic actions to support the above achievement:</p> <ul style="list-style-type: none"> • Increase delivery of GCP, make it easier to access online courses (equitable provision across the East Midlands region). • Ensure that support follows recruitment and make sure that support not only goes to the Trust but filters down to the PIs involved. • Trusts are required to provide evidence of support and action is taken by CRN: East Midlands if this support is not forthcoming. <p>Specific actions:</p> <ul style="list-style-type: none"> • Nominate a surgical lead in each specialty in each Trust and provide them with GCP training in a manner that is convenient for them. • Set up specialty specific cross-regional groups. • Monitor performance and take interventional action as appropriate in cases where delivery is not being achieved. 	<ul style="list-style-type: none"> • As per national NIHR statistics the CRN East Midlands is currently placed in the top three LCRNs recruiting into surgery studies • Recruitment attained: 2027, an excellent performance and significant contribution to the national recruitment for this Specialty.
		Local Recruitment Target	Local Recruitment Target	327		

Table 3: Clinical Research Network: East Midlands achievements against the Operating Framework Compliance indicators

Domain		Objective	Information requested in Annual Report Commentary	Commentary on LCRN Performance in 2014-15
1	LCRN Management Arrangements	A: Clinical Research Leads, Clinical Research Specialty Leads, Divisional Research Delivery Managers, Cross-Cutting Team and Support Team are in post	Provide brief reflective commentary on local performance in 2014-15	The appointment process for all Clinical & Specialty Leads, along with the Delivery Managers was completed by 1 June, with the exception of our Industry Delivery Manager, who commenced in post on 1 September 2014 and Business Intelligence Lead, commencement date 1 December 2014. Additionally, work has taken place to review the support arrangements for this senior team and our wider work-streams; much of this is complete, with some final revisions in roles still going through HR processes and expected to be complete by the end Q1 of 2015/16.
		B: LCRN leadership and management groups are established (LCRN Executive Group, Clinical Research Leadership Group and Operational Management Group)	Provide brief reflective commentary on local performance in 2014-15	These were largely established in early 2014/15. The main changes observed have been frequently combining the OMG with the CLG. We have found this to be successful, however there is still a need for some exclusively dedicated Clinical Leadership meetings, which will be reinstated in 2015/16, although with less frequency as the Clinical Leads are invited to and do regularly attend the OMG. In addition to these mandated groups a series of Working groups with membership from POs and other stakeholders, for example the area HRA Change Facilitation Lead have been established, with good attendance, clear actions and progress made towards annual objectives.
2	Research Delivery	A: LCRN Partner organisations adhere to specified national systems and Standard Operating Procedures in respect of research delivery	Provide brief commentary reflecting on local performance in 2014-15 in relation to: <ul style="list-style-type: none"> • Adherence to National SOPs for commercial service delivery • Contribution to the national Study Support Service programme • Implementation of local elements of the Study Support Service 	<ul style="list-style-type: none"> • POs work closely with CRN East Midlands in ensuring compliance with NIHR National Processes and procedures for both commercial and non commercial research. RM&G Staff are trained in the use of the CSP Operating Manual and associated modules of proportionate and pragmatic RM&G training. Where required POs have amended local policy and procedures. There is a single point of entry email address for Industry and for CSP enquiries. All studies are processed in line with the NIHR definition of a Valid Research Application, we are confident that the metrics represent accurate timeframes for the processing of studies. • The National Study Support Service is led by the Lead RM&G Manager, with support from the Senior RM&G Manager and Primary Care Locality Manager who have all been involved in a number of working groups - Early Engagement with Researchers/Pre Application Support, Expression of Interest, Early National Intelligence and Feasibility and lastly Managing NHS Support Costs for Independent Contractors. All provide input and feedback to SOP development and circulate for wider CRN East Midlands Network and PO survey completion and feedback of comments, as requested. Additionally there is good level of engagement and commitment to this from our partner organisations. • Details of the Study Support Service has been presented to POs and also at a Network Team Away Day • The RM&G Working Group is taking the lead on the implementation of local elements of the Support Service. Three task and finish groups have been set up with a lead being identified for each. All groups have membership representative of the group function, for example the Early Engagement with Researchers/ Pre application group has representation from HEIs, Sponsoring Organisations, CCGs and Research Design Service. Similarly for the other two groups, EOI/ Feasibility and Study Set Up, membership is from relevant areas of experience and expertise.
		B: Timely processing of study wide and local reviews within the CSP process (15 days respectively)	Provide brief reflective commentary on local year to date performance for 2014-15 ³	The year 2014/15 has posed challenges for CRN East Midlands RM&G Teams, mainly due to a significant loss of staff (c.25%) and absence of confirmation of a definitive implementation date or significant detail for HRA Assessment and Approval. The remaining RM&G team have enabled the network and its partner organisations to achieve 55% of SW Reviews (National Data) in 15 days or less and 72% of local reviews in 15 days or less. All reviews are undertaken in full compliance with the NIHR CSP Operating Manual and DH definition of a Valid Research Application for studies going through CSP. 91.6% of all studies in CRN East Midlands processed through CSP obtained NHS Permission in 30 days or less with a number of POs achieving 100% in 30 days or less. To improve performance the following has been introduced in this reporting period:

³ For performance data please refer to the March 2015 LCRN Management Group report (on the Information Managers' portal or the vBIU)

				<ul style="list-style-type: none"> • Increased delegation of responsibility across the Network for undertaking study wide review. • A single network RM&G Study Tracking system has been introduced - previously RM&G tracking of information in the former networks had been stored in varying different systems. Now staff can see where studies are taking place in a number of Trusts and utilise the system to track timelines and workload locally • Promoted the importance of early engagement with Trusts and CIs at funding application stage or at point of PAF being received into the CSP System. • Active performance management and monitoring of study progress through local and national systems (RM&G Tracker, weekly RAG Reports, CSP and ODP) • Problem solving and escalation at Trust, CCG or colleague Network level, depending on where Researchers experiencing difficulties. • Introduction of increasing levels of flexible working across the network geography for RM&G staff.
		C: Support the delivery of the Government Research Priority of Dementia	This has been an important priority locally, and a considerable challenge due to a low baseline. Much of this is reported through table 1, section 7 and table 2, DeNDRoN specialty. In summary however, the East Midlands has more than doubled the recruitment goal set under HLO7, recruiting 1,050 participants against a goal of 510. We have increased the number of trained raters in the region, attracted a high level of interest from Care Homes, through establishing an ENRICH office and embraced the opportunities provided through Joint Dementia Research.	
3	Patient, Carer and Public Involvement and Engagement (PCPIE)	Promote research opportunities in line with the NHS Constitution for England, including informing patients about research conducted within the LCRN and actively involving and engaging patients, carers and the public in research	Provide brief reflective commentary on local performance in 2014-15 to include examples of methodologies employed to understand patient experience	<ul style="list-style-type: none"> • Prior to appointment of Business Delivery Manager 'transitional' programme of work initially led by (current) Division 3 Manager • Successful appointment of (3) Research Advocates who have contributed to the direction of network business by advising on PPI/E, by presenting and contributing to staff appointment panels • CRN: East Midlands Steering Group established reporting to the OMG. Group creates opportunity for collaborative working between divisions, partner organisations and other NIHR partners offering expertise, advice and prevention of 'silo' working • 2015/16 work programme identified and agreed • Involvement in the East Midlands Research Engagement with Patients and the Public (REPP) group, led by the AHSN; the CRN has participated in various REPP event(s) and has membership of a newly formed Organisational Lead Group which is inclusive of HEE and SCN representatives • Key focus to date has been around raising patients and public perception and awareness of research and the potential to engage in research opportunities • Survey undertaken to determine gaps in opportunities for patients to offer advice to clinical teams • Existing or newly formed Advisory Groups set up/supported in association with successful grant applications awarded by AHSN • Support successfully secured for continuation of Young Persons Advisory Group • Event hosted promoting 'Living Well with Dementia' and JDR as a result of successful grant application awarded by former Division 4 CC • Collaborative working with CRN: West Midlands to promote JDR • Identification of local dementia champions • Development of multilingual video clip to promote importance of participating in dementia research as a result of successful grant application awarded by former Division 4 CC
4	Continuous Improvement	Promote and sustain a culture of innovation and continuous improvement across all areas of LCRN activity to optimise performance	Provide brief reflective commentary on local performance in 2014-15	<ul style="list-style-type: none"> • Majority of activities have centred around streamlining day to day functionality to aligning key workstreams especially in relation to former working patterns within the Host office base (Leicester, former LNR CLRN host) and the Nottingham office base (former Trent CLRN host), examples include: • Development and implementation of improved feasibility process prior to determining study set up • Implementation of new procedures to refine and join-up RM&G pathways and processes • Developing and designing Business Intelligence Service through participation in Six Sigma project approach • Implementation and issue of regular suite of performance reports and access to responsive service

				<p>addressing bespoke queries</p> <ul style="list-style-type: none"> • Harmonising service support costs across two former CLRN regions, with differing approaches • Review of staffing profile to provide key contacts to support portfolio coordination and administrative requirements • Alignment of separate research delivery teams to recreate a single Research Support Team to work flexibly, effectively and efficiently across the region when emergency delivery support is required • Development of a finance forum(s) to robustly discuss and challenge financial plans • Development and delivery of our Hub Fundamentals training package to 130 staff. that has been developed locally, this has been shared nationally via the Hub News Digest, NIHR monthly hub update magazine. CRN: East Midlands has been highlighted in every issue of the magazine to showcase the extraordinary progress that we have made in the region around the hub. We've overcome barriers, challenges and hurdles across the region to ensure that the hub is embedded within the organisation. • Development of contacts database to aid communication pathway • Tracking of CI projects at a local level and input of key project work at a national level • Presentation at network event to promote CI, seek participant input and analysis of feedback
5	Workforce Development	Develop and implement an LCRN Workforce development plan in partnership with relevant stakeholders and other local learning providers	Provide brief reflective commentary on local activities, priorities and engagement in 2014-15	<ul style="list-style-type: none"> • 'Business as usual' approach to achieve continuity of performance in relation to recruitment activity and other work programmes • Key priority has been to ensure stability of existing workforce throughout change period and make key appointments to new positions in line with overarching CRN management structure • Embedding of new management positions determining role, relationship and function • Identification of inherited workforce by conducting a review to determine profile and geographical location • Alignment of staff where relevant to new line management structure and/ or team in order to reduce isolation and enhance support mechanism • Scrutiny of workforce where vacancies have arisen to ensure that reappointments are essential and value for money. Working group set up during first half of the year to review every funded vacancy resulting in identification of significant savings as well as demonstration of the potential to work more creatively and flexibly • Engagement with workforce via regular e bulletin briefings and opportunities to attend events that provide updates and information on CRN activity e.g. Showcase Event • Establishment of WFD Steering Group reporting to OMG comprising of divisional and partner organisation representatives who have collaboratively agreed a WFD strategy • Scoping exercise conducted to identify training provision across region • Continued provision of key NIHR learning programmes e.g. Good Clinical Practice • Streamlining activities of two former CLRN workforce teams to create economies and efficiencies • Identification of future 'core' NIHR training programme to be offered and overarching WFD work programme for 15/16 • Appointment of additional GCP training facilitators to deliver NIHR programme(s) • Provision of support to ensure required rater training is provided and maintained • Collaborative working with other workstreams providing advice and support for rollout of essential programmes e.g. EDGE, Hub training. • Members of the Information team and Training Team in East Midlands are part of the national Learning Taskforce. We'll be driving forward training for CPMS, LPMS, LMS and the Hub including any other Information Systems that the centre may roll-out in the future. We've run workshops, conferences (hangouts), one-to-one sessions for the Change Champions in the region. We have also designed and delivered bespoke training for individuals and teams. The training that we delivered to the Change Champions empowered them to deliver cascade training across the region. • Review and alignment of former Taskforce(s) to a single functioning Research Support Team whose remit is to provide emergency or short term help/expert advice when and where required. • Appointment of lead research nurse to provide support, advice and guidance to partner organisations and their research teams

6	Financial Management	A: LCRN Host and Partner organisations must meet minimum control standards, as specified by the national CRN Coordinating Centre	Provide brief commentary reflecting on local performance in 2014-15	The host audit, as detailed below, has been an excellent opportunity to review standards at both the host and partner organisations. A number of the resultant actions will give further confidence that minimum controls will be met, or indeed in many cases, continue to be met. Work is currently ongoing in relation to use of commercial income and assurance in relation to CRN income. Overall there were no major findings, thus indicating most partners and the host meet the required minimum standards.
		B: LCRN Host organisation must meet minimum requirements for the scope of internal audit work, as specified by the national Coordinating Centre	<ul style="list-style-type: none"> • Provide brief commentary reflecting on local performance in 2014-15 • If the LCRN has been able to factor in an internal audit in 2014-15⁴, provide a brief commentary 	The Host organisation, University Hospitals of Leicester NHS Trust, included the hosting of the CRN within the audit programme for 2014/15, with an audit undertaken in Q3. The audit report has been presented at UHL's Audit Committee, where the Clinical Director attended for questions. It has also been discussed at both the Finance Working Group and Executive Group meetings. The audit looked at 6 different areas, 5 of which were finance related, and at our request, a review of the governance and hosting processes in place. Five of the six areas were classed as low risk, one was considered medium risk, resulting in an overall medium score. The area ranked as medium risk was in relation to commercial funding, which we did indicate early we would be unlikely to meet. An action plan has been established to meet all of the points raised, to date 4 of the 6 required actions have been met, with the further 2 due by the end of July. We have every confidence of meeting these. We would be happy to share both the audit report and our associated plan in due course, should this be required.
7	Information Systems	LCRN Host and Partner organisations have access to the required information systems and services	<p>Provide confirmation that key named systems are in place, including:</p> <ul style="list-style-type: none"> • LPMS systems are in place as required • Provision of an LCRN Service Desk function and provide contact details • Access to NIHR Hub systems and services, <p>Or describe steps being taken to implement them and provide a target delivery date.</p> <p>Provide brief commentary reflecting on local performance in 2014-15 against the remaining areas in section 13 (Information Systems) of the NIHR CRN Operating Framework</p>	<ul style="list-style-type: none"> • A contract with EDGE, the East Midlands system of choice has been signed by the Host organisation and data migration is under way. We have a dedicated project manager to lead the implementation of EDGE across the region and expect this to be completed by October 2015. A number of engagement events with Partner Organisations were held to facilitate the procurement and implementation of the LPMS. • A LCRN service desk has been implemented and can be accessed via CRNEMBI@nihr.ac.uk. • All network employed staff are using the NIHR Hub system and local Hub Change Champion roles have been developed. 130 people across the region have been trained on the Hub Fundamentals. Training and access has been provided to all partner organisations. There remain a small number of organisations who have reservations about the benefits of Google platform through Chrome, where implementation and use is not widespread. We have worked with partners to overcome this, however some issues remain. • We have developed a LCRN Business Intelligence Service, led by the Business Intelligence Lead and supported by information, finance and specialty support teams. There is a Business Intelligence Working group, chaired by the COO, which reports to the Operational Management Group. • The Host organisation provides a financial system (CEDAR) to ensure correct financial management. An audit was undertaken in year by the Host organisation to ensure best practice in financial management. • Additionally all partner finance leads use the Google platform for the completion and submission of their monthly and quarterly returns.
8	Communications	LCRN communications function and delivery plans in place, and budget line identified	Provide a brief commentary reflecting on local performance in 2014-15 and on the LCRN's contribution to national NIHR / CRN campaigns	<ul style="list-style-type: none"> • In September 2014 the LCRN was successful in appointing a Communications Lead to the Business Delivery team, reporting to the Business Delivery Manager. • Since coming into post the Communications Lead developed a new Communications Strategy for 2014/15, which was shared with the Communications Delivery Group for comment and feedback, before sharing the final version with the host Executive Group for review and approval. • One of the key themes within the strategy was the review of social media tools that could add value to LCRN communications and engagement activity. We succeeded in creating a Twitter presence @NIHRCRNEastMids and built the number of followers to 150. This proved to be a useful tool for engaging with our partner organisations and having a regular dialogue with key stakeholders • By developing more local content within the LCRN website and expanding the functionality we have succeeded in increasing the amount of direct traffic to the site by 40% • Join Dementia Research <ul style="list-style-type: none"> ○ We involved our partners early on in the promotion of Join Dementia Research, with the

⁴ In light of the timing of the issuing of the associated guidance, this requirement has been extended through to 2015/16.

				<p>EMAHSN including pieces in EMAHSN News (which goes out to over 1000 key stakeholders across the region) and through their Twitter feed</p> <ul style="list-style-type: none"> ○ We worked with partners to find regional spokespeople to support the press launch, with resulting coverage appearing across Lincolnshire and Derbyshire local newspapers and online, reaching a total circulation of 52, 223 people, as can be seen in the attached breakdown ● The LCRN created a new stakeholder newsletter Network News which included news on key priority areas for this year, along with key developments in each of the LCRN workstreams ● Keeping our partners informed of developments around our new local portfolio management system EDGE has also been important this year, with bulletins appearing in our newsletter and within a dedicated section on our website which contains support materials ● Additionally, we developed a suite of collateral to support stakeholder events, including a new LCRN leaflet and banner
9	Information Governance	LCRN Host and Partner organisations comply with CRN Information Governance (IG) requirements	Report IG Toolkit 2014-15 version 12 scores for the LCRN Host organisation and LCRN Partner organisations and confirm attainment of Level 2 or above on all requirements, or any exceptions which arise from or impact on LCRN-funded activities	The Host and all Partner Organisations have attained level 2 or above on all requirements in the IG toolkit, with one exception. Lincolnshire Partnership NHS Foundation Trust did not attain level 2 overall due to having insufficient evidence regarding requirement 12-514 (An audit of clinical coding, based on national standards, has been undertaken by a Clinical Classifications Service (CCS) approved clinical coding auditor within the last 12 months). We do not believe that this will impact on any LCRN funded activities within this organisation. All other standards in this organisation attained level 2 or above.

Table 4: Report on the conduct of the organisation: University Hospitals Of Leicester NHS Trust

Domain	Objective	National CRNCC Approach	Reflective commentary on LCRN Host organisation Performance in 2014-15
1 LCRN Leadership and Management	Deliver effective leadership and management of the LCRN	<ul style="list-style-type: none"> Annual survey by the national CRN Coordinating Centre of all LCRN Partners to be conducted post 2014-15 year-end (survey April-May 2015, first formal annual meetings to be arranged in September 2015); Reviewing overall LCRN performance, through Performance Review meetings with the national CRN Coordinating Centre. 	<p>The host trust is assured that the relevant HR processes were followed in the appointment of the senior leadership team for the CRN. The Leadership and management team appointed have skills and knowledge of the NHS research environment, expertise in the operational management of research and networks, and the ability to provide excellent leadership and direction. The appointment of clinical leads for research specialties also provides dispersed leadership which is visible across the East Midlands geography.</p> <p>The feedback received following the NIHR Co-ordinating centre performance review, undertaken in February, suggests the management and leadership team have begun to establish appropriate systems and processes to support the research delivery environment across the region.</p>
2 LCRN Research Delivery Infrastructure	Deliver a responsive and flexible NHS support service that meets the needs of researchers, funders and industry.	Annual survey by the national CRN Coordinating Centre of LCRN service users to be conducted post 2014-15 year-end	<p>We understand that a national survey will be undertaken in due course, however as the Host, we appreciate that through transition this has been a challenging task. As the year has progressed and the CRN are in receipt of increasingly detailed intelligence regarding existing research staff, a clearer view on the pipeline of studies along with the demands of existing studies, the required infrastructure has been developed to meet the emerging, and evolving, need. One change, to increase flexibility within trusts, has been to develop a more agile research workforce which is increasingly able to work across a number of clinical specialties, in order to adapt to a changing portfolio. Progress has also been made towards re-launching the two former Taskforces into one smaller group of flexible research professionals able to support trusts to increase their ability to deliver portfolio research and fill any short term gaps or overcome difficulties.</p>
3 Financial Management	Deliver robust financial management using appropriate tools and guidance	<ul style="list-style-type: none"> Measured by percentage variance (allocation vs expenditure) quarterly and year-end (target is 0%)⁵; Measured by percentage of financial returns completed on time (target is 100%)⁶. 	<p>This target has been achieved through regular financial reporting and the active management of any in-year variances to budget. We have developed a system of monthly reporting on actual expenditure across the entire Network. We have also established a Finance working Group which meets 4-6 weekly, with one function to review variations, making suggestions for movements across budget lines, as necessary. All financial returns are also reviewed by the Host and COO prior to submission.</p> <p><i>Data on local performance from national CRN Coordinating Centre:</i></p> <ul style="list-style-type: none"> Variance = 0% Performance for LCRN Annual Plan 2014-15 and Q1-Q3 2014-15 returns = 100% <p>Additionally we note that all NIHR feedback received in relation to finance returns has been light, with only fairly minor points identified for action, which would suggest the Co-ordinating Centre are assured by our approach.</p>
4 Allocation of LCRN funding	Distribute LCRN funding equitably on the basis of NHS support requirements	Comparison by the national CRN Coordinating Centre of 2014-15 main allocations vs. recruitment to be conducted following year-end and once cleansed recruitment data is available	<p>The opening budget for 2014/15 was largely influenced by historical funding as the Network had limited opportunity to make major funding decisions given the limited time and information available. The major driver at that time was providing stability for Partner Organisations. However, since then we have undertaken a major review of the funding allocations across all CRN budgets during 2014/15. This included a review of the actual performance of the Partner Organisations and also considered their future requirements in terms of recruitment. This led to the development of a new funding model for 2015/16 budget setting which gave due to consideration to stability,</p>

⁵ Variances for Q1-Q3 2014-15 pre-populated by national CRN Coordinating Centre in commentary column of row 3

⁶ Performance for LCRN Annual Plan 2014-15 and Q1-Q3 2014-15 returns pre-populated by national CRN Coordinating Centre in commentary column of row 3

				performance and equity.
5	LCRN Governance (Host Board)	Ensure that the Host Board has visibility of LCRN business and fulfils its agreed assurance role	Review of Host Board meeting minutes submitted in response to request from the national CRN Coordinating Centre (April 2015)	<p>The host organisation delegated the Medical Director as the accountable Executive Director for CRN business. The Medical Director chairs CRN Executive meetings, ensuring actions are achieved, risk is managed and monitored, and were necessary escalating any host related matters through appropriate routes within the host trust.</p> <p>The Host Board received a formal CRN paper in 2014/15, which was prepared and presented by the Clinical Director. The Board were also able to comment and discuss the 2015/16 Annual Plan, which was presented at the Board meeting by the Chief Operating Officer.</p> <p>As outlined in Table 3, section 6b, as a host we have instructed our internal auditors to undertake an Audit in relation to the hosting function. The CRN: East Midlands Clinical Director attended our internal audit committee, presenting a targeted action plan with assigned leads for each area. Overall the audit is not considered high risk to the trust, with 5 of the 6 findings rated as low, one as medium. To date 4 of 6 of the actions have been achieved.</p>
6	LCRN Governance (Partner Engagement)	Ensure all LCRN Partners are engaged in the work of the Partnership Group	<ul style="list-style-type: none"> Annual survey by the national CRN Coordinating Centre of all LCRN Partners, to confirm Partner involvement, to be conducted April-May 2015; Review of Partnership Group minutes, submitted in response to request from the national CRN Coordinating Centre to confirm Partner participation (April 2015). 	<ul style="list-style-type: none"> The Partnership Group terms of reference have been updated and confirmed through the meetings. Group attendance is mixed, with some attendees at Chief Executive and Board level, and some as R&D Directors, although Board level membership has been encouraged. We have responded to the request for Partnership Group minutes, as requested. In addition to engagement through the Partnership group, the host is assured of a range of other routes to effective engagement between the Senior CRN team and Senior Officers across partner organisations.
7	Management of Risk	Establish and maintain an assurance framework and risk management system for the LCRN, including an escalation process	Monitoring through the LCRN Annual Plan and Performance Review meetings with the national CRN Coordinating Centre (first formal annual meetings to be arranged in September 2015)	Risk is formerly managed through the Executive Group, which meets on a 4 - 6 weekly basis. Risks are identified, reviewed and assessed against a clear framework, then mitigating actions discussed and assigned. A copy of this risk register is provided as Appendix 1, as requested.
8	Management of LCRN Performance	Ensure delivery of LCRN performance against the LCRN Annual plan	Monitoring through Performance Review meetings with the national CRN Coordinating Centre (first formal annual meetings to be arranged in September 2015)	<p>A formal monitoring of all HLOs and progress towards this takes place through the Executive Group, on review of the CRN "dashboard". Additionally, a monthly report of exceptions is submitted to the Quality & Performance committee, a sub-group of the Host Trust Board. There is an expectation that an action plan is required where exceptions are reported.</p> <p>2014/15 has seen some considerable challenges, not least due to the instability brought on by transition and managing a budget reduction. Overall, the CRN: East Midlands has performed well, meeting the majority of both nationally and locally set targets, although specifically through exceeding the very ambitious target of 50,000 recruits and over recruiting against the Dementia challenge recruitment goal. Additionally, there has been a significant review of the approach to budget setting, making this a much more transparent and open process, working in partnership with our local NHS organisations.</p>
9	Host Corporate Support Services	Deliver high quality Corporate Support Services as specified in the NIHR CRN Performance and Operating Framework	Feedback from the LCRN Leadership Team at Performance Review meetings with the national CRN Coordinating Centre (first formal annual meetings to be arranged in September 2015)	<p>The host supported the network with a range of services; of note in 2014/15 the CRN has moved accommodation within the Host Trust. The needs of the CRN were carefully considered when assigning the accommodation which offers large and smaller offices, a kitchen and dedicated meeting room, with access to other meeting rooms.</p> <p>In 2014/15 significant Human Resources support has also been provided, which has been essential during the transition period. This included support with a series of</p>

					<p>“Management of Change” processes and the Host HR engaging with other NHS HR departments across the region, with consensus being reached over staff movement and changes. Host finance support has remained strong.</p>
--	--	--	--	--	---

Scoring legend	1	2	3	4	5
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high

**Appendix 1 – example University Hospitals of Leicester NHS Trust
NIHR Clinical Research Network: East Midlands Risk Register**

Owner of Risk Register: Executive Group

#	Risk Description	RISK SCORE			Consequence of failure to manage	STATUS	Mitigating Action Plan	Responsibility	PROGRESS UPDATE / REQUIRED DATE
		Likelihood (1-5)	Impact (1-5)	Overall Risk score					
1	Concerns due to the reduction in NIHR budget allocation for 2014/15 and associated management	1	4	4	<ul style="list-style-type: none"> The 2014/15 financial year is drawing to a close and this is no longer a risk 	CLOSED	<ul style="list-style-type: none"> Regular Partner finance meetings Vacancy factor further revised to 3.5% Monthly returns from Trusts Apr-Aug centrally managed, Sep-Mar Partners to manage own vacancy factor and agree savings plan. 	Finance Lead and Chief Operating Officer	
7	Local Portfolio Management System (LPMS) will not be implemented by 31 March 2015	3	3	9	<ul style="list-style-type: none"> POF 2015/16 has been reworded to ensure LCRN research delivery is supported by an LPMS solution (13.6) - the requirement to have it implemented by a given timeframe has been removed. 	CLOSED	<ul style="list-style-type: none"> Procurement decision, EDGE preferred product, contract negotiations and implementation planning has commenced. Implementation Lead assigned (Mark Howells), about to appoint a 1 WTE Project Manager and work underway to identify other resource required, data migration strategy and data dictionary. 	Chief Operating Officer	
8	LCRN fails to deliver on Dementia Challenge	1	4	4	<ul style="list-style-type: none"> HLO7 recruitment into DeNDRoN studies is green (over target) 	CLOSED	<ul style="list-style-type: none"> Interim Project Lead & plan in place. Project Manager role to be advertised soon. Prof Tom Dening appointed as Specialty Lead Lobbying CRN for co-adoptions to be counted towards recruitment metric (action for TD and CD) Project group for ENRICH and Steering committee established. 	Clinical Director Division 4 Clinical Research Lead and Research Delivery Manager Executive Group	

Scoring legend	1	2	3	4	5
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high

9	Potentially destabilising Partners due to changes to the Funding Model for 2015/16	3	5	15	<ul style="list-style-type: none"> Risk superseded by Risk 12 	CLOSED	<ul style="list-style-type: none"> Early communication of the principles and finance change Early modelling to show change and notification of likely funding envelopes Engage partners on how to manage any changes Continue to hold regular Finance Engagement events 	Chief Operating Officer Clinical Director	
10	LPMS contract not signed and first invoice not paid by 31/3/15	3	4	12	<ul style="list-style-type: none"> Contract negotiations longer than expected due to tripartite agreement with SCC, University of Southampton and UHL If first quarterly invoice (Jan-March 2015) not received by 31/3/15 then risk CRN CC could request money allocated be returned, knock on effect 2015/16 budget 	OPEN	<ul style="list-style-type: none"> Weekly t/c to discuss contract progress since January Draft contract received 10/3/15 with t/c booked 18 March to discuss First quarter price agreed with SCC and UoS, SCC waiting for UoS to be set up with an account number before UoS can send invoice to SCC. Have requested that SCC invoice UHL without waiting for UoS invoice (16/3) Potential to accrue funding 	Project Manager	Update COO weekly
11	HLO2a: Proportion of commercial contract studies not achieving recruitment target is too high (target 80%, currently c45%)	5	4	20	<ul style="list-style-type: none"> Damage to East Midlands reputation Potential loss of future commercial contract research to the region Reduction in funding from the CRN CC for time and target performance 	OPEN	<ul style="list-style-type: none"> Recovery plans in place for Division 1,2 and 5, including 2 weekly meetings with Industry Delivery Manager and Research Delivery Managers (RDMs) Migration of performance data onto one system to track performance 2014/15 Implementation of a performance management process involving Industry team and RDMs to escalate studies not recruiting to target Planned meetings with key research teams to discuss target setting approach Collation of local info to report to National Industry team to reduce lag with national data Contacting sponsors to understand 	Industry Delivery Manager and Research Delivery Managers	Monthly updates to COO and Executive Group

Scoring legend	1	2	3	4	5
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high

1 2	Reduced capacity to deliver research due to 5% reduction in 2015/16 budget	4	4	16	<ul style="list-style-type: none"> Received the maximum 5% budget reduction for 2015/16 Partners concerned about capacity to deliver current Portfolio and expectation to increase in year Decrease in size of Research Taskforce, less generic staff available to support studies 	OPEN	<ul style="list-style-type: none"> Consult with Partners on how to change current practices and explore alternative ways of working i.e. not replacing like for like, working across Specialities Continue to hold Finance Engagement events Deployment of Senior Research Nurse to Trusts to explore new ways of working 	Chief Operating Officer, Research Delivery Managers	Monthly updates to Executive Group
1 3	Inability to deliver a robust RM&G service across the region	3	4	12	<ul style="list-style-type: none"> Uncertainty with RM&G service due to coming HRA changes and implementation of CRN Study Support Service Lack of clarity from both the CRN CC and HRA about impact of upcoming changes Staff leaving and not being replaced due to above, reduced capacity 	OPEN	<ul style="list-style-type: none"> Established 3 working groups to take forward key piece of work Regular updates to R&D Leads group Establishing a work programme of readiness for changes 	Lead RM&G Manager in partnership with Trust R&D/I staff	
1 4	Impact of LCRN reputation due to delays in agreeing Excess Treatment Costs across provider and commissioner trusts	5	4	20	<ul style="list-style-type: none"> Ongoing delays in the agreement of ETCs due to lack of understanding between commissioners, providers and researchers of the process and the sign off procedures Reduction in studies open in the East Midlands leading to reduced overall recruitment Delays in setting up research damaging East Midlands reputation for future research opportunities 	OPEN	<ul style="list-style-type: none"> Working through Div 5 lead to support and inform commissioners CRN EM offer to create clear guidance for commissioners, providers and researchers to aid understanding National feedback to Nancy Lester regarding local problems Very difficult as out of our hands to action in full 	Lead RM&G Manager Division 5 Clinical Lead and RDM COO	

Scoring legend	1	2	3	4	5
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high

		Impact					
		1	2	3	4	5	
		Very Low	Low	Medium	High	Very High	
Likelihood	1	Rare	1	2	3	4	5
	2	Unlikely	2	4	6	8	10
	3	Possible	3	6	9	12	15
	4	Likely	4	8	12	16	20
	5	Almost certain	5	10	15	20	25

RISK RATING (SCORE)	ACTION REQUIRED
Low (1-6)	Acceptable risk requiring no immediate action. Review annually.
Moderate (8-12)	Risk may be worth accepting with monitoring. Continue to monitor with action planned within six months. Place on risk register.
High (15-20)	Must manage and monitor risks. Action planned within three month. Review at monthly intervals. Place on risk register.
Extreme (25)	Extensive management essential. Action planned and implemented ASAP. Review weekly. Place on risk register.

Scoring legend	1	2	3	4	5
Likelihood	Rare	Unlikely	Possible	Likely	Almost Certain
Impact	Very low	Low	Medium	High	Very high



***National Institute for
Health Research***

Clinical Research Network
East Midlands

First Floor, Knighton Street Outpatients Department
Leicester Royal Infirmary
Leicester
LE1 5WW

Tel: 0116 258 6185

Web: www.crn.nihr.ac.uk/east-midlands