CRN: East Midlands Quarterly Host Board Report

Author: Prof. David Rowbotham Sponsor: Mr Andrew Furlong Trust Board 5 May 2016 paper K

Executive Summary

Context

University Hospitals of Leicester (UHL) NHS Trust is the Host organisation for the National Institute of Health Research (NIHR) Clinical Research Network: East Midlands, (CRN). Whilst there are appropriate governance arrangements in place, UHL is contracted by the Department of Health to take overall responsibility for the monitoring of governance and performance of the network. The purpose of this regular update paper is to summarise our performance, major achievements, challenges and actions. In addition, we require input from the UHL Board to formally approve our Annual Plan 2016-17 (Annex I) and review our Governance Framework (Annex II) which has been updated for 2016-17. This report was taken to the CRN: East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive lead for the CRN) in April 2016 and was considered by the UHL Executive Performance Board on 26 April 2016.

Questions

1. In order to provide assurance to the Host, what are the major achievements and challenges of the Network, performance up to end of March 2016 and operational plan for 2016-17?

Conclusion

1. The narrative style report summarises our Annual Delivery Plan, current performance, budget allocation for 2016-17 plus generic challenges and actions. Appended to this written report is a dashboard detailing key performance measures for 2015-16. Our Annual Delivery Plan is included as Annex I and our updated Governance Framework as Annex II.

Input Sought

We would welcome Trust Board review and approval of the attached report.

Annex Paper Title	Description of paper and input required
I. CRN East Midlands Annual Delivery Plan 2016-17	This paper sets out the strategic direction for the LCRN within the reporting year. The LCRN Annual Plan includes the specific activities and strategic initiatives to support the achievement of the NIHR CRN performance objectives as set in the NIHR CRN Performance and Operating Framework 2016-17 (POF). The Annual Delivery Plan requires formal approval by the Trust Board (contractual requirement).

II. CRN East Midlands Governance Framework 2016-17	This paper describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN. This framework is updated on an annual basis in order to reflect any changes in governance, assurance and escalation processes. In this Annual update there are no fundamental changes to the governance framework. It has been updated with some minor organisational changes summarised in the change control table. This paper requires review by the Trust Board.
III. Progress in making the UK one of the best places in the world for delivery of clinical research	This paper is provided in response to a request from the Trust Board to include a brief presentation covering topics of wider interest with respect to clinical research in the NHS. This is the first presentation. This paper is for interest only; Prof. David Rowbotham will be present at the Trust Board for further discussion.

For Reference

1. The following **objectives** were considered when preparing this report:

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

2. This matter relates to the following **governance** initiatives:

Organisational Risk Register	[Yes]
Board Assurance Framework	[Yes]

3. Related **Patient and Public Involvement** actions taken, or to be taken: N/A

4. Results of any **Equality Impact Assessment**, relating to this matter: N/A

5. Scheduled date for the **next paper** on this topic: [Trust Board August 2016]

6. Executive Summaries should not exceed **1 page**. [My paper does comply]

7. Papers should not exceed **7 pages.** [My paper does not comply]

NHS
National Institute for Health Research

Clinical Research Network
East Midlands

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
NIHR Clinical Research Network: East Midlands
Quarterly Host Board Report: Progress, challenges and performance update
Quarter 4 2015-16

1. Background

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

1.2 The purpose of this paper is to: (i) present our Annual Delivery Plan 2016-17 (Annex I) for which we ask UHL's Board for its approval (contractual requirement); (ii) summarise our performance, major achievements and challenges and (iii) present our updated Governance Framework 2016-17 (Annex II) which requires annual review by the UHL Board. Finally, (iv) a brief presentation (Annex III) has been included as requested by the UHL Board Chair. This is for interest only and will be presented at the UHL Board Meeting by Prof. David Rowbotham.

1.3 This paper will be taken to the CRN: East Midlands Executive Group, chaired by Andrew Furlong (Medical Director and UHL Executive lead for the CRN) in April 2016. It will then be considered by the UHL Executive Performance Board, and submitted for UHL Board review with the Annual Delivery Plan in May 2016.

2. Annual Delivery Plan: 2016-17

2.1 CRN: East Midlands Annual Delivery Plan 2016-17 sets out our strategic and operational priorities for this financial year. It is prepared in consultation with network partner organisations and public representatives, and approved by our Partnership Group.

2.2 The plan gives assurance to the host and CRN Co-ordinating centre about our approach to delivering and working within the NIHR CRN Performance and Operating Framework (POF) 2016-17. The plan covers our regional contribution to the national strategic priorities and high level objectives describing the activities and initiatives we will undertake, including contributions from all clinical specialties and partners within the East Midlands.

2.3 Our plan has a particular local emphasis on: working in true partnership with regional NHS organisations; communication; improving cost-effectiveness and flexibility; innovative methods of working; patient and public engagement; developing and recognising network staff; further improving our commercial performance; financial management.

3. Current performance

3.1 In line with the meeting schedules of the CRN: East Midlands Executive and UHL Trust Board, our previous report on performance covered the period Sept 8 – Dec 4, 2015. This report covers early December to the end of March, 2016. These figures do not give an accurate end of year position as presently all annual data has not have been uploaded to the national database. Our next Board report, due in Sept 2016, will include finalised year-end performance for 2015-16.

3.2 Performance highlights as of March 2016 include:

- We remain in 5th position out of 15 Local Clinical Research Networks in the national table for recruitment into NIHR portfolio studies
- We have remained the same in terms of percentage of population recruited to studies at 7.6%
- We are in 3rd place out of 15 Local Clinical Research Networks for commercial performance measured through the recruitment to time and target in closed studies
- For Research Governance and Management (RM&G) we are measured on study wide and local approval processes, both with a target of 80%, we continue to meet these targets with 84% and 95% respectively.

3.3 By the end of 2015-16, the East Midlands is likely to have contributed 45,000 participants to the NIHR CRN High Level Objective for portfolio research recruitment. This is below our original target of 56,688 (local target of 53,000). This issue has been highlighted to the Board previously, with actions taken to address this. The drop in recruitment has been caused by a number of reasons, not least: the closure of a number of high recruiting studies; a reduced pipeline across some clinical specialties and a shift in the national portfolio towards smaller sample size, more intensive studies. We have also had a particular recruitment drop in one of our key NHS partner organisations, and are working with them to address this. The table below provides further detail in relation to concerns and related actions.

3.4 In addition to this short narrative report, appended is a dashboard detailing key performance measures for 2015-16 under which the CRN: East Midlands is performance managed. These are discussed in detail at the host Executive meeting and Operational Management Group meetings of the CRN: East Midlands.

4. Budget allocation 2016-17

4.1 The budget allocated from the centre is influenced predominantly by recruitment performance, relative to other regions (approx. 70%) in the previous 2 years with a increase/decrease limit of 5%; the remainder is linked to other performance measures (c.10%) and due to a number of fixed elements. Our confirmed budget allocation for this

year is £21.4M which represents a maximum increase allowable (£364,880) plus an additional direct allocation to partner Trust via the network of £443,185; this is in recognition of commercial performance over the past 18 months. This increase, and the fact that early financial plans were agreed with partners assuming a 5% reduction, means that we are able to be more innovative in our allocations this year, including establishing a strategic fund.

5. Challenges and Actions

5.1 A table is included below which summarises challenges and details associated actions to address these, in relation to core CRN activities. Many of these are reflected in the risk register.

Challenge or concern	Associated action
Reduced pipeline in some specialties may affect ability to achieve total recruitment target (HLO1)	▪ Working with Specialty Leads to get better information on national pipeline ▪ Working with Trusts & other parties to encourage adoption of studies where possible ▪ Keep a balanced portfolio of specialties with varying pipelines ▪ Keeping an accurate log regarding studies offered and uptake across partners with a view to better targeting and understanding of issues/blocks
The CRN are in the process of establishing a Study Support Service for researchers across the region, which presents some challenges relating to staffing and clarity of offering	▪ Have established a regional Programme Board to lead this work ▪ Established an overall project plan, with two targeted pilots in operation – for researchers in primary care and mental health settings ▪ Need to increase communications approach ▪ Delivering skeleton Early Contact Service ▪ Have transitioned staff into this new service and are working with partners were staffing gaps exist
The new regulatory environment has introduced HRA Approval, which requires research Sponsors to take on more responsibilities; however some delays are seen relating to communication issues & sponsor expectations / responsibilities not yet realised	▪ Continued communication with sponsors locally ▪ National CRN communication with sponsors through SSS Programme Board ▪ Share guidance document – 'CRN HRA readiness principles' with LCRN, Partners, ▪ Work with POs to encourage joint working Sponsors ▪ Better tailoring of the SSS (above) to ensure researchers can be supported during this time of change

6. Summary and recommendations

6.1 UHL Trust Board is asked to:

(i) Consider and approve the CRN: East Midlands Annual Delivery Plan 2016-17, in its capacity as the Host Organisation on behalf of the Department of Health

(ii) Review our present performance, achievements, challenges and mitigating actions, proving any comments or feedback you might have

(iii) Note the changes proposed within the CRN East Midlands Governance Framework 2016-17

(iv) Note the increase in budget allocation from the centre for this financial year

Annexes

The following papers have been included as annexes to this Report:

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I. CRN East Midlands Annual Delivery Plan 2016-17	This paper sets out the strategic direction for the LCRN within the reporting year. The LCRN Annual Plan includes the specific activities and strategic initiatives to support the achievement of the NIHR CRN performance objectives as set in the NIHR CRN Performance and Operating Framework 2016-17 (POF). The Annual Delivery Plan requires formal Trust Board approval.
II. CRN East Midlands Governance Framework 2016-17	This paper describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN. This framework is updated on an annual basis in order to reflect any changes in governance, assurance and escalation processes. In this Annual update there are no fundamental changes to the governance framework. It has been updated with some minor organisational changes. This paper requires review by the Trust Board.
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Appendix 1 - Dashboard

Clinical Research Network: East Midlands **Refreshed: 13/04/2016 - NOT YEAR END FIGURES - TO BE FINALISED BY 31/05/2016** **(Previous: 12/02/2016)** **Network Progress Overview**

	HLO Description	Study Type	Target		Progress/Summary				Actions	Status	Owner	Year End RAG Assurance
			England	East Midlands	Curr YTD	Previous	Trend					
1	Number of patients recruited into NIHR studies	All	650,000	56,688	**42,160**	**34,371**	↓3%	77% of Year to Date goal (54,508) (previously 80%) CRN: East Midlands in 5th position out of 15 LCRNs (n.b. 83% of local Year to Date goal)	-Review time & target of existing studies -Review UKCRN database for potential studies and open new sites -Detailed action plan in place	Ongoing	Chief Operating Officer	Red
2	Proportion of NIHR studies delivering to recruitment target and time	Commercial	80%	80%	**72%**	**72%**	↔	104 studies recorded as closed and reported recruitment. CRN: East Midlands in 3rd position out of 15 LCRNs	-Monthly performance meetings -Robust target setting process -Attendance at Site Selection Visits in areas of poor performance -Workshops & teleconferences in Primary Care to embed performance management culture	Ongoing	Industry Operations Manager	Amber
		Non-commercial	80%	80%	**70%**	**66%**	↑4%	66% (26) for 37 closed HLO studies	-BI analysis of time & target position of existing studies -Contact study teams & Trusts for underperforming studies	Ongoing	Chief Operating Officer	Amber
4	Proportion of eligible NIHR studies obtaining NHS permission within 30 calendar days of valid research application	All	80%	80%	**93%**	**95%**	↓2%	Implementation of the HRA approval system may affect the CRN's control over this HLO.	-Senior RM&G Manager is actively monitoring & reviewing progress	Ongoing	Lead RM&G Manager	Green
6	Proportion of NHS Trusts recruiting into NIHR studies	All	99%	99%	**100%**	**100%**	↔	16 out of 16 Trusts reporting recruitment.	Target achieved	Complete	Chief Operating Officer	Green
		Commercial	70%	70%	**63%**	**63%**	↔	10 out of 16 Trusts currently reporting commercial recruitment. Need 12 out of 16 to achieve target.	-Studies currently in set-up at DHCFT & NottsHCFT -Develop site identification template at mental health trusts to improve selection chance -Working with EMAS, DCHS & LCHS to develop potential	Ongoing	Industry Operations Manager	Amber
	Proportion of General Medical Practices recruiting into NIHR studies	All	25%	25%	**58%**	**51%**	↑7%	350 out of 601 GPs, Surgeries & Health care sites currently reporting recruitment.	Target achieved	Complete	Division 5 Research Delivery Manager	Green
7	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) NIHR studies	All	13,500	1,250	**983**	**773**	↑3%	86% of Year to Date goal (938) (previously 83%) Require 24 recruits per week.	-Link with study teams and sponsors to closely monitor studies with high recruitment potential -Build relationships with universities to ensure studies are adopted onto NIHR portfolio where possible	Ongoing	Division 4 Research Delivery Manager	Amber

Sources: Commercial Reporting on ODP 13/04/2016, Portfolio ODP Last update: 13/04/2016, Portfolio ODP 1415 Annual Cut Last update: 28/05/2015, CSP Reporting on ODP Last update: 13/04/2016

Network Summary Report 21/03/2016, Commercial Team update: 13/04/2016 Provided by: CRN: East Midlands Business Intelligence Team

N.B: HLO 3 & HLO 5 are not included as these relate to national objectives

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Clinical Research Network
East Midlands

Annual Delivery Plan: 2016/17

Clinical Research Network: East Midlands

Delivering research to make patients, and the NHS, better

About this document

In advance of each financial year, Clinical Research Network: East Midlands publishes an Annual Operating Plan which sets out our priorities and describes the work we will be conducting in the coming year. This document is our Plan covering the financial year 2016/17. The Plan is prepared in consultation with the key accountability structures of the CRN and is formally submitted by the Host Organisation of the CRN: East Midlands, University Hospital of Leicester NHS Trust; it will be reviewed by the Trust Board prior to enactment. Included in the plan is assurance in relation to the NIHR CRN Performance and Operating Framework (POF) 2016/17.

The plan covers our regional contribution to the NIHR Clinical Research Network High Level Objectives describing the activities and initiatives we will undertake and key contributions from all of the clinical specialties across the East Midlands. Further detail can be found within Appendix 2 and 3. We also summarise our wider programme of work linking to the NIHR strategic priorities and national CRN strategies. The final section outlines our approach to financial management.

Contents

Foreword - from Host Chief Executive – John Adler

Hosting, and being accountable for, the NIHR Clinical Research Network: East Midlands remains a strand in the University Hospitals of Leicester's (UHL) strategy to make a major contribution to the creation of a world-class health research system within the NHS. We also take pride in having a leadership role in ensuring that patients in the East Midlands have easy and equitable access to new and exciting approaches to the treatment and prevention of a wide variety of conditions, as well as contributing to national and regional economic growth in the life sciences sector.

Our Board takes a keen interest in reports and presentations from the network team and has full confidence in its governance and workforce. We fully endorse this annual plan for 2016-17 and welcome approval from the network Partnership Group and other stakeholders. I am particularly impressed with the emphasis on working in true partnership with regional NHS organisations and plans for improving cost-effectiveness, innovation, patient and public engagement, staff development, financial management, communications, flexibility and inclusiveness.

This year will be another challenging time for clinical services and research in the NHS but there will also be many opportunities to improve and develop. The landscape is changing significantly; clinical researchers and the network need to understand and respond to this in order to continue to serve our patients in the best way possible. We believe that this annual plan provides a framework for this and other challenges.

UHL and many other healthcare providers in the East Midlands have been involved with the NIHR since its inception. This year marks the 10th anniversary of the NIHR and we all are looking forward to celebrating its magnificent achievements throughout the year, including a major regional meeting.

We will continue to support and supervise the Clinical Research Network in the East Midlands and expect to be reporting another successful year of operation at the end of 2016-17.

John Adler

Chief Executive, University Hospitals of Leicester NHS Trust

Introduction - Chief Operating Officer & Clinical Director

2016-17 will be the Clinical Research Network: East Midlands' third full year of operation. Many of the initiatives implemented over the last two years have contributed to our improved performance leading to this year's regional budget increase. By the end of next year, we will target investment in growth areas which will demonstrate clear return through improved delivery. This can only be achieved with the support of others and we will be ensuring our partnerships at every level are mutually beneficial and productive. This encompasses relationships with patients and the public, NHS partners, NIHR partners (CLAHRC, RDS, CTUs, MindTech, BRU/Cs), Academia, Life Sciences and wider stakeholders across the East Midlands and further afield (Academic Health Science Network, Health Education England, Clinical Senate & Networks, Public Health England).

We will ensure our structures and processes operate to maximum efficiency through the application of continuous improvement methodologies in all aspects of decision making. We have an increasingly lean management team, which will be further refined following with the loss of one further senior post; this team will be supported to deliver across the breadth of our activity. Investing in Workforce Development across the CRN workforce is important in 2016-17, we need the excellent people we have in the region to be developed and supported to excel in enabling and delivering NIHR portfolio research. We have also commenced a regional research initiative for trainees with Health Education England, both for trainees to establish and build on trainee research networks and potentially an Out of Programme opportunity for a senior trainee to develop experience within CRN management.

Delivering well across commercial and non-commercial research studies is essential, with time to target and portfolio balance of as much significance as overall recruitment numbers. We have consistently delivered for the life sciences industry in the East Midlands and are committed to improving our efficiency, striving for 90% by 2017-18. We have set a number of internal metrics to assist us in reaching these goals.

Whilst we will continue to work towards the NIHR CRN strategic goals and national strategies, it is also important that we have a regional identity which can be articulated to all members of the CRN: East Midlands and our current and future stakeholders. We have previously established a set of Values which underpin all that we do and a clear Vision of how performance can be demonstrated. For 2016-17 we have added 3 strategic priorities following discussion and consultation with our Partnership Group and Operational Management Group; we will weave these across all work-streams and through focussing on these, will reach our regional and national goals.

Professor David Rowbotham

Clinical Director, Clinical Research Network: East Midlands

Elizabeth Moss

Chief Operating Officer, Clinical Research Network: East Midlands

Strategic oversight

Established in 2014, the Clinical Research Network: East Midlands introduced some early goals and expectations for our diverse and highly research active region. The first year of inception saw us exceed our ambitious recruitment target of 50,000 participants into NIHR research studies. We built upon these goals to develop a clear vision and set of values for our region, these are now supplemented by three strategic priorities for 2016-17.

Vision

To be a high performing CRN demonstrated through:

- **Recognised good people**
- **Innovation**
- Recruitment & balance
- Efficient systems
- Effective use of resources
- Ability to meet range of targets and goals
- Contribution to setting the national agenda

Values

True Partnership
Transparency
Communication
Delivering value for money
Efficiency
Responsiveness
Flexibility
Inclusivity
Supportive

Strategic Priorities 2016-17

- Embed Partnership working in all that we do
- Ensure the patient voice and clinical insight is balanced alongside the managerial drivers
- Be clear in how we communicate to all audiences

The East Midlands contribution to NIHR CRN Performance Objectives

By the end of 2015-16, the East Midlands is likely to have contributed 45,000 participants to the NIHR CRN High Level Objective for portfolio research recruitment. This performance, along with that seen last year, has resulted in an uplift in regional budget for 2016-17. The recruitment goal set for 2016-17 is based on recruitment achievement, alongside a thorough review, by specialty, of current and projected pipeline studies. Our target for 2016-17 is 48,000 participants to be recruited into NIHR studies in the East Midlands. When setting this challenging target, in addition to reviewing realistic specialty goals and further stretching these; we also had a robust discussion at the Partnership Group around the importance of an absolute annual goal to be considered against a more balanced local portfolio of studies. The Partnership Group recognises that a balanced portfolio across interventional and observational studies plays an important role in income flow to the region, something we are keen to maximise if the region is to further flourish and increase our opportunity to offer more research to more patients. The Partnership Group would like some further work to be done in this vein and we are likely to introduce some local performance measures in relation to the balance of studies across the three well recognised categories of simple, observational and interventional.

Working with our partners remains important, with some specific work to be undertaken in 2016-17, some of the key areas are summarised below, where further work is needed:

Partner focussed work	Overview of activity
Nottingham University Hospitals NHS Trust	Continue our work with NUH, building on recent changes in R&I management to further understand and reverse the significant reduction in recruitment
Working with all acute trusts	Keen to maximise portfolio breadth across all specialties, ensuring focus is not always at larger sites, including looking at referral models, with all sites acknowledged for their contributions.
Nottingham University Hospitals NHS Trust & Sherwood Forest Hospitals NHS Foundation Trust	Recent announcement of a long term partnership between these two trusts will provide an opportunity to review systems for research set-up and delivery.
Mental Health and Community Trusts	Working to ensure community services have the opportunity for research involvement and are supported.
All NHS partners, especially those leading studies	Aim to scope the level of non-portfolio research across partners, with a view to understanding reasons for this, and where possible seeking to actively encourage portfolio adoption at an early stage.
Non-NHS providers, who are providing NHS services, such as Circle, LOROS, Councils	Scope potential for further involvement with these partners to aid study set-up and delivery, identifying any barriers to closer working.
NIHR regional partners – BRU/BRCs, CTUs, RDS, ECMC, CLAHRC, MindTech, Senior Investigators and other NIHR faculty members	Further establish these regional alliances and partnerships, aiming to hold an East Midlands-wide event to celebrate NIHR at 10

Divisional Plans & Priorities

Appendix 3 provides significant detail in relation to the Specialty breakdown; however, below is a summary by Division which sets out priority areas and specific initiatives alongside associated opportunities and challenges.

Key Priorities	Summary plans	Concerns	Opportunities
Division 1: Cancer			
• Stabilise recruitment and understand reasons for falling numbers • Essential to maintain the commercial reputation of the region • Continue to work with our POs to ensure a delivery infrastructure that has a suitable skills mix, with excellent clinical links across the region (driven by LCRN presence at ECAG)	• Develop regional plan to address recruitment issues, led by RDM & CL, supported by Sub-specialty Leads, Lead Nurse, R&D/I Managers & Cancer Teams leads within POs • Regular meetings for the Cancer team leads of the region to try to regain a sense of community, increased moral and the sharing of best practice • Div 1 Ops Manager and appropriate Sub-specialty Lead as members of the East Midlands Senate and Strategic Clinical Network Expert Clinical Advisory Group (ECAG) will regularly present performance & benchmarking information, and discuss referral pathways as necessary. For 2016/17 we will revisit the information provided at the ECAG, to ensure fit for purpose. • Portfolio review of current & future studies across all tumour sites, and investigate opportunities and threats to performance • Aim to bring new studies to the East Midlands in a timely fashion, adopting a truly regional approach and strive to offer equity of studies across our geography (opening studies in multiple sites concurrently or through PICs)	• Significant reduction in recruitment seen in this Division in 2015/16, particular issue within one of our two large teaching trusts • Changes to service provision in the south of the region, Northants, could have significant impact on the way research will be made available to patients	• Palliative Care: the RDM and joint Palliative Care Sub-specialty leads will improve links and awareness within hospices. RDM to meet with colleagues in West Mids to learn about their model and look to implement in the East Midlands. • Potential to share this learning with other specialties outside of Division 1
Division 2: Renal, Diabetes, Cardiovascular, Metabolic & Endocrine, Stroke			
• Significant links to the BRUs (possible BRCs) in the region, thus NIHR collaboration remains essential for this Division • Diabetes remains an important priority for the region, due in part to population and locally based national research leaders • Ensure Hyperacute Stroke Research in Nottingham is well performing through investment and support	• Within the Cardiovascular specialty, we are keen to look to mentor/create more local PIs to help increase the participation in studies and avoid saturation of existing PIs • In Diabetes, pipelines for both for immuno-therapy and prevention studies are strong with some studies already in set-up • In our Renal portfolio, we intend to increase recruitment from Northamptonshire Haemodialysis Unit (consisting of Kettering and Northampton sites) and increase the number of portfolio Transplant studies across the region • All areas of the stroke pathway will be met across East Midlands, although all sites will not be able to contribute equally to all 4 areas e.g. Hyper acute complex studies in Nottingham HSRC but will continue to work with all sites to build on recent improved recruitment	• Both Cardio and Diabetes recruitment can be recorded as primary care, whilst not a threat, we are keen to collaborate as a region • Equally renal activity can sometimes be assigned to Haematology with can appear to underestimate the performance of this Division	• Potential new BRC in Leicester, with themes within this Division and, if successful, will present further opportunity for collaboration • Changes to management structures will see RDM for Division 2 also work across Division 5, again opportunity for further collaboration with primary care

Division 3: Children, Genetics, Reproductive Health & Childbirth, Haematology			
• Seek to have well performing studies in place across all sites with Children's services • In Genetics we will maximise awareness of regional participation in the NIHR UK Rare Genetic Disease Research Consortium • Seek opportunities to engage trainees in Haematology studies	• In Children's, the portfolio support team will work on identifying new studies including perinatal studies, through the engagement of our Specialty Leads nationally and linking with other Divisions effectively • In Genetics, we are keen to work with our newly appointed Specialty Lead; we will organise quarterly meetings to showcase open studies, and will develop some materials to remind clinical genetics teams about active studies • As with a number of other specialties, within Haematology we aim to explore opportunities for trainee involvement. We will work with our local Health Education England and learn from the experience of other specialties • Investigate further the Reproductive Health & Childbirth portfolio, seeking opportunities to open a balanced portfolio of studies, including studies which appear to have some logistical issues by overcoming any barriers	• Genetic specialty performance likely to be impacted by the 100,000 Genome Project - not an NIHR portfolio study. Locally, Genetics teams are feeling the pressure of delivering this, which needs to be considered for current and new studies with genomic requirement	• Following the funder's decision to prematurely close the Life study in Leicester, we will seek opportunities to make the best use of expertise, facilities and experience of this centre; including delivery of BSS (sub study), and potential work across all Divisions
Division 4: Mental Health, Dementias and Neurodegeneration, Neurological Disorders			
• Continue to grow JDR database locally as an effective recruitment tool • Continue with ENRICH regional engagement, sharing the good practice across especially to the south of the region • Build on the regional CAMHS service provision & integrate research • Harness the interest shown through the mental health targeted work to open and deliver on more commercial research	• Continue partnership with Nottingham University, commitment for 7,000 staff and 3,000 students to volunteer for JDR • Involvement in Alzheimer's Society Roadshows in 8 sites across East Midlands • In addition to links to CAMHS service, also link to the Department of Child & Adolescent Psychiatry at Nottingham University with a view to developing CIs and increasing study throughput • Intention in 2016-17 is to work with our nominated leads in the following neurological disease areas: Huntington's, Parkinson's, Epilepsy, MS and Brain Infections, to determine opportunities for study roll out locally. To scope and develop capacity to support these studies where possible	• Pipeline concern has led to reduced recruitment goals, especially in DeNDRoN; we could deliver more if there were more studies available • Concern over inconsistent approach to Rater experience, plans detailed in following section	• Opportunity to further explore and promote JDR at GP practice level, including the ability to harness the power of Patient Practice Groups • Potential for further collaboration should the Nottingham based BRC application be successful, with two themes having overlap in this Division

Division 5: Primary Care, MSK, Dermatology, Ageing, Oral & Dental, Public health, Health services & delivery research			
• For MSK, will work with new centres including Kettering and Lincoln • For Ageing, research will engage across Lincolnshire • Continue investment in RSI scheme for GPs • Evaluate and refine leadership site model, including promotion of dementia research • Target to have 14 pharmacy sites research ready accredited	• To reinvigorate Dermatology following significant service reconfiguration through a region-wide Dermatology meeting, and look for further synergies across other specialties, e.g. MSK • Continue links for MSK using existing audit meetings, and run a half day workshop for delivery staff across the region to share good practice and aid delivery • Develop a registry of NHS and private sector dental practices to aid study placement (If more studies available) • Primary care remains a strong area for us, plans include: ➢ Within RSI - further engagement with practices to build on RSI performance indicators, build capacity, and promote confederated models of research delivery ➢ Continue to engage with practices outside of RSI scheme to support and promote participation in research ➢ Engage with local GP training schemes, promoting research with newly qualified GPs ➢ Engage with other specialities to enable recruitment of patients within a primary care setting ➢ Further plans for Community Pharmacy in Appendix. 3	• Concerns over HSDR, PH and Oral and Dental pipeline with a lack of available studies • Concern over collapse of large academic unit at NUH	• Unlike some specialties there is a strong pipeline for Dermatology studies, which along with recent re-engagement with Circle Treatment Centre could be further capitalised upon • New leadership for HSDR is an opportunity which will be further explored • Changes to management structures will see one RDM working across Divisions 5 and 2, with opportunities for further collaboration
Division 6: Anaesthesia, Critical care, ENT, Gastroenterology, Hepatology, Respiratory, Ophthalmology, Surgery, Infectious diseases, Injuries & Emergencies			
• Further support MERCAT (Midlands (East) Research by Critical Care and Anaesthetics Trainees) • Increase participation of intensive care units in research to 60%. • In ENT, increase collaboration with NIHR Hearing BRU (or BRC in due course) to ensure all potentially eligible studies are portfolio adopted • Inc. from 90% to 100% the proportion of acute Trusts recruiting to Gastro studies. • Inc. from 50% to 80% the proportion of acute Trusts recruiting in to	• Supporting MERCAT with the provision of GCP training to trainees for participation in iHYPE (intra-operative hypotension in the older surgical patient) • Working with the Deanery to organise events for trainees interested in developing research networks - like MERCAT, to further facilitate involvement in clinical trials, this is not only Division 6 specific, although will have a significant impact here • For Critical care, we will support POs to develop a workforce to cross cover Anaesthesia, Critical Care, I&E and other specialties using workforce to best effect • Forge stronger relationships with Gastro & Hepatology teams across the East Midlands to raise profile of research and of NIHR portfolio studies; work with Industry Team to open and deliver on more commercial studies, with use of simple patient databases to assist identification • Specialty Lead to make links across trusts providing eye services outside of two large teaching trusts • Explore possible Trainee initiative in Ophthalmology • Need to maintain & expand infrastructure to increase recruitment to research databases supporting Asthma, COPD, Bronchiectasis and other	• As with Division 4, the biggest concern for this Division is study pipeline, across the majority of specialties (CC, Anaesthetics, ENT, Ophthalmology) this is identified as a risk are, with concern about future studies	• Opportunity to work more as a collective Division making better use of synergies across Divisions • Potential new BRC in Leicester, if successful, will include Respiratory, further collaboration opportunity • The East Midlands Thoracic Society has reformed, this is an opportunity to ensure CRN and NIHR business is visible • The East Midlands Surgical Academic Network (EMSAN), a Trainee Initiative open to all Surgical Trainees in the

Ophthalmology studies. • Maintain surgery recruitment across at least 11 sub-specialties • Maintain high levels of trust participation in I&E studies and build on good relationships with EMAS	respiratory research across Primary, Secondary, Tertiary Care, supported by the large teaching hospitals • Expand Surgery recruitment through Specialty Lead engagement across Surgery subspecialties not currently represented, although portfolio dependant • To aid Infectious Diseases and Microbiology, we will scope current capacity across Trusts and in the community, we will establish new links with centres not previously research active or which have recently ceased research activity; we will work to identify & overcome barriers • Specialty Lead to hold monthly TC to discuss I&E research opportunities and raise awareness of the NIHR CRN Portfolio studies • Cross regional Injuries & Emergencies (I&E) event is planned in the Autumn		region is recently reinvigorated, and we are keen to support this.

To ensure local Specialty leads are best supported, we recognise that a number of elements are important. It is essential to establish a link to the national Specialty Lead, along with suitable local support to undertake the role and establish key local deliverables, which can be well monitored. In the East Midlands, we actively work with our Specialty Leads and have a performance framework which ensures we have the right person for the role and enables them to understand the needs of the region. The main driver is engagement with clinical specialists across the region and we have a portfolio support team who aid widespread engagement, encouraging sharing of studies across the region, not just where Key Opinion Leaders are based. It is important for Leads to participate in the national meetings as this facilitates communication both ways and allows early identification of the forthcoming pipeline. RDMs link with the Specialty Leads following these meetings for feedback and sharing of intelligence. Each Division also holds Divisional meetings with Specialty engagement, along with regional meetings for Specialty and Clinical Divisional leads; in 2016-17, we will hold two of these East Midlands wide meetings.

Commercial contribution

In addition to overall recruitment and portfolio balance, regional performance and contribution to commercial metrics is an important area for the East Midlands. We consistently perform in the top three CRNs for commercial activity and intend to remain there next year. Our goal is to deliver at least 80% of our commercial studies to time and target in 2016-17, and look to increase this threshold to an aspirational 85-90% in 2017-18. We will achieve this through embedding the standard operating procedure for the review of site intelligence forms to draw on the network expertise at all levels. We will specifically focus on areas not delivering to time and target to ensure future targets can be delivered and lessons are learnt where studies have underperformed. Emphasis will be placed on promoting a widespread understanding of the importance of well set and clearly communicated targets within new and existing research teams, which we will build through continued training, education and workshops. Additionally, we intend to harness the potential of Edge, our local portfolio management system (LPMS), as a source for performance updates between network and partner organisations to track performance across the East Midlands.

It remains important that commercial activity is delivered across as many partner organisations as possible, ensuring wide participation in ground-breaking research for patients. The majority of commercial activity in the East Midlands is undertaken within acute secondary care and primary care settings, although there is interest from partners across other settings. There are fewer potential studies to offer these sites; however, we will endeavour to influence our commercial partners where appropriate, taking into account that care patterns and service delivery approaches are constantly changing. In line with national expectations, our regional goal is to have 75% of partner organisations engaged in commercial research in 2016-17 and 2017-18. This will be achieved by increased engagement and planning with our Community Health Trusts, building on their interest in commercial research. Additionally, our intention is to build on previous work done to develop site profiles for the Mental Health Trusts, forging links with Industry through increased engagement at the Industry Working Group. Within Division 4, we will maintain, and market, the improvements seen in recruitment performance, which is currently at 100%. We will support and facilitate collaboration between Mental Health Trusts and commercial sponsors building on an increased portfolio of studies which we are hoping to see.

To aid us in reaching the national high level objectives, we also intend to have a number of regional performance measures for commercial work. In 2015-16, we have recruited to commercial studies in all Divisions, across 21 Specialties; we are intending to increase this to at least 24 Specialties in 2016-17. We have seen an increase in recruitment, more than doubling in the region in the last 5 years. In 2015-16 commercial recruitment was 1,680; we aim to increase this to 1,800 in 2016-17, reflecting our ambition for growth.

Another element which would significantly assist in opening up additional sites to commercial studies would be for more robust and timely feedback to be made available to us regarding the reasons sites are not selected for commercial studies, so that partner organisations can use the feedback to develop services in line with sponsor expectations. We will continue to lobby for this.

In order to ensure regional contribution to HLO3 (national commercial portfolio) remains high, it will be important to increase presence with SMEs and MedTech across the East Midlands. Working with the AHSN, and as part of the Study Support Service, we will provide support and signpost these organisations as appropriate with a view to increasing the commercial portfolio. We will raise awareness of the role of the CRN, and indeed all NIHR regional partners, through engagement events and an increase in the Industry workshops we deliver to support teams across the region. We will also endeavour to seek all opportunities to collaborate with the evolving programme of work across the Midlands developing the Midlands Engine for Growth.

Non-commercial and engagement activities

Whilst commercial performance is undoubtedly a critical success factor, our non-commercial portfolio will also be well supported. In 2015-16 the East Midlands reported 70% of studies recruiting to time and target under HLO 2b, representing the qualifying closed non-commercial studies. We intend to bring the goals for both HLO2a and b together with targets mirrored to 80% in 2016-17 and 90% the following year. As detailed in relation to our commercial studies, one way to improve this is accurate recruitment predictions and timelines at the start of the study. As the Study Support Service (SSS) becomes further established we intend to use the Early Contact support to improve this. We will harness the experience of the Study Start Up team to ensure that robust feasibilities are undertaken at participating sites in the region.

Partner and stakeholder engagement in non-commercial studies is also critical to our success, with all Trusts and CCGs in the region contributing recruitment to at least one study in 2015-16, which is an exceptional achievement. We would aim to continue with this in 2016/17. In the East Midlands we have 601 GP practices, of which 56% (340) practices have actively recruited to research studies in 2015/16. Over the next 12 - 18 months years we intend to grow this to 60%. As part of the changing landscape of healthcare, more patients will be treated in primary care and out of hospital settings, as a LCRN we need to adapt with this change and encourage our research leads to use GP practices as a valuable research delivery resource. We will continue to invest in the RSI scheme, and look at other methods to support and develop practices to increasingly offer research through the primary health care contact point most of the population will experience.

The changes in relation to the swift set-up and recruitment of participants into NIHR portfolio studies is most welcomed by the CRN and partners, with alignments cross the various metrics for these activities. These changes, reflected in HLO 4 and 5, have acted as a springboard to establish the Study Support Service in partnership with NHS organisations, and allow the CRN an opportunity to be ready for the HRA changes. In the coming year, we intend to embed the Study Support Service across all elements of the support we offer to researchers. We are currently piloting tailored services in primary care and mental health research settings, which will be evaluated and revised or implemented accordingly. We will further develop a support network and appropriate services for researchers across acute and teaching hospital settings, with investment in Early Contact support to ensure good engagement from the early stages and effective signposting to other stakeholders, such as the NIHR RDS and NHS R&D/I teams, both of whom are pivotal to effective delivery. We will continue to work closely with Trusts to ensure HRA readiness is achieved and the delivery of the HRA expectations locally in relation to Asses, Arrange, Confirm, integrating with relevant elements of the Study Support Service.

The Research Delivery Managers and their teams will play an important role in study delivery assessment, working with the support of the Senior Research Nurse and RST to look at feasibility, recruitment plans and study milestones. As part of our Business Intelligence Service, the information team will be essential in the provision of information to aid study monitoring and performance. Further embedding Edge, will allow accurate, timely data to be collected, which can then be used to make productive decisions to enhance and improve performance for researchers. Alongside the RDMs, there is a portfolio support team and, as the Study Support Service is further shaped, this team will actively take on the role of performance review with clear guidance to understand how the region can increase performance and ensure lessons are learned.

Another opportunity we intend to capitalise on as a result of the harmonisation of data points is in relation to “first patient in” metrics. We have been working with Partner Organisations to increase the number of studies that have recruited their first participant within 30 days of NHS permission, over the past few years and with the introduction of the HRA Approval, the metrics for LCRNs and Trust now align. Currently, the rate of local studies recruiting the first participant in 30 days is significantly below the target of 80%. As the measures are now aligned, it will be easier to collectively work to achieve this; we will be aiming for 80% in 2016/17. Current performance initiating and delivery (PID) data is 86% and therefore converging the metrics should make this achievable.

Dementia Challenge

Since the introduction of the Dementia Challenge and associated recruitment goal, in 2014-15, the East Midlands has contributed to this important priority area. Whilst there is much willingness across the region to further contribute in 2016-17, there are two problematic areas which have prevented us from increasing our target above that set for 2015-16. Firstly, the size of the portfolio opportunity has limited our potential for growth and secondly the approach to Raters. Over the past 12 months, we have seen a reduction in studies which are available for us to participate in and it is difficult to find studies in this area which are open to new sites. However, should the study pipeline widen with more opportunity available, we have commitment from all NHS partners that they are keen to get involved in delivery of this important research area. In relation to Raters, we have recently seen a lack of transparency and consistency in relation to a national standard for Global Rating. Different Sponsors set the required experience and, despite some very well trained and experienced Raters, we have found they do not all consistently met these differing standards. Additionally, as regular application of these rating skills is a key requirement, in order for Raters to be recognised, the reduction in available studies (within which new, trained Raters can gain this experience), is further compounding this challenging issue.

With these constraints in mind, however, we do intend to do significant work to ensure patients have the best opportunity to get involved in these studies. We have appointed a dedicated Dementia Challenge Project Manager to work across the region to specifically work on this important priority. She is a champion for the Join Dementia Research (JDR) work, supporting Partner Organisations, providing training and raising awareness around JDR and other dementia initiatives. We will continue to promote JDR as an important recruitment tool with Principal and Chief Investigators in the region. We will have our first CRN: East Midlands led Dementia study, PRAISED, opening in 2016-17, and this includes JDR as a key recruitment strategy.

With our increased dialogue across all parts of the NIHR in the region, we will engage and raise awareness with stakeholders such as CLARHC, AHSN, BRUs/Cs and Academia to promote that all appropriate Dementia and Neurodegeneration studies which could be deemed eligible for portfolio adoption are processed through this pathway as standard practice. In relation to the concern over Raters, with will endeavour to develop and build capacity through workforce training in PANNS and Rater scales as appropriate. We will contract with experienced trained Raters to mentor and support new Rater trainees across the region, providing backfill from the Research Support Team (RST), where appropriate. We will ensure trained Raters maintain competencies and skills through the NIHR work programme that will be delivered by the local workforce development team.

Looking forward into 2017-18, we would hope these initiatives would provide an increased regional pool of Rater trained personnel that can be flexed across the region to enable a "Green Shoot Initiative" to be promoted at all sites which will increase commercial activity across the East Midlands. We will continue to engage with all Partner Organisations to map and facilitate access to lumbar punctures, imaging and radiology etc. and assist Partner Organisations in sourcing and setting up SLAs between Acute Trusts and Private Providers for access to these procedures in a consistent manner. By working with our partners and supporting researchers through the Study Support Service, we also hope to see an increased proportion of Chief Investigators and Lead LCRN studies coming through the pipeline meeting the needs and ensuring access to good quality studies for the population of the East Midlands.

The East Midlands contribution to NIHR CRN Strategic Priorities

In addition to the delivery of the HLOs, the NIHR Clinical Research Network has set out a number of strategic goals and has recently published national strategies. In the East Midlands, it is essential that our work-streams make a significant contribution and deliver to these national expectations. To ensure these cross-cutting themes are embedded into all the work we do, we have established clear leadership of all themes within our senior team (detailed below, along with any planned changes). This section of the plan provides an overview of our cross-cutting work summarising key deliverables in each area; appendix 4 has further detail on each area and the specific actions we will take.

Patient and Public Involvement and Engagement (PPIE)

Management Lead: Harpal Ghattoraya, Research Delivery Manager, Division 2

Workstream Vision

The aim for PPIE in the East Midlands is to be a portal of information for clinicians, researchers and members of the public. Engaging with partners, groups and like-minded organisations to collaborate on new and exciting local initiatives to raise the profile of PPIE, this will be a collaborative approach building on the systems and processes already in place both locally and nationally. We will continue to focus on supporting members through learning development initiatives and new technological methods where possible.

Key Deliverables

- Scheduling at least one programme of Building Research Partnerships programme into the workforce training schedule for the LCRN
- Work with members of the PPIE Working Group and via the R&D Leads Meeting to identify Patient Research Ambassadors within Partner Organisations/Groups
- Undertake trial of national questionnaire in the East Midlands, initially working with our BRU/C partners
- Encourage and Promote local innovation initiatives to ensure PPIE continues to be at the forefront of innovation and continuous improvement

Planned approach

The PPIE working Group continue to meet on a bi-monthly basis with good representation from lay members and partners across the LCRN. The group also works closely with the REPP steering Group lead by the AHSN and feeds into the EM wide newsletter. The lead also links into the national meetings, website and forums on a regular basis. The objectives listed above will be regularly reviewed and monitored as part of the groups function. Support for the PPIE Lead and this function is currently being revised. There will be further investment in this area to move these projects forward.

Workforce Development

Management Lead: Louise Young, Research Delivery Manager, Division 5; will change in early 2016-17, as Louise is leaving the CRN: East Midlands

Workstream Vision

Our vision is to enable a highly motivated, well skilled and responsive workforce to deliver a mixed portfolio of studies across the East Midlands. To achieve this we need to have the right people in the right place at the right time to delivery on our strategy, adding value and continually improving our service offering. By year end, we intend to have in place a robust local strategy that will communicate our vision and organisational culture to the workforce. We will promote clinical research as a core activity of the NHS and the value of a well trained workforce to achieve this.

Key Deliverables

- Agree a local workforce strategy that outlines the Network's vision and strategic priorities for the next 5 years.
- Establish an appropriately resourced network of practice lead facilitators to support the development of a rater community to deliver the dementia challenge.
- Establish a pool of generic facilitators to deliver national programmes of training across the East Midlands.
- Establish workforce intelligence across the region and undertake a training needs assessment
- Ensure the workforce is equipped with the appropriate skills and experience to deliver a mixed portfolio of studies
- Recognise and reward workforce achievements and excellence across the region, to inspire and motivate people

Planned approach

Deliverables will be achieved by scheduling 6-8 weekly workforce development steering group meetings to drive forward the planning and delivery, attending national workforce development meetings, continually monitoring performance against an implementation plan and feeding up to the Operational Management Group (OMG) to ensure the workforce development work stream activity is supported.

We will establish task and finish working groups as required to lead and deliver discreet workforce initiatives e.g. developing a local competency framework. We will host a research forum/conference to inspire learning, share best practice and to act as a platform to bring the workforce together. We will also host an annual awards ceremony to recognise and celebrate the excellent work that is taking place across the region.

Life Sciences Industry

Management Lead: Daniel Kumar, Industry Delivery Manager

Workstream Vision

The East Midlands will continue to actively contribute and drive forward the model of one network and make best use of this national network to continually share best practice and support the development of key initiatives. To be recognised as a key area of delivery of Recruitment to Time and Target by achieving 80% RTT by year end, with a stretch goal of 90% in 2017-18, and contributing to an increased number of research studies on the NIHR portfolio through engagement with SMEs. To raise the profile of commercial research and the key drivers through partner organisation engagement as well as with commercial partners. By year end to contribute to the implementation of a robust mechanism to provide feedback to sites on reasons for non-selection to support a plan for growth in this sector. Development of the strategy linking partner organisations with commercial sponsors through the continually evolving Industry Working Group.

Key Deliverables

- Recruitment to Time & Target at 80% for year end
- Goal to have an increased number of GP sites selected for commercial studies
- Single source of information for the Coordinating Centre and all LCRN's on study specific issues
- Mental Health Trusts with increased commercial research
- Increased presence with SMEs across the East Midlands
- A robust mechanism to give feedback on reasons sites are not selected for commercial studies

Planned approach

Roll out the commercial study life cycle workshop so that training is available across the region for those interested in commercial research.
Review of studies that have not achieved the set network target for lessons learnt with a summary across each division once the year end data is confirmed for discussion at the Industry Working group.
Build upon work developing site profiles for the Mental Health Trusts with increased engagement at the Industry Working Group forging links with Industry with an outcome of 4 of the 5 Mental Health Trusts having commercial studies in set-up, open to recruitment or with recruits in year.
Increased presence with Small and Medium-sized Enterprises (SMEs) across the East Midlands providing support and signposting to increase the number of portfolio studies. Measure of engagement with at least 5 SMEs to progress towards at least 2 research studies on the NIHR portfolio.
As further feedback is made available as to reasons sites not selected for commercial studies, we will feedback and share this with partner organisations, in order to develop sites and services in line with sponsor expectations.

Communications & NHS Engagement

Management Lead: Elizabeth Moss, Chief Operating Officer

Planned approach

Our Vision is to improve the visibility of the CRN: East Midlands through effective communication. We must ensure our communications are appropriate to the different audiences we need to engage – internally within the CRN, across the NHS, with other NIHR partners and wider stakeholders, and to patients and the public. We will improve our profile and enhance our engagement strategy with all partners and stakeholders.

Key Deliverables

- Through the Comms Working Group, we will successfully manage the implementation of new NIHR brand guidelines across the region.
- We will further work up and then deliver a collaborative campaign that highlights the strengths of the East Midlands, with a view to attracting more research to be delivered here
- Support the delivery of national communication programmes focused on specific health conditions that we know resonate most with patients, carers and clinicians.
- Continue communications work to support Join Dementia Research (JDR), increasing awareness and engagement within the East Midlands
- Regular, informative newsletters and further producing and promoting the monthly COO Video blog
- Regional NIHR @ 10 campaign, with links to all regional NIHR stakeholders
- Enhance partner engagement further through use of Senior team Links

Planned approach

Continue with the bi-monthly Communications working group meetings involving a wide range of key stakeholders to lead this work stream. Also ensuring Comms is represented at management meetings including the Executive and Operational Management Groups. Ensure the key deliverables are planned for the team such as Newsletter and COO Vlog; further strengthening the Comms team, due to planned maternity leave. Some elements of the Comms activity in 16/17 will require the support and buy-in of our Partner Organisations and key stakeholders, so ensuring that stakeholders are briefed on details in a timely manner will be important.
Increase of engagement work through reinstating the 6 monthly meetings with all Partner Organisations, COO, CD and Senior Team link.

Information & Knowledge

Management Lead: Kathryn Fairbrother, Business Intelligence Lead

Workstream Vision

Business Intelligence can be used to support a wide range of business decisions, both operational and strategic. An intelligent network will utilise both qualitative and quantitative data to identify where strengths and weaknesses are and how to improve performance and competitiveness, whilst ensuring effective patient care in research. We want the CRN: East Midlands to be an intelligent network; more able to effectively plan and manage our operations.

Key Deliverables

- Develop EDGE workflows to support delivery of the Study Support Service
- Ensure that Network staff are CPMS ready and able to deliver business as usual within the new system
- Provide appropriate platforms to aid Clinical Divisional & Specialty Leads and Research Delivery Managers to understand and proactively manage divisional performance
- To ensure that all East Midlands led studies upload recruitment in a timely fashion and ensure that no recruitment is lost for both Activity Based Funding and Annual upload deadlines.
- Provide a reporting structure to enable informed decision making across the network including live information streams rather than the production of paper reports

Planned approach

We will establish a Task and Finish group to identify the needs of each Partner Organisation in terms of 'live' reporting, hold monthly BI meetings to identify areas that will enable the CRN to achieve HLO 1. We intend to ensure all process flows within the Study Support Service capitalise on the use of Edge and capture key data within that system, rather than establish new recording and reporting arrangements outside of LPMS. We will engage across our clinical leaders to better understand their needs to aid their decision making.

Additional notes on Information Governance

In line with the terms set out in the Performance and Operating Framework, CRN: East Midlands shall comply with the legal framework for information storage and access and CRN information governance requirements. CRN: East Midlands shall also comply with the Acceptable Use Policy for the NIHR Hub issued by the Department of Health. CRN: East Midlands shall complete the Information Governance Toolkit annual return in the timeframe specified by the NHS Health and Social Care Information Centre and report scores to the National CRN Coordinating Centre to the Information Governance (IG) Manager.

CRN: East Midlands have established a process for reporting Information Governance incidents arising from LCRN funded activities to the National CRN Coordinating Centre, and communicated this to partners. All CRN funded posts are expected to comply with relevant Information Governance requirements of their employing organisations, including the required trust mandatory training for staff. As necessary the Host organisation will make available someone with specialist knowledge of information governance to respond to queries raised relating to LCRN-funded activities; further details can be provided, as needed.

Continuous Improvement

Management Lead: Louise Young, Research Delivery Manager, Division 5; will change in early 2016-17, as Louise is leaving the CRN: East Midlands

Workstream Vision

The future priorities for this work stream are to deliver a high performing LCRN, ensuring capacity and capability to deliver innovation and improvement across the region. We will focus on developing our unique approach to continuous improvement, which will include: developing a culture of continuous improvement across the CRN; implement the CRN continuous improvement competency framework across identified staffing groups when available; ensure skilled and knowledgeable workforce of expert facilitators are available to support the CRN to deliver its objectives. By year end, we will achieve 3 primary goals: to have in place a continuous improvement steering group that supports the delivery of CI projects and initiative across the regions; establish a dedicated workforce to drive forward CI activity; contribute and implement national innovation and improvement programmes, and projects, through an identified workforce, including support for digital CRN.

Key Deliverables

- Establish and deliver a consistent Study Support Service that reaches the entire research community
- Increase rater trainers to ensure the dementia challenge is delivered
- Lead on local continuous improvement initiatives and support the CRN digital
- Have an identified Continuous Improvement senior lead to oversee and drive forward key initiatives and deliverables
- Support self-directed learning of CI material across the workforce

Planned approach

Continue to hold regular study support service board meetings to plan and drive forward a unified SSS. To ensure we meet the dementia challenge, we will identify and continue to develop rater trainers across the regions. We plan to appoint a learning technologist to support the delivery on CRN digital and wider CI initiatives. This will also help to progress and further develop good work already underway and embed a culture of digital innovation locally. We shall identify a replacement continuous improvement lead for the LCRN whose role will be to oversee CI across the region. Key will be to link local initiatives and support national programmes of CI work. The CI lead will support and steer the implementation of self-directed learning across the network once the national material becomes readily available. He/she will look to develop a programme of work in conjunction with the workforce lead. Key will be to establish a CI steering group to provide oversight and support to all CI initiatives, and act as a peer group for local projects. The CI lead will have overall responsibility to drive the work programme forward and strive to ensure continuous improvement is at the forefront of everything we do.

Financial management

Funding allocation model

The approach used for allocating infrastructure funding in the East Midlands is intended to be both transparent and collaborative. In 2015/16 the Finance Working Group were charged with reviewing the funding process introduced the preceding year. A survey was conducted with Partner Organisations R&D Leads, Finance Managers, Clinical Leads, Specialty Leads and Research Delivery Managers to inform the approach taken and the model itself for 2016-17 budget decision making. Survey findings were shared, along with recommendations, these were discussed and then a further paper produced which detailed options; after discussion a final paper was produced outlining the planned approach. At each stage papers were circulated and discussed with the Partnership Group, Operational Management Group (OMG), Executive and R&D Leads, with opportunity for feedback and comment.

In 2016-17 the CRN has built upon the model introduced for 2015-16, which is best described as an activity driven model, with a consideration of historical funding. A performance premium has been introduced this year to recognise time to target performance for closed studies. The final funding model used incorporated an historical element (41%); activity based element (56.5%) and performance premium (2.5%). The cap and collar this year was broadened to allow further movement across the region, driven by relative performance.

The data set used to deriving the activity based element of the budget reflects the national dataset, using a rolling two year period which ends 30 September 2015. Budget modelling was originally undertaken in November 2015, based on a worst case scenario of a 5% budget reduction. The output of the modelling resulted in indicative budget envelopes for partner organisations; these were communicated to partners in late December, along with a local guidance document, with budget plans required by mid-February. Once final budgets were confirmed in March the budget model was re-run to reflect the budget increase, and the cap and collar revisited. Budget envelopes were again notified to partners with revised budget plans agreed.

The complexity ratios used in our regional funding model were based on the original bandings of 1 : 3: 14; however, next year, we will mirror the changes to the national model, using the recently published ratios. Due to a budget uplift, the cap and collar percentages used within our local model ranged from a maximum 20% increase and 7.5% reduction. Additionally, our improved budget in 2016-17 has allowed us to establish a strategic funding to support new initiatives and innovative approaches to increase NIHR research delivery across the East Midlands.

Budget management approach: internally & with partners

Key to this funding approach is the continued close partnership working between the Partner Organisation Senior R&D/I Leads & Finance contacts with CRN senior clinical & managerial teams. To support this, we have strengthened the previously established role of “Senior Team Link”. All partner NHS organisations have a named member of the senior team, the IOM, RDM or Delivery Operational Manager, who they primarily link with for a range of matters. The role is key in the provision of a point of contact for any decision making in relation to portfolio research and significantly supports both the PO and the CRN in budget management. This allows a rich understanding of the organisation as a whole and enables smarter decision making. The link will support them in preparing, and later formally agreeing, their budget plan; will understand the partner organisation and be the first port of call for advice and support. Good dialogue and discussion is expected, with the Senior Team Link also playing a key role of internal communications across the Divisions.

All CRN budgets, both at PO level and the central network costs are actively managed by the Business Intelligence Lead and the Host Finance Team, with overall oversight, accountability and decision making by the Chief Operating Officer and Clinical Director. Every month, the Partner Organisations submit a monitoring spreadsheet which identifies actual spend as per the Trust finance ledgers and any changes explained. Any significant fluctuations are discussed with the Senior Team Link for that Organisation, the Responsible (R&D/I) manager at the organisation and the finance team to ensure that fluctuations are managed to enable the reduction in any vacancy factors and to avoid unnecessary under spend.

Any anomalies in managing the budgets are discussed in the Finance Working Group (FWG) and, where necessary, escalated to the OMG or PG. The FWG is chaired by the Host Finance Lead, with representation also from Partner Organisations and network staff, the group reports to the Operational Management Group. The group makes recommendations and in some areas is empowered to make decision regarding financial flows necessary in order to manage any significant underspend/over-commitment. The network holds regular finance engagement events throughout the year to engage with the research leads and their finance teams to ensure that there is a good level of understanding in relation to the responsibilities and principles of managing the network infrastructure budgets. Any new initiatives are also discussed at the FWG, these may be in response to continuous improvement programmes for finance work or suggestions raised at OMG/PG.

Current and Future Initiatives

In late 2015/16 the CRN commenced a piece of pilot work, to introduce a 'Trigger Payment' process for service support costs for some primary care stakeholders. This is intended to improve the way practices are paid for work undertaken to deliver NIHR portfolio research through improving accuracy and timeliness of payment, alongside reducing the burden on practices and the host finance team in raising & paying invoices for potentially small amounts of funding. In 2016/17 we will evaluate this and if successful, we plan to roll out the pilot across primary care in Q2 2016/17. This is something that secondary and community care Partner Organisations have expressed an interest in, and we would like to review the possibility of some pilot work with other organisations in Q3 and Q4.

Appendix 1: Host Contract Compliance

1.1. Please confirm that the Host Organisation is delivering the LCRN in full compliance with the DH/LCRN Host Organisation contract

Yes ☒

No ☐

1.2. Please confirm if your LCRN is operating in full compliance with Appendix A Performance and Operating Framework 2016/17

Yes ☒

No ☐

1.3. If you have answered no to either of the above, please set out how full compliance will be achieved. Please specify each area of non-compliance and plans to achieve full compliance in 2016/17.

One point of feedback in relation to Table 4 - Operating Framework Compliance Indicators - Objective 1B, which states: "*LCRN leadership and management groups (LCRN Partnership Group, LCRN Executive Group, Clinical Research Leadership Group and Operational Management Group) are fully operational*". We have made a decision locally to have an inclusive group combining the Clinical Research Leadership Group and Operational Management Group. The Operational Management Group reviews performance across Divisions and Partner organisations along with review of time and target. Each Division also has a consistent Steering group structure where business and performance are discussed. Furthermore, there are two annual meetings for all Clinical Specialty Leads to attend.

1.4. Please confirm that the enclosed Delivery Plan has been approved by the LCRN Host Organisation Board or is scheduled to be approved by the LCRN Host Organisation Board

Signature: A Furlong	
Name and job title of signatory: A.J. Furlong.	Mr Andrew Furlong – Medical Director, University Hospitals of Leicester NHS Trust
Date of signature: 7.4.16.	
Date when approval was obtained or is expected:	05-May-2016 (UHL Board meeting date)

Appendix 2: Contribution to High Level Objectives

Objective		Measure	National CRN Target (2016/17)	LCRN baseline performance (2015/16)	LCRN's planned contribution in 2016/17	LCRN's planned contribution in 2017/18
1	Increase the number of participants recruited into NIHR CRN Portfolio studies	Number of participants recruited in a reporting year into NIHR CRN Portfolio studies	650,000	41,817 (at date of submission, 8 April 2016)	48,000	51,500
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%	72% (at date of submission, 8 April 2016)	80%	90%
		B: Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	80%	70% (at date of submission, 8 April 2016)	80%	90%
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	650			
		B: Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA	75%			

		approvals for Phase II–IV studies				
4	Reduce the time taken for eligible studies to achieve set up in the NHS	Proportion of eligible studies achieving NHS set up at all sites within 40 calendar days (from “Date Site Selected” to “Date Site Confirmed”)	80%	93% (CSP metric)	80%	80%
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 days at confirmed Network sites (from “Date Site Confirmed” to “Date First Participant Recruited”)	80%	31%	50%	80%
		B: Proportion of non-commercial contract studies achieving first participant recruited within 30 days at confirmed Network sites (from “Date Site Confirmed” to “Date First Participant Recruited”)	80%	20%	50%	80%
6	Increase NHS participation in NIHR CRN Portfolio Studies	A: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies	99%	100%	100%	100%
		B: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio commercial contract studies	70%	79%	75%	75%

		C: Proportion of General Medical Practices recruiting each year into NIHR CRN Portfolio studies	35%	56%	58%	60%
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	20,000	983 (at date of submission, 8 April 2016)	1,250	1,250

Appendix 3 – Specialty targets and actions

Specialty	Objective	Measure	National Target	LCRN activities and initiatives to contribute to achievement of objective(s)
Ageing	Proportion of Ageing-led studies on the NIHR CRN Portfolio which are multicentre studies is maintained at 50% or above	Proportion of Ageing-led studies which are multicentre studies	50%	Currently 91% of Ageing studies which are active across the East Midlands LCRN area are multi-centre. We expect this to continue in 2016/17 for existing studies, plus pipeline studies. We are making efforts to engage historically inactive Trusts into taking forward multi-centre Ageing studies, as recruiting sites. The first of these to be approached is United Lincolnshire Hospitals, which is active and in a geographical area of great potential for Ageing studies. Later in the year, we will encourage the other inactive Trusts to look into taking further Ageing studies. Lincoln and surrounding areas has great potential due to its elderly population.
Anaesthesia, Perioperative Medicine & Pain Management	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	8	Engaged with the Anaesthetic Trainees at the local Winter Scientific Training Meeting in Dec 2015. Liaising with and supporting the set up of MERCAT (Midlands (East) Research by Critical Care and Anaesthetics Trainees) through the nominated anaesthetic registrar. MERCAT is now affiliated to RAFT (Research and Audit Federation of Trainees and will be taking part in the annual national project iHYPE (intra-operative hypotension in the older surgical patient). Through the CRN East Midlands Workforce Development manager a rollout of GCP training is being offered to the trainee groups. The Deanery is supportive of this Initiative: They will organise two events later in the year for trainees interested in developing their own research networks- like MERCAT, to further facilitate involvement in clinical trials. HEE and CRN to see whether it might be possible to generate an Out of Programme opportunity for a senior trainee to develop leadership and management experience in the CRN. The CRN East Midlands Network will draw up a list of PIs who are willing to have a "portfolio study-ready" trainee as a sub-investigator on a clinical study and then match them to the Schools and training programmes. The Deanery will also work with the Head of School and Training Programme Directors to encourage the trainees to match with PIs to start contributing to CRN portfolio trial activity across the East Midlands both in Primary and Secondary Care.
Cancer	Deliver a portfolio of studies including challenging trials in support of national priorities	Number of LCRNs achieving recruitment to NIHR CRN Portfolio studies in 4 challenging areas which is either improved from 2015/16 or exceeds the following national targets: a) Cancer Surgery: 4 recruits per 100,000 population served b) Radiotherapy: 6 recruits per 100,000 population served c) Rare Cancers (ASR <6): 12 recruits per 100,000 population served d) CYP: 3 children per	15	Within the East Midlands the Research Delivery Manager and Clinical Lead are conducting an exercise in trying to stabilise recruitment figures which have drastically reduced over 2015/16. Input is being sought from Sub-specialty Leads, R&D Managers and Cancer Teams leads within the Partner Organisations. It is hoped that with support from the Network Lead Nurse, the LCRN and Partners will be able to steady the decrease in recruitment figures and maintain the commercial reputation of the region, whilst realising financial constraints. We will continue to work with our Partner Organisations to ensure we have a delivery infrastructure within the Division that has a suitable mix of skills, with excellent clinical links across the region (driven by LCRN presence at regional ECAG meetings). The LCRN will facilitate bi-annual meetings for the Cancer team leads of the region to try to regain a sense of community, increased moral and the sharing of best practice. The Division 1 Operations Manager and appropriate Sub-specialty Lead are members of the East Midlands Senate and Strategic Clinical Network Expert Clinical Advisory Group

		100,000 population served,* and all LCRNs to record the number of 16-25 year olds participating in cancer studies *LCRNs which do not include a PTC to provide evidence of referral pathways to access research		(ECAG) and regularly present performance and benchmarking information, and discuss referral pathways as necessary. For 2016/17 we will revisit the information currently provided at the ECAG, to check it is fit for purpose. This scoping work will be undertaken by the Division 1 Operations Manager. 2016/17 will see us take forward a piece of work to promote link between the LCRN and the hospices in the region. The RDM and the joint Palliative Care Sub-specialty leads we will develop links and awareness in this community. The RDM will be meeting with research delivery colleagues in neighbouring CRN: West Midlands to learn about their existing palliative network model and look to implementation in the East Midlands. The Research Delivery Manager, Operations Manager and Portfolio Support team will support the Clinical Lead and Sub-specialty Leads in developing and delivering an appropriate portfolio of studies across the tumour sites, and investigate opportunities and threats to our performance. For example the Portfolio Support team will investigate opportunities to set up sites in the East Midlands for existing studies that are not currently open in the region; and will also endeavour to bring new studies to the East Midlands in a timely fashion. We will adopt a truly regional approach and strive to offer equity of studies across our geography (through opening studies in multiple sites at the same time or through PICs). The Operations Manager will encourage engagement across the region through participation in the ECAG meetings. Using monthly RAG reports, the Portfolio Support team will monitor and collect intelligence regarding the 'Time to Target' metric. Where appropriate the Operations Manager will work with our partners to resolve issues, to enable studies to be delivered in line with 'Time to Target'. The Sub-speciality Leads will continue to be supported and fully engaged with the national requirement for meetings, and will bring any key messages back to the region. Cancer Surgery: To date in 15/16 the East Midlands region has recruited 95 participants into Cancer Surgery studies (recruiting into 5 studies). Recruitment has been contributed from all of our 8 appropriate sites. To achieve the national target of 4 recruits per 100,000 population served the East Midlands will need to recruit 178 participants into Cancer Surgery studies. Although we would strive to achieve this national target, realistically the East Midlands should aim to improve upon 15/16 recruitment. Of the 5 studies currently recruiting 3 have significant recruitment periods left: - UKCRN 869 (observational) open until 31/12/17 (potential to recruit approx. 70 participants). All of our sites have this study open, and are recruiting. UKCRN 3771 (interventional) open until 31/03/2018 (potential to recruit 2 participants). Currently open in 3 of our sites and recruited in 2. We will investigate if this study can be opened elsewhere in the region, to push our potential to 8. UKCRN 17640 (interventional) open until 01/02/18 (potential to recruit 1). Currently open in two of our sites and recruited in one. We will investigate if this study can be opened elsewhere in the region, to push our potential to 8. Worth noting of those with a shorter remaining recruitment period is: - UKCRN 1762 (interventional), also counts towards Radiotherapy group studies; open until June 2016 (potential to recruit 6). This is open at 7 of our Trusts, and we will recommend that there is a recruitment push wherever possible. Radiotherapy: Currently in 15/16 the East Midlands region has recruited 490 participants into Radiotherapy studies (recruiting into 18 studies). Recruitment has been contributed

				from all of our appropriate sites. To achieve the national target of 6 recruits per 100,000 population served the East Midlands would need to recruit 266 participants into Radiotherapy trials. Of the 18 studies which recruited in 15/16, 6 have now closed or will be closing very soon. However we have a significant opportunity to capitalise on some existing studies, particularly studies with significant time periods left, that are open to new sites but not open at all of our sites (e.g. UKCRN 7890 Interventional, not open in three of our Trusts, open until 21/09/2017; UKCRN 11723 Interventional, open until 28/02/17, not recruiting at five of our open sites and not opened in two; UKCRN 16069 Interventional, open until 31/03/18 open in six of our Trusts and lead from the East Midlands; UKCRN 1471 Observational, open until 31/07/18, only open in three of our Trusts, but is open to new sites; UKCRN 1409 Interventional, open until 31/12/2020, open in five of our sites, potential to open at UHL and Northampton). Our biggest recruiting study is UKCRN 16077 Observational, open until 31/03/2017, active in three sites. We are working locally to understand the delivery situation with this study as continued success could be jeopardised due to a research fellow contract ending. This study alone is responsible for 288 recruits. Within the East Midlands we will aim to improve upon our 15/16 recruitment, thus also exceeding the national target, however this will depend on us resolving any issues with study UKCRN 16077 and continuing to deliver it throughout 16/17. Rare Cancers: Currently in 15/16 the East Midlands region has recruited 517 participants into Rare Cancer studies (recruiting into 61 studies). Recruitment has been contributed from seven of our sites. To achieve the national target of 12 recruits per 100,000 population served the East Midlands will need to recruit 533 participants into Rare Cancer trials. Within the East Midlands we will strive to achieve this national target, whilst improving upon 15/16 recruitment. We will aim to continue to recruit large numbers to studies like UKCRN 6570 and UKCRN 11319 whilst maintaining a broad portfolio of Rare Cancer studies. CYP: Currently in 15/16 the East Midlands region has recruited 5 participants into CYP studies (recruiting into 1 study). To achieve the national target of 3 recruits per 100,000 population served the East Midlands will need to recruit 133 participants into CYP trials. This would clearly be a very big leap for us, so we will plan to improve upon 15/16 performance. We have already carried out an analysis of the Portfolio, and many of the high recruiting studies in CYP have closed in 15/16, or are single centre. One possibility for increasing activity in CYP is study UKCRN 16295 and we are investigating the feasibility of delivering this study locally. In year as our partners begin to operationalise their work on LPMS, we will work with them to ensure LPMS can be utilised to record all 16 - 25 year olds participating in cancer studies. Using the information provided to us in the ODP system, we will ensure that our partners are aware of which studies link to the national specialty objective and will support them as far as possible in developing effective recruitment strategies. We will identify those challenging trials that are open in the region, but are not active and the Research Delivery team will work with our partners to identify and resolve blocks to delivering the studies.

Cardiovascular disease	Increase NHS participation in Cardiovascular Disease studies on the NIHR CRN Portfolio in challenging and priority areas	Number of sites recruiting to Congenital & PAH, Surgery and CV Prevention studies	5% increase	The increase of 5% target has been agreed via the EM Regional Cardiovascular Group representing all partner organisations. There are discussions to look to mentor/create more local PIs to help increase the participation in studies and avoid saturation of existing PIs. Congenital & PAH; Nationally there are only 5 PAH Centres in the UK, EM now has a shared care agreement with our nearest site in Sheffield and will be able to do initial visits and prescribing, we will also be looking to do PAH studies through BRU/BRC adoption of studies across the EM. BRAVE is a Congenital Study (now adopted) and will be rolled out across the EM. Other open multi centre studies are being reviewed by local leads. Surgery; 3 Studies open/in set up (UK Tavi, HYDRA-P, MARACAS). CV Prevention; BRICCs and GENVASC (primary care from Cardio) continue to be the main prevention studies for the region.
Children	All relevant sites that provide services to children are involved in research	Proportion of NHS Trusts recruiting into Children's studies on the NIHR CRN portfolio	90%	Within the East Midlands we have a Childrens specialty which performs well, with a resource that increasingly offers support to studies which are counted under another speciality. We are working with our Partner Organisations to encourage this cross-working, and locally we recognise this with unique reporting. In 2015/2016 there are 8 Trusts within the East Midlands that have Childrens services that are not recruiting to NIHR Portfolio Childrens research. We hope to improve upon this metric in 16/17. We have a cluster of activity at our two teaching Trusts, and within our DGHs. In 15/16 one secondary care site, Chesterfield Royal has not contributed directly to the specialty. They have 5 Childrens studies open, but have had some staffing issues for most of the year. These have now been resolved, and the Trust hopes that recruitment will pick up again. East Midlands Ambulance Service is not currently involved in recruiting to Childrens studies but does have a longer term plan. They will be participating in an NIHR i4i programme looking to redesign the neonatal transport system, EMAS should become involved in this work within 18 months. The remaining 6 Trusts are Community and Mental Health Trusts, who on the whole deliver a portfolio of research that is not badged as Childrens, but can often include children in its inclusion criteria (for example UKCRN 15795 an Oral & Dental study; and UKCRN 16940 which recruits babies, but is recognised as a Dermatology study). We do have one Childrens study across most of these Trusts, UKCRN 16735 but our sites operate as PICs not recruiting sites. A challenge that we face in 16/17 is to work closely with sites to quickly identify and match Children's studies that are delivered in the community and mental health settings. We hope to achieve this through the Portfolio Support teams work on identifying new studies, through the engagement of our Specialty leads nationally and through linking with other Divisions effectively.
Critical care	Increase intensive care units' participation in NIHR CRN Portfolio studies	Proportion of intensive care units recruiting into studies on the NIHR CRN Portfolio	80%	Currently 38% of intensive care units are contributing in to Critical Care studies on the NIHR CRN Portfolio. However, over 90% of the region's intensive care units are supporting the AIRWAYS2 portfolio study which is badged under the Injuries and Emergencies specialty. Dependent upon the types of studies that are opened (relatively few on the portfolio pipeline at present) we believe by year end the total number of intensive care units taking part in Critical Care studies will increase to 60%. This year, recruitment has dropped significantly to 27% of the 350 patient target. This has been partly due to the closure of

				several high-recruiting studies. Equally the currently recruiting studies are due to close shortly, with no visible pipeline replacements which we are aware of. A forecast reduction in the overall recruitment target unless replacement pipeline can be identified. In addition: 1. Need to quantify activity at all Intensive Care Units across the region. 2. Identify, engage and support enthusiastic clinicians in the smaller non-active units to identify barriers to research and possible ways of overcoming these barriers. 3. The proven model of utilising research nurse support to cross cover Anaesthesia and Critical Care studies is being adopted in the larger acute Trusts.
Dementias and neurodegeneration (DeNDRoN)	Optimise the use of "Join Dementia Research" to support recruitment into Dementia studies on the NIHR CRN Portfolio	The proportion of people identified for Dementia studies on the NIHR CRN Portfolio via "Join Dementia Research"	6%	We have increased the JDR database from 306 (April-15) to 1096 (Feb-16). Average of 72 volunteers a month. 2nd CRN in JDR database growth 15-16. Plan for 2016-17 to continue to be one of the fastest growing JDR databases, and aim is to be the number 1 LCRN in JDR database growth. With support from the dedicated Dementia Challenge PM and division 4 team initiatives include: Collaborating with a top University to become dementia friends and encourage staff (7000) and students (30000) to volunteer to JDR. Primary care to continue promoting JDR in GP practices. JDR leaflets included in carer's pack. Continue collaborating with the AS. Attending AS Roadshow in 8 sites in the EM. Work with Dementia signposting services to include Dementia Research. Increase awareness of JDR within NHS staff by including a JDR leaflet with payslip. Attending PPG groups event promoting JDR and looking for JDR champions. CRN communications plan to promote JDR in EM. Plan for JDR software to improve. Changes in matching system and interface. To provide training to sites on new software. EM part of the national team involved in the improvement. Visit sites for discuss 15-16 JDR use identify effective JDR process and barriers. Support overcoming barriers. Share with other sites effective process and prevent barriers. Continue promoting JDR as a recruitment tool with PI. EM dementia study opening 16-17 (PRAISED) has included JDR as part of their protocol for recruitment. It will be the first study that the CRN East Midlands will be leading on in JDR
Dermatology	Increase NHS participation in Dermatology studies on the NIHR CRN Portfolio	Number of sites recruiting into Dermatology studies	160	Dermatology studies are active at 9 centres across the region. This year's performance has seen recruitment far surpass target expectations. Dermatology have 154% of target for 2015/16. There is a strong pipeline of studies and it is anticipated this will likely improve further next year in 2016/17. The privately owned Circle Treatment Centre at NUH is now opening its first studies in adult dermatology, which should see recruitment improve further. With the re-inclusion of the Circle Treatment centre, we now have active dermatology research in each of the Trusts which operates a significant dermatology service. Relationships at Circle are expected to continue well and we intend to build on in 2016-17. Plan on running a second East Midlands wide dermatology meeting in autumn, bringing together key researchers and delivery staff to build engagement and momentum. To extend on the successful event last year, we are considering developing synergies in particular with rheumatology (MSK), as there is a great deal of overlap with dermatology studies.

Diabetes	Increase participation in studies relating to areas defined to be of national priority for Government agencies and Research Funders	A: Number of LCRNs recruiting and/or referring into immuno-therapy studies for recent onset T1 diabetes. B: Number of sites participating in studies relating to the prevention of diabetes and its complications.	A. 15 B. 5%	A. In Tandem II (Lexicon) (DIAB 4268) and Ease 2 (DRN 3771) running with a further 2 feasibilities completed in Dec 2015. Pipeline for these studies is steady and many are at feasibility stages. B. Girls Active, Pre-Start, Glint and Propels are all ongoing Prevention studies.
Ear, nose and throat	Increase NHS participation in Ear, Nose and Throat studies on the NIHR CRN Portfolio	Increase NHS participation in Ear, Nose and Throat studies on the NIHR CRN Portfolio	40%	Number of Trusts currently recruiting to ENT studies across the East Midlands is 2 which equates to 30%.This year, recruitment has dropped significantly to 10% of the 1000 patient target. This has been partly due to the closure of several high-recruiting studies. Equally the currently recruiting studies are due to close shortly, with no visible pipeline replacements which we are aware of. A forecast reduction in the overall recruitment target unless replacement pipeline can be identified. In addition: Look to establish new links with Trusts across the region which are not currently recruiting in to ENT studies or which have not been previously research active. Work with these Trusts to identify barriers to research activity and possible ways of overcoming these barriers. Increase collaboration between the NIHR Hearing BRU and CRN. Ensure all new studies that would be eligible for Portfolio adoption are pursued as standard practice. Increase engagement with clinicians across the region and ensure research activity is a key part of our POs strategic plan in all Directorates. The support provided by the ENT specialty group, highlighted at major national conferences, journal articles etc., to be disseminated across the East Midlands where appropriate.
Gastroenterology	Increase NHS participation in Gastroenterology studies on the NIHR CRN Portfolio	Proportion of acute NHS Trusts recruiting into Gastroenterology studies on the NIHR CRN Portfolio	90%	Currently 90% of acute Trusts across the region are recruiting in to NIHR CRN Portfolio Gastroenterology studies. By end of 2016/17 we expect this to rise to 100%. Need to forge stronger relationships with all units across the East Midlands. Specialty Lead with support from CRN is organising meetings with clinicians in the smaller acute Trusts (Northampton and Lincoln) to raise profile of research and of the NIHR portfolio studies. Look to identify research champions within each Trust to take forward commercial sponsored studies in areas of interest, and with support of the CRN Network, RDM and Industry team help them get these studies set up. Look to identify opportunities to work collaboratively with colleagues across all specialties to increase recruitment in studies such as HALT IT (badged as Injuries and Emergencies).
Genetics	Full geographic access for patients with rare diseases to participate in Genetics studies is maintained on the NIHR CRN Portfolio	Number of LCRNs recruiting into multi-centre Genetics studies through the NIHR UK Rare Genetic Disease Research Consortium	14	The CRN: EM currently participates in the NIHR UK Rare Genetic Disease Research Consortium. Our Trusts UHL and NUH currently lead on these studies. It is our aim during 2016/17 to maximise awareness of these studies with the genetics staff at the two sites. This work will be led by our newly appointed Specialty Lead with support from the LCRN Delivery team. Initially we anticipate organising quarterly meetings to showcase open studies, and will develop some materials to remind clinical genetics teams about active studies. Currently in 15/16 we are recruiting well (year to date 410 recruits from 16 studies), and our larger recruiting studies will remain open in 16/17. However, there is a risk to the Specialty performance which needs to be noted within our plans. There are several studies likely to be impacted in terms of recruitment due to the 100,000 Genome Project and as such are likely to fail to deliver to target. The 100,000 Genome is a study run by Genetics England funded by the DoH, a national initiative tasked with achieving 100,000 genomes from

				patients with rare diseases. This hasn't and won't be submitted for NIHR Portfolio adoption. Locally our Genetics teams are feeling the pressure of delivering this piece of work and we will need to take this into consideration for current and new portfolio studies with genomic requirement.
Haematology	Increase trainee involvement in supporting recruitment to Haematology studies on the NIHR CRN Portfolio	Named Haematology Trainee identified in each LCRN	15	We have had a successful year in Haematology, recruiting well to studies and recently appointing into the Specialty Lead post. Our largest recruiting study has now closed, so 16/17 will see the need for attracting new studies to the region. During 16/17 we aim to continue to deliver a broad portfolio of haematology studies, with support from the LCRN Portfolio Support and Research Delivery teams. We will also develop trainee involvement, not just as a single named trainee, but as a small network. The Specialty Lead and Research Delivery Manager will develop plans to set up a local trainee network across the region in year, with a focus in ULH, UHL and NUH initially (our highest recruiting Trusts into Haematology studies). We will seek support from our Clinical Director and link to work being undertaken with the Health Education England team in the East Midlands. Phase one: the Specialty Lead and RDM will contact the Assistant Specialty Cluster Lead, Vanessa Poustie, to outline our plans and gain any national steer. Phase two: Local scoping work will take place to identify potential interested trainees. Phase three: A support package and objectives will be developed, based on work already completed in another specialty locally. Phase four: named haematology trainees will be appointed in each region Phase five: performance will be monitor against developed objectives, and support given as needed.
Health services and delivery research	Develop research infrastructure (including staff capacity) in the NHS to support clinical research	Number of LCRNs with a lead for HSDR	15	Traditionally HSDR has recruited well, despite having no firm leadership in place across until later on in 2015-16. Over the last several years it has recruited around 1000 patients per annum. This year, recruitment has dropped significantly to 29% of the 1000 patient target. This has been partly due to the closure of several high-recruiting studies. Equally the currently recruiting studies are due to close shortly, with no visible pipeline replacements which we are aware of. The forecast reduction in the overall recruitment target unless replacement pipeline can be identified. We have appointed a specialty lead late 2015-16 to provide leadership to the specialty and help grow the HSDR portfolio. This appointment is a joint one, between CRN: East Midlands and CLAHRC East Midlands.
Hepatology	Increase access for patients to Hepatology studies on the NIHR CRN Portfolio	Number of LCRNs recruiting into a multi-centre study in all of the major Hepatology disease areas: Viral Hepatitis, NAFLD and alcohol, Autoimmune Liver Diseases including (AIH, PBC and PSC)	15	CRN: East Midlands is recruiting into studies in all of the major Hepatology disease area, thus achieving this goal, which we will seek to maintain. Additionally, there is the potential to increase the amounts of sites across the region that can contribute, and the newly appointed Specialty Lead in this area will be instrumental in supporting the RDM to identify sites and forge stronger relationships with the clinicians by undertaking the following: 1. Establish an East Midlands wide monthly TC to discuss EM Hepatology / Gastroenterology Portfolio studies with agenda and minutes circulated. 2. Ensure all relevant sites have a simple database of patients with HCV/HBV and Autoimmune hepatitis/ PSB/PSC set up. 3. Increase commercial activity in specific centres, i.e. Leicester and Derby. There is a large number of commercial studies in set-up that cover a number of different disease areas: viral, metabolic and immunological disease. 4. There is a number of studies in the pipeline with the potential for all sites across the region to take part in and, hence, access for patients will be increased.

Infectious diseases and microbiology	Increase access for patients to Infection studies on NIHR CRN Portfolio	Increase the number of Infection commercial studies on the NIHR CRN Portfolio	10% increase	Currently the region is supporting 2 portfolio adopted Infection commercial studies. Depending up on the types of commercial studies that are available this year it is hoped we can increase this figure by 10%. At present >60% of acute Trusts are recruiting patients to the Infectious diseases and Microbiology studies on the NIHR CRN Portfolio. Newly appointed Specialty Lead will engage and link in with the national Infectious Diseases and Microbiology Specialty group meetings and circulate appropriate articles and information to clinicians across the region. Need to quantify and scope current activity across the region both in Trusts and in the community i.e. GUM clinics and Sexual Health clinics. Look to establish new links with these centres across the region which have not previously been research active or which have recently ceased research activity. Work with these centres to identify barriers to research activity and possible ways of overcoming these barriers. Need to raise the awareness of CRN: East Midlands to both clinicians and microbiologists across the region, and forge collaborations between clinicians and academia.
Injuries and emergencies	Increase NHS emergency departments' participation in NIHR CRN Portfolio studies	Proportion of acute NHS Trusts recruiting into Injuries and Emergencies studies on the NIHR CRN Portfolio	50%	Injuries and Emergencies has had an excellent year in 2015/16, surpassing expectations with 327% of the total recruitment target, with still a month in hand to recruit. Currently 90% of acute Trusts are recruiting into Injuries and Emergencies studies on the NIHR CRN Portfolio. This is in part due to the success of the AIRWAYS II study conducted by the East Midlands Ambulance Service (EMAS). Need to identify opportunities to work collaboratively with colleagues in all divisions to improve recruitment in studies such as SALI. Need to identify champions of research within each Trust to take forward commercial sponsored studies in areas of interest, and with support from the CRN Network, RDM and Industry team help them to set these up. Within NUH the team have a research active advanced nurse practitioner on board, this has increased capacity within the team to increase recruitment and moving forwards there is a plan to develop this service further. To increase engagement with clinicians across the East Midlands the Specialty Lead with the support from the CRN team is to set up monthly TC to discuss research opportunities and raise awareness of the NIHR CRN Portfolio studies. In addition a cross regional event is planned in the Autumn 2016.
Mental Health	Increase participation in MH studies involving children and young people	Number of LCRNs with Child and Adolescent Mental Health Service (CAMHS) champions	15	Currently 6 sites are active in recruiting into Mental Health studies involving children and young people. There is an already strong Child and Adolescent Mental Health Service (CAMHS) across the East Midlands. To increase participation of children and young people there needs to be a steady flow of NIHR Mental Health studies to the region and flagged to our Partner Organisations in a timely manner (this will be dependent upon an increase of NIHR funded MH studies coming through the pipeline looking for new sites). We plan on developing links with these services across the region and with the department of Child and Adolescent Psychiatry at the University of Nottingham with the aim of forging collaborations between clinicians and academia to increase the number of Chief Investigators and produce a robust throughput of NIHR adopted Portfolio studies where the CRN: East Midlands is the Lead LCRN. With the support from the Clinical Lead in 2016/17 a champion for Child and Adolescent Mental Health Service within the region will be identified.
Metabolic and endocrine disorders	Increase access for patients with rare diseases to participate in Metabolic and Endocrine Disorders studies on the NIHR CRN Portfolio	Number of participants with rare diseases recruited into studies	10%	At present there is an Acting Lead for this speciality. Therefore focus will be on maintaining and growing performance at the 10% rate, given that these studies are subject to presentation of rare diseases.

Musculoskeletal disorders	Increase NHS participation in Musculoskeletal studies on the NIHR CRN Portfolio	Number of sites recruiting into Musculoskeletal studies on the NIHR CRN Portfolio	350	Currently 8 centres are active in delivering MSK studies. Across 2015-16 MSK has had an excellent year overall and has surpassed expectations with 108% of the total recruitment goal, with a month in hand to recruit. MSK has a good pipeline of studies, with existing unopened studies able to account for some of those expected to close early into 2016/17. We are to increase recruitment by bringing Kettering and Lincoln on board and developing robust partnership working, early contact has been made already. We also plan on developing links with the Nottingham Circle Treatment centre to increase output there. Currently the centre delivers well on Rheumatology studies in conjunction with NUH and we are looking to expand this in 2016-17. The Specialty lead had regular meetings with colleagues in the East Midlands via the Audit forum to update them with any new developments. Plans to run a half day MSK workshop for delivery staff (nurses) across the region, with the aim of developing a network of support and links with colleagues to support and progress delivery.
Neurological disorders	Increase clinical leadership capacity and engagement in each of the main disease areas in the Neurological Disorders (MS; Epilepsy and Infections) Specialty	Number of LCRNs with named local clinical leads in MS; Epilepsy and Infections	15	Currently 5 sites are active in delivering neurological studies. Although recruitment has not reached the local target of 800 (YTD 646), the CRN East Midlands is currently ranked third out of 15 LCRNs The Specialty Lead has successfully negotiated with the CI for the TONIC study to add a further 3 sites across the East Midlands to help support the delivery and recruitment to this study. Intention in 2016/17 is to work with our nominated leads in the following neurological disease areas: Huntington's - Dr Gillian Sare, Parkinson's - Dr Nin Bajaj, Epilepsy, MS and Brain Infections - Professor Cris Constantinescu, Epilepsy - Dr Singhal Sumeet; to determine opportunities for study roll out locally.
Ophthalmology	Increase NHS participation in Ophthalmology studies on the NIHR CRN Portfolio	Proportion of acute NHS Trusts that provide eye services recruiting into Ophthalmology studies on the NIHR CRN Portfolio	80%	Currently 50% of acute Trusts that provide eye services are recruiting in to Ophthalmology NIHR CRN Portfolio studies. Current activity centres around the two larger acute Trusts in the region. Depending up on the types of studies that are available this year it is hoped that this can increase to 80%. Need to forge stronger links with all Trusts that offer eye services, Specialty Lead to engage with the clinicians across the region and ensure meaningful research activity is a key part of the strategic plan for all Directorates. Explore possible Trainee Research Network Initiative based on a similar model to the Anaesthesia Trainee Network. There is a planned Trainee event where this initiative can be explored in March 2016.
Oral and dental health	Increase access for patients and practitioners to Oral and Dental studies on the NIHR CRN Portfolio	Proportion of participants recruited from a primary care setting into Oral and Dental studies on the NIHR CRN Portfolio	30%	Oral and dental have 6 recruits from an annual target of 10. There is no visible pipeline for this specialty and the only active study is due to close in September 2016. Intentions to work with Oral and Dental Specialty lead to determine opportunities for study roll out locally. To scope and develop capacity to support these studies as required by developing a registry of NHS and private sector dental practices in the East Midlands. The forecast is lower that national targets due to the lack of dentistry portfolio studies within the East Midlands; this may be revised upwards if the number of studies increases

Primary care	Increase access for patients to NIHR CRN Portfolio studies in a primary care setting	Proportion of NIHR CRN Portfolio studies delivered in primary care settings	15%	The forecasted recruitment remains the same as the previous financial year due to the reduction in portfolio studies available for recruiting participants. This will undoubtedly impact on recruitment targets and a conservative forecast that is the same as the last financial year is proposed. Studies delivered in a primary care setting already make up 47% of our total recruited participants across CRN: East Midlands. It is likely that this strong recruitment, supported by pipeline will continue. Plans for 2016-17: • Continue to deliver a successful RSI scheme and ensure this scheme adds value. • Further engagement with practices to build on RSI performance indicators, build capacity, and promote confederated models of research delivery. • Continue to engage with practices outside of RSI scheme to support and promote participation in research. • Engage with local GP training schemes to promote research activities and engagement with newly qualified GPs. • Evaluate and refine leadership site model; Leadership sites will have greater responsibility for recruitment, commercial research, confederated working and delivery and promotion of dementia research, together with providing a leadership function at a county and/or regional level. • Engage with the National School of Primary Care Research to work in closer partnership and raise awareness of study support service (primary care) • Engage with other specialities to enable recruitment of patients within a primary care setting. Community pharmacy: • Ongoing development of a database of research interested pharmacists • Engage with the R and D Lead for Boots (Nottingham) to enable Boots pharmacies to engage with Portfolio studies (via National CRN Pharmacy Champions group) • Target to have 14 pharmacy sites research ready accredited (subject to available studies studies) • Target to enable primary care clinical pharmacists - GP practice based pharmacists (part of the Across City Federation GP /Pharmacy pilot) to be research ready accredited (target: 9 pharmacists) • Engage with division 5 Portfolio manager and study support service (primary care) team to influence principal and chief investigators to include primary care pharmacy teams in study design (target: identify at least two studies)
Public health	Increase the number of Public health-led studies on the NIHR CRN Portfolio	Number of new PH studies entering the CRN (England led) Portfolio	15	There currently is one active study in the Public Health specialty, new to the portfolio in 2015/16. We will need to open an additional study in this area to meet this objective in 2016/17. Though no target has been set for Public health at the outset of the financial year, the Public Health specialty has achieved 96 recruits so far, through one study - SMArT Work. This exceeds expectations, for this very small specialty. We are keen to appoint a public health specialty lead to provide leadership to this specialty and encourage studies from outside of the region into East Midlands.

Renal disorders	Increase commercial research capacity within the field of Renal Disorders research	Number of renal units recruiting into commercial contract studies	10% increase	Two main areas of focus to increase Renal research in EM: a. Increasing recruitment from Northamptonshire Haemodialysis Unit (consisting of Kettering and Northampton sites) from zero to at least 2 studies by the end of the year. b. Increase in the number of portfolio Transplant studies across the region
Reproductive health and childbirth	Establish a national network of sites supporting reproductive medicine studies	Number of LCRNs recruiting into reproductive medicine studies on the NIHR CRN Portfolio	15	2015/16 has been a challenging year for Reproductive Health and Childbirth. Recruitment has not been as anticipated, as the region lost a significant study (Life) due to funding issues centrally. We have two main challenges to address in 16/17. Firstly we need to maximise on opportunities to offer research studies to patients in our region, in order to bring our recruitment levels back to the expected level. We hope to be able to do this by delivering the BBS (a sub study of Life), and by using the CRN infrastructure invested in Division 3 to deliver flexibly across all of reproductive health and childbirth, to ensure we can take on a well balanced portfolio of new studies. We have recently appointed 2 Reproductive Health and Childbirth Research Champions, one is based at SFH and one at UHL, it is hoped that this role will really help to raise the profile of research within the clinical teams and foster a culture of sharing best practice. With the advent of HRA Approval and Assess Arrange Confirm, we hope to be able to bring together the district general hospitals as a collective, to allow them to be considered for studies that may otherwise have gone only to the larger Teaching Trusts. Our second big challenge will be to begin to recruit into reproductive medicine studies. The current NIHR Portfolio for Reproductive & Sexual Medicine shows 0 studies in setup, and 11 studies 'open'. Of this 11, 82% are not open to new sites in England, of the remaining studies UKCRN 4917 has been open in the East Midlands, but the study end date is recorded as 30/09/2015. UKCRN 14252 is an observational study that is open until August 2016, it currently stands at 86% of its target of 800. It seems this study has not been through our local EOI process, and this is something we will investigate. There is little opportunity on the current portfolio to offer these studies to our patients. However, we understand that there are some studies with funding, but there are logistical issues that will need co-ordination during set up, as they clash. Locally our Portfolio Support team will investigate the status of UKCRN 4917 and 14252, and the Specialty Lead and RDM will link with the Assistant Specialty Cluster Lead to discuss and try to resolve the issue with access to open studies.

Respiratory disorders	Increase access for patients to Respiratory Disorders studies on the NIHR CRN Portfolio	Number of LCRNs recruiting participants into NIHR CRN Portfolio studies in two of the main respiratory disease areas: asthma; COPD; bronchiectasis; rare diseases	15	CRN: East Midlands is currently recruiting participants in the main respiratory disease areas of Asthma, COPD and Bronchiectasis. We need to maintain and expand current infrastructure required to increase recruitment to research databases for Asthma, COPD, Bronchiectasis and other respiratory infections across the East Midlands area including Primary, Secondary, Tertiary Care areas, supported by the large teaching hospitals. The Specialty lead is instrumental in forging closer links and relationships with the respiratory departments /colleagues in the acute Trusts across the region. The East Midlands Thoracic Society has reformed and the first meeting will be in March 2016 and the second is planned for early Autumn. Need to ensure the new focused research clinics, i.e. “Acute Asthma clinic”, “Advanced COPD clinic”, “Pulmonary Fibrosis” and “Bronchiectasis” are maintained. These clinics will contribute to PI-initiated and Trust/University sponsored studies as well as commercial activity.
Stroke	Across all LCRNs, average RCT recruitment should be at least 6% of SSNAP-recorded hospital admissions, balanced across the hyper acute, acute, rehabilitation and prevention stroke care pathway, each domain contributing at least 1%.	% of SSNAP-recorded admissions recruited into RCTs across the entire stroke pathway (hyper acute, acute, prevention, rehabilitation) on the NIHR CRN Portfolio.	6% (1% per domain) calculated at national level.	All areas of the stroke pathway will be met across EM, although all sites will not be able to contribute equally to all 4 areas e.g. Hyper acute complex studies in Nottingham HSRC but will continue to work with all sites to build on recent improved recruitment. Recent improved performance in smaller sites in addition to sustained performance in larger centres needs to be maintained. Adequate resourcing of the Hyperacute Centre based at NUH, whom we have engaged with on this matter, will impact on overall performance as a region and needs to be monitored.
Surgery	Increase patient access to Surgery research studies across the breadth of the surgical subspecialties	Number of LCRNs recruiting into at least 11 of the following 15 subspecialties: breast, cardiac, colorectal, endocrine, general, head & neck, hepatobiliary, neurosurgery, orthopaedics, plastics and hand, transplant, trauma, upper GI, urology, vascular	15	CRN: East Midlands is currently supporting recruitment in 11 out of the 15 subspecialties stated within the measure. The Specialty Lead will be instrumental in forging closer links with surgery teams across the region that undertake the subspecialties we are currently not supporting, although this will in part depend upon the NIHR CRN Portfolio studies being suitable for our region and open to additional sites. The CRN: East Midlands is at present supporting the rebirth of the East Midlands Surgical Academic Network (EMSAN) a Trainee Initiative open to all Surgical Trainees in the region. It is envisaged that this Trainee Network will work alongside the emerging Anaesthetic and Critical Care Trainee Networks to not only develop their own research ideas but help to support the delivery and recruitment in to NIHR CRN Portfolio studies.

Appendix 4 – Cross-cutting Work-stream Action Plans

Patient and Public Involvement and Engagement			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Talk about research in the NHS; work with partners, healthcare professionals, patients and carers to support and recognise the importance of involvement and engagement in the entire research delivery pathway.	Working with Workforce Development to implement the Building Research Partnerships Programme into the CRN EM Annual Training Plan - to run one programme in the first year	HG/ME	31/03/2017
	Work with Communications Lead to provide Localised Information Leaflet and access to National Resources to PPIE Working Group members from partner organisations	HG/KT	30/09/2016
	Work with members of the PPIE Working Group and via the R&D Leads Meeting to identify Patient Research Ambassadors within Partner Organisations/Groups to ensure partnership working, engagement in the local PPIE strategy and links to the national initiative (Website, forums etc.)	HG	31/03/2017
	Promotion of the MOOC across the network to support members through learning and development	HG	Ongoing
2. Make it easy for people to participate; linking with partners and collaborators to share ideas and pooling of resources to raise the profile of research engagement within the East Midlands	Continue with membership and engagement of the REPP	HG	Ongoing
	Undertake trial of the national patient questionnaire within the EM BRUs	HG	31/03/2017
	Continue to promote the Public Face Newsletter / mailing list and Calendar hosted by the AHSN to provide a single approach to PPIE in the East Midlands	HG	Ongoing
	Review the pilot of the locally supported Sharebank Initiative and how this can be expanded to cover the whole of the East Midlands along with collaborators e.g. AHSN, RDS etc.	HG	31/03/2017
3. Reach out	Identify and support local initiatives via the PPIE working Group that reach out to harder to reach groups; e.g. Younger People.	HG	31/03/2017
	Support and promote national initiatives; JDR, UK Clinical Trials Gateway, MOOC, OK to Ask etc.	HG	Ongoing
	Continue to Identify and link with smaller PPI Groups working across specialities and enabling greater collaboration with CRN, Partners and Nationally.	HG	Ongoing
4. Connect with the Public, Healthcare Professionals and Partners	Continue to link in with National PPIE Working Groups to keep appraised of national initiatives and provide feedback locally.	HG	Ongoing
5. Support and Value patient public involvement and engagement	Ensure at least one Lay member representative present at each local PPIE working Group meeting	HG	Ongoing
	Continue to identify local issues via the PPIE Working Group to engender an innovate and supportive environment for new ideas	HG	Ongoing
	Provide feedback to partner organisations via the various EM wide meetings (e.g. R&D Leads Mtg) to ensure the wider message of PPIE is spread.	HG	Ongoing

Workforce Development			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Finalise the local workforce development strategy, setting out vision and priorities.	Draft final strategy to go to workforce development steering group for ratification	ME	01/06/2016
	Review local strategy to ensure it aligns to the national strategy	ME	TBC
	Disseminate to key stakeholders across the region	ME	Ongoing
	Develop workforce development implementation plan to deliver the strategy	ME	TBC
2. Establish a centrally funded role(s) to support a network of practice lead facilitators to develop capacity and capability of a rater community to deliver the dementia challenge	Scope existing raters across region to identify practice lead facilitators and industry accredited raters	G-EAJ	01/05/2016
	Action plan in place to take forward the practice lead facilitator role, to enable the development of a rater community	G-EAJ	01/06/2016
	Develop a programme of activity to support the development and delivery of raters across the region	Practice Lead Facilitator	01//06/206
	Engage with national lead to facilitate cross network working	TBC	Ongonig
3. Establish a pool of generic facilitators to deliver national programmes of training across the East Midlands	Arrange a generic facilitation skills training session and send out a call for potential facilitators	ME	30/04/2016
	Establish a programme of ongoing coaching and support to develop facilitators to deliver specific training programmes	ME / PS	30/04/2016
	Establish an ongoing quality assurance process to ensure the quality of the training provision across the East Midlands	ME / PS	Ongoing
	Establish local lead facilitators for each programme of training	ME / PS	Ongoing
4. Establish workforce intelligence across the region to develop local capability and capacity.	Using local finance tool and local portfolio management system, map the current workforce supporting portfolio studies across the East Midlands	Learning Technologist (TBC)	01/11/2016
	Develop training needs survey and send to the identified workforce	Learning Technologist (TBC)	30/01/2017
5. Recognise and reward workforce achievements and excellence across the region, to inspire and motivate people.	Plan an annual awards ceremony	ME	29/04/2016
	Recognise excellence and share via quarterly newsletter	KT	Quarterly
	Optimise opportunities to celebrate success e.g. at research forum, team meetings	ME	Ongoing

Life Sciences Industry			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Build on the Commercial Study Actions tracker that we were key in implementing and piloting to ensure that CPMS or other appropriate systems are utilised to facilitate a single source of information for the Coordinating Centre and all LCRNs on study specific issues that all involved collaborate on and update as a live data source	Industry link Local Portfolio Manager for CPMS within the East Midlands CRN to feed in at a national level to ensure this is taken up	DK	01/09/2016
	Keep this as a standing item on national Industry Operations Managers meetings/teleconferences to receive updates on progress and input into the design of this within the system	DK	01/09/2016
2. Education of teams new to research on the importance of targets and to support a First Global recruitment drive	Roll out the commercial study life cycle workshop so that training is available across the region for those interested in commercial research	DK	01/05/2016
	Increased education of target setting via the quality of the information provided by research teams on the site intelligence forms. Supported by queries at an appropriate level where confidence is required to assure the target is achievable	DK	Ongoing
	Attendance at research events and other forums across the region to talk about commercial research and the drivers of performance at a site, regional and national level. To target primary care and mental health trusts in particular.	DK	Ongoing
3. Focus on areas not delivering to time and target to ensure future targets can be delivered	Review of studies that have not achieved the set network target for lessons learnt with a summary across each division once the year end data is confirmed for discussion at the Industry Working group and if appropriate the OMG	DK	01/07/2016
4. Primary care and Mental Health Trust engagement	Building upon work developing site profiles for the Mental Health Trusts with increased engagement at the Industry Working Group forging links with Industry with an outcome of 4 of the 5 Mental Health Trusts having commercial studies in set-up, open to recruitment or with recruits in year	DK	31/03/2017
	Building on primary care workshops to further develop site profiles and engagement in commercial research through the primary care network team to achieve a minimum of 2 new practices being selected for a site selection visit for their first commercial study	DK	31/03/2017
5. The National strategy focuses on the ability for the NIHR CRN to be flexible and apply the service and tools appropriately and/or signpost to other areas of expertise, to further engage with 'New' customers e.g.: Academic Health Science Networks, Medilink and linking with the growth of the Medical Technology strategy	Increased presence with SMEs across the East Midlands providing support and signposting to increase the number of portfolio studies. Measure of engagement with at least 5 SMEs to progress towards at least 2 research studies on the NIHR portfolio	DK	31/03/2017
	Engagement with AHSN and Medilink with shared literature and collaboration at least one event in the year and regular meetings as required	DK	31/03/2017
	Development of the strategy through the continually evolving Industry Working Group	DK	31/03/2017

6. Integration of the local LPMS as a source for performance updates between network and partner organisations to track performance across the East Midlands	Use of LPMS and development of CRN processes that complement and align with partner organisation input	DK	01/09/2016
7. To campaign for a robust mechanism to give feedback on reasons sites are not selected for commercial studies, so that partner organisations can use the feedback to develop services in line with sponsor expectations	To add as an action point in the annual plan to promote as critical issue at a national level	DK	01/03/2016
	To raise at all forums with commercial partners where the Industry team is present	DK	31/03/2017
	To further develop the initial progress on the new study mile schedule process informing each LCRN they were not selected to add in the reasons for non-selection	DK	01/09/2016
Communications & NHS Engagement			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Review Communication strategy to ensure best fit to meet overall Comms & Engagement Vision	Review and Discuss at Comms WG, consulting with key stakeholders	EM	01/07/2016
	Ensure operational plan flows from this with key targeted communications for different stakeholders	KT/EM	01/08/2016
2. With support of the Communications Working Group, successfully manage the implementation of new NIHR brand guidelines across the region	After receiving confirmation of sign off from DoH, pull together a plan of how the rollout will be managed and implemented within the region, with dates details of who will take responsibility for different elements	KT	15/05/2016
	Discuss and agree the plan with the Communications Working Group	KT	01/06/2016
	Successfully manage the implementation using a phased approach	KT	01/01/2017
	Ensure that all materials are refreshed and replaced before the national deadline	KT/MO	01/01/2017
3. NIHR @ 10 campaign for the East Midlands	Engage with NIHR stakeholders to plan event, Sept/October 2016	EM	08/04/2016
	Event to be held within the region to promote the NIHR and the various work-streams, achievements and progress made over the past 10 years	EM/CS/ G-EAJ	Sept/ October 2016
4. Ensure NHS Engagement remains high both through targeted Comms and through formal twice yearly meetings with each PO	Arrange and attend formal meetings with all partners at least twice yearly	EM/DJR	Ongoing
	Continue to reinforce and strengthen the Senior team Link role not just at budget setting, but throughout the year	EM & Senior Team	Ongoing
	Attendance at monthly East Midlands R&D Leads meetings, with specific CRN agenda items and clear communication with this important stakeholder group	EM/DJR & Senior team	Monthly
5. To manage the successful delivery of a collaborative campaign to highlight what makes the region unique, focussing specifically on the delivery of first class	Discuss and agree the plan with the next Communications Working Group	KT	TBC
	Include a reference within forthcoming Research Awards, to ensure Network colleagues are aware of how they will be asked to contribute and support	KT	29/04/2016

research in one of the UK's most diverse and multicultural regions	Ensure that deliverables and timescales are included in new Communications Strategy and Communications Plan for 16/17	KT	30/05/2016
6. Continue with the BAU elements of the Comms work required, although ensuring these elements are in line with new strategy	Support the delivery within the locality of a series of national communication programmes focused on specific health conditions, as advised, that we know resonate most with patients, carers and clinicians	KT	As required by NIHR CRN CC
	Support the migration of the CRN: East Midlands website to the new, improved NIHR website: prepare a plan of how the migration will be managed and implemented within the region, with dates and details of who will take responsibility for different elements of migration	KT	In line with CRN CC advice
	Continue to produce at least quarterly newsletters in print and electronic, with feedback and input to be incorporated from the Comms WG	KT/MO	On going
	Continue to produce monthly COO Video blog and upload to youtube; consider additional Vlogs from other senior CRN leaders/work-stream leads	EM	Monthly
7. To support the promotion of the Dementia Challenge and Join Dementia Research within the region	Work with the Project Manager to discuss and agree a series of awareness raising activities that can be delivered in 16/17	KT / G-EAJ	20/04/2016
	Ensure that this is included in new Communications Strategy and Communications Plan for 16/17	KT	30/05/2016
Information and Knowledge			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Integrate Business Intelligence across all workstreams in the Network.	Ensure all network staff and Partner Organisations are aware of the Business Intelligence Service and how it supports the day to day running of the network.	KF	01/06/2016
	Information Sessions for all central network staff regarding the BI Service.	Info. Team	01/06/2016
	Explore technological solutions to enhance this process	Business Support Analysts	01/07/2016
	Explore digital invoicing for Service Support Costs managed through LPMS	KF	28/02/2017
2. Ensure that the local Portfolio Management System is fully operational across all workstreams and Partner Organisations	Implement training programmes for Network staff required to use LPMS	Info. Team/ WFD Team	01/05/2016
	Provide quarterly updates with partner Organisations regarding the use of EDGE to avoid duplication and sharing of best practice.	BI Programme Manager	Ongoing
3. Ensure that Recruitment Data Contacts are informed about the changes to recruitment uploads and the use of CPMS.	Provide onsite training to Research Activity Coordinators across the region in the use of CPMS	Information Team	01/05/2016
	Educate RAC's and Chief Investigators to the importance of timely uploads.	Comms. / Info. Team	Ongoing

4. Provide system support to underpin the Study Support Service across the Research Pathway.	Develop the use of EDGE to record local SSS activity	SSS Staff / Information Team	Ongoing
	Actively performance manage studies to time and target using LPMS/CPMS/ODP	PST	Ongoing
5. Enable a paperless reporting system to ensure live reporting in in place across the Network	Pilot live reporting via Google Hub with a Partner Organisation initially to understand the needs of our Partners and a collaborative reporting platform	KF / Info. Team	01/09/2016
	Understand the needs of Partner Organisations by undertaking a survey on the reporting needs of each organisation to enable development of reports that are beneficial to both the Partner and the Network.	KF / Info. Team	30/09/2016
Continuous Improvement			
Objective	**Actions required to achieve objective**	**Action owner**	**Action deadline**
1. Establish a consistent and efficient study support service	SSS board to continue to provide direction throughout the year	BM	Ongoing
	Primary care pilot SSS to be reviewed and feed back lessons learnt into final service offering	SSS Manager	01/10/2016
	Mental health SSS pilot to be reviewed and feed back lessons learnt into final service offering	SSS Manager	01/11/2016
	Remaining SSS pilot to be agreed and implemented	SSS Manager	01/10/2016
2. To ensure we have sufficed and well trained rater trainers to deliver on dementia challenge	Identify minimum raters and agree role and remit	G-EAJ / ME	01/05/2016
	Develop rater work plan	G-EAJ/rater Leads TBC	30/06/2016
	Identify training needs and develop a plan to ensure raters are fully training	G-EAJ / ME	30/06/2016
3. Embed a culture of innovation and improvement across the CRN	Establish a CI steering group, and schedule regular meetings	CI Lead TBC	Ongoing
	Establish a database of CI projects from across the region. All CRN staff to be contacted	CI Project support	Quarterly
	Support ongoing projects and learning	CI Lead TBC	Ongoing
	Delivery key CI sessions to senior management team and partner organisations	CI Lead TBC	Ongoing
4. Have in place a highly trained workforce	Develop local CI training programme for supporting Continuous Improvement training and development through a mixture of self directed learning and facilitated sessions, once national training made available	CI Lead TBC	01/07/2016
5. Deliver on national programmes and initiatives	Implement and delivery national CI programmes and initiatives locally	CI Lead TBC	Ongoing
	Deliver CRN digital where applicable	Learning Technologist	Ongoing

National Institute for Health Research

Clinical Research Network East Midlands

NIHR Clinical Research Network: East Midlands

GOVERNANCE FRAMEWORK

Host Organisation:

University Hospitals of Leicester NHS Trust

Delivering research to make patients, and the NHS, better

Change Control

Version	Date	Changes made
1.0	01.04.14	Original document – approved by UHL Executive Strategic Board
1.1	08.04.14	More detail on roles of the Clinical Research Divisional Leads and additions to section 7.1.
1.2	22.09.14	Changes to risk management process (section 10)
2.0	13.03.15	Annual review (2015/16) with the addition of Financial Management section (8)
2.1	02.07.15	Update to Executive Director, removal of Business Delivery Manager post
3	29.01.16	Annual Review – added reference to Study Support Service (section 5), Clinical Leadership Group included within Operational Management Group (section 5), listed Working Groups (Section 6), updated Executive Group details (section 6), updated reporting assurance to quarterly Board Report (section 7), updated staff responsible for operational management of Service Support budget (section 8), updated table for LCRN financial cost codes and delegated authorisation allowances (section 8), updated resolution to audit findings (section 9).

NIHR CLINICAL RESEARCH NETWORK: EAST MIDLANDS

Governance Framework

C O N T E N T S

NIHR CLINICAL RESEARCH NETWORK: EAST MIDLANDS

Governance Framework

1. INTRODUCTION

1.1 The National Institute for Health Research Clinical Research Network (NIHR CRN) is the clinical research delivery arm of the NHS in England. Its purpose is to ensure patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research; integrate health research and patient care; improve the quality, speed and co-ordination of clinical research; increase collaboration with industry partners and ensure that the NHS can meet the health research needs of industry.

1.2 Before April 2014, there were over 100 clinical research networks in England hosted by NHS Trusts in adjacent localities. From April 2014, there will be only one research "branch" of the NIHR CRN in each NHS region; these are termed Local Clinical Research Networks (LCRNs). The formal name of the LCRN in the East Midlands is NIHR CRN: East Midlands (the LCRN). University Hospitals of Leicester NHS Trust (the Trust) successfully applied to host this network on behalf of the NIHR and partner organisations in the East Midlands (Derbyshire, Nottinghamshire, Lincolnshire, Leicestershire, Rutland and Northamptonshire).

1.3 The Trust is committed to providing safe high quality care and has developed a range of policies, systems and processes which together comprise robust and integrated Financial Management, Assurance and Escalation, and Risk Management Frameworks. The principles of which have informed this document to ensure high-level, informed accountability of the Trust Board for the good governance of the LCRN.

1.4 The LCRN was launched on 1 April 2014. This document describes the processes and controls established by the LCRN to ensure good governance. This document provides governance assurances for delivery of the Department of Health issued Contract and Performance and Operating Framework which is concerned with (i) the transition of 10 NIHR research networks into the NIHR CRN: East Midlands and (ii) the hosting of the LCRN after fully transitioned.

2. PURPOSE

2.1 This framework describes the LCRN's scheme of delegation, Board controls and assurances, financial management, assurance framework, risk management system and escalation process for the management of the LCRN.

2.2 This framework will be reviewed by the LCRN Executive Group and the Trust Board on an annual basis in order to reflect any changes in governance, assurance and escalation processes.

3. GENERAL PRINCIPLES

3.1. The Trust Board is accountable for the good governance of the LCRN. The Board should apply, in a proportionate and appropriate way, the principles of good governance and thereby promote:

- Robust, transparent and accountable LCRN governance;
- Effective and supportive LCRN hosting arrangements;
- Effective and proportionate contracts with Partners and other organisations in receipt of LCRN funding or resources;
- Responsible financial management including budgetary control and the production of financial reports;
- A structure that ensures effective local performance management,
- Partner participation and engagement, research delivery and value for money.

3.2. The Trust, along with the LCRN leadership, are responsible for developing governing structures, systems, terms of reference and local working practices for working for the LCRN. The specific governance requirements required are detailed in this framework and in respect of:

- The Accountable Officer;
- The nominated Executive Director;
- Scheme of delegation and Host Board controls and assurances;
- Financial management
- Assurance framework and risk management system;
- Escalation process;
- LCRN Leadership and Management Groups.

3.3. NHS patients and the public are the key stakeholders in NIHR CRN research, and are to be included in LCRN governance arrangements. Patient or public representatives have been included in the agreed membership of the LCRN Partnership Group.

3.4. LCRN governance arrangements are required to be formally signed off by the Trust Board and by the national CRN Coordinating Centre.

4. LEADERSHIP TEAM

4.1 The **LCRN Accountable Officer** is the Trust's Chief Executive Officer, John Adler.

4.2 The Nominated **Executive Director** for the LCRN is the Trust's Medical Director, Mr Andrew Furlong.

4.3 The Trust has appointed Professor David Rowbotham as the **LCRN Clinical Director**. The Clinical Director has local overall responsibility for the LCRN reporting to the Nominated Executive Director and the national CRN Coordinating Centre. The Clinical Director also leads in the engagement of the regional clinical and research community, promoting research and building clinical research capacity.

4.4 The Trust has appointed Elizabeth Moss as **LCRN Chief Operating Officer** who is responsible for the operational delivery of the contract and overall operational management of the network. The Chief Operating Officer reports to the LCRN Clinical Director and the national CRN Coordinating Centre. The Board understands that it is a contractual obligation to ensure that the Chief Operating Officer is a Trust employee.

4.5 The governance responsibilities of the LCRN Leadership Team are to:

- Deliver the core activities of the LCRN, in line with the agreed governance requirements within the Host Contract and Performance and Operating Framework;
- Ensure any activities are carried out as may be necessary for the proper governance of the LCRN;
- Ensure that a proper and auditable process is developed and executed for the fair and effective distribution of LCRN funding;
- Be available for regular meetings as a core Leadership Team;
- Support scrutiny and transparency, for example by providing any information as required for the internal auditors, and attending the audit committee of the Trust as requested;
- Ensure the timely delivery of performance and other reports;
- Support the Trust by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements;
- Convene regular Partnership Group meetings;
- Make freely available to the Trust and all Partner organisations, as requested, any information that is not commercial and/or in confidence and in line with national NHS policies;
- Manage the LCRN so as not to compromise either the Host organisation or Partner organisations through reasons of conflicting issues such as competition law or data protection.

5. MANAGEMENT TEAM

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

- **LCRN Divisional Research Delivery Managers** who provide day-to-day operational management of research activity in each of the six operational divisions;
- **Lead RM&G Manager** with oversight of the research management and governance operations and the evolving Study Support Service
- **Industry Delivery Manager** who is responsible for commercial research within the LCRN;
- **Business Intelligence Lead** who is responsible for monitoring budget expenditure and LCRN overall performance

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

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

5.3 Figure 1, illustrating the management structure, is included below:

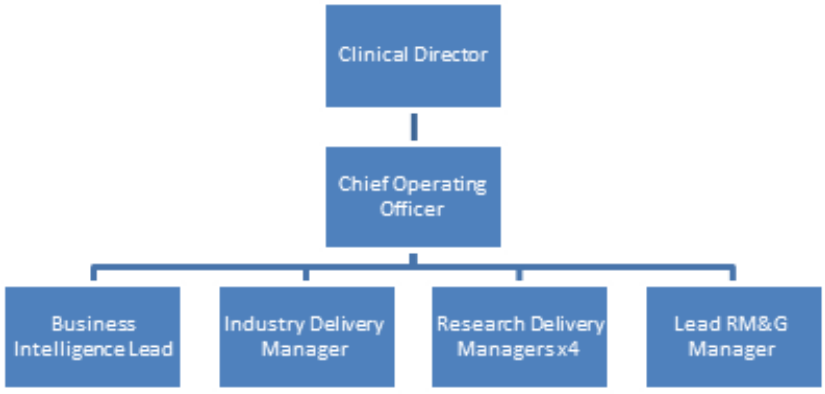


Figure 1 - CRN: East Midlands Senior Management Structure

LCRN Clinical Research Leads

5.4 The LCRN has appointed six **LCRN Clinical Research Leads**, one for each research delivery division. These clinicians represent the clinical activity interests of all specialties within their research delivery division, liaising closely with the Clinical Research Specialty Leads. They work closely with their Divisional Research Delivery Managers and are members of the Operational Management Group (see below).

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

- Address resource allocations and the balance of the LCRN portfolio across specialties, sites, trusts, care settings, patient groups and study composition;
- Provide clinical intelligence and advice to support research delivery within the division, including a view of the clinical implications of national policy locally;
- Support Clinical Research Specialty Leads with the identification and development of research communities within the LCRN area, across all NHS partners.

LCRN Clinical Research Specialties

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

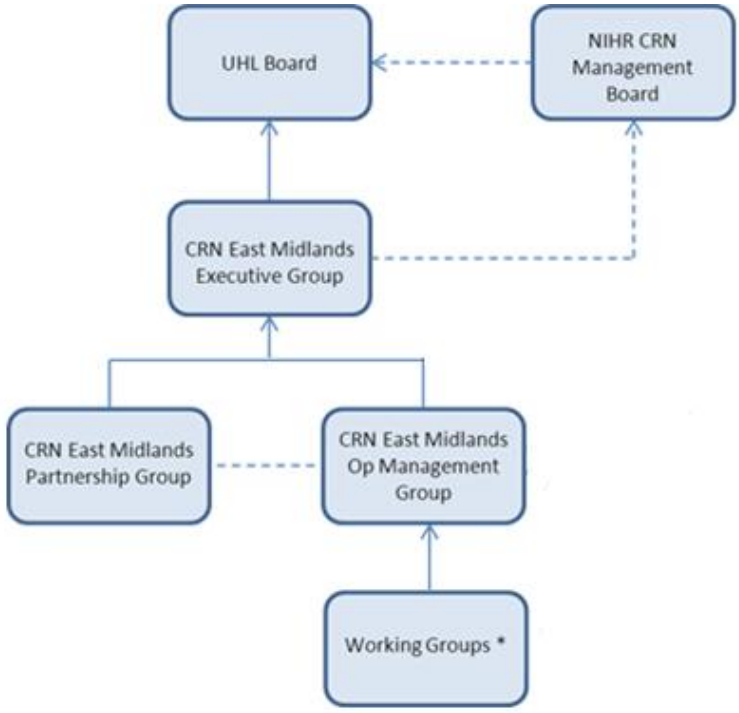
5.7 The 30 Clinical Research Specialties are grouped into 6 Divisions for operational management purposes:

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

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

6. LCRN GOVERNANCE STRUCTURE

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



*Workforce Development Steering Group, Life Sciences Working Group, Business Intelligence Working Group, Communications Working Group, Finance Working Group, Patient and Public Involvement Working Group, Study Support Service Programme Board, Dementia Challenge Steering Group & EnRICH Advisory Group

Figure 2 – CRN: East Midlands Governance Structure

6.2 The Trust has established the **LCRN Partnership Group**. The Group is a formal forum of LCRN partners (those receiving significant funding from the LCRN). Its role is to provide active oversight and constructive mutual challenge on LCRN plans, activities, performance and reports in order to support the LCRN to achieve its objectives and raise the ambitions for clinical research of the LCRN Partners. The Trust has appointed an independent Chair (Peter Miller, Chief Operating Officer, Leicestershire Partnership NHS Trust) and the group will be attended by the Trusts' Nominated Executive Director, LCRN Clinical Director and LCRN Chief Operating Officer. The Group meets four times per year.

6.3 The Trust has established a **LCRN Executive Group** chaired by the Nominated Executive Director reporting to the Trust Board. Membership includes LCRN Clinical Director, LCRN Chief Operating Officer, LCRN Business Intelligence Lead, LCRN Project Manager, LCRN Financial Lead, and LCRN Communications Lead. Its purpose is to oversee and deliver good governance of the LCRN as defined by the Host contract and LCRN Operating Framework. The Group will meet every 8 weeks.

6.4 The Trust has established a **LCRN Operational Management Group** chaired by the Chief Operating Officer or Clinical Director and reporting to the LCRN Executive Group. Its purpose is to maintain oversight of overall management of the LCRN and be the forum to address cross-divisional and cross-cutting needs for support and intervention. Membership includes all LCRN senior operational managers, all Clinical Divisional Leads and representatives from Partner Organisational Research & Development departments. The Group will meet every 8 weeks.

6.5 The Trust does not have a separate Clinical Leadership Group. All Clinical Divisional Leads are included within the Operational Management Group. The role of the Clinical Leads is to provide: (i) advice on clinical implications of national policy at the local level; (ii) intelligence to determine resource allocations and (iii) clinical intelligence and advice to support LCRN research delivery.

7. HOST BOARD CONTROLS AND ASSURANCES

7.1 The Trust Board will agree to review and/or sign off the following LCRN activities:

- Receipt of the LCRN Annual and Finance Plans, from the Executive Director, for approval;
- Receipt of an LCRN Annual Report, from the Executive Director, for approval;
- Submission of the Annual Plan, Finance Plan and Annual Report to the national CRN Coordinating Centre for approval;
- Provision of the approved Annual Plan and Annual Report to all the members of the LCRN Partnership Group;
- Report to Trust Board quarterly on the work of the LCRN alongside the quarterly report on UHL R&D;
- Inclusion of LCRN key performance indicators in the quarterly Trust Board Report

7.2 The Trust, as the Host organisation, has an obligation to ensure the proper management of the LCRN in terms of compliance with the governance framework and processes of the Host, including human resources, standing financial, audit and standards of business conduct instructions. The Trust shall ensure that internal policies and standing financial instructions, as they affect the LCRN, do not unreasonably diminish the efficient management of the LCRN.

7.3 The Trust, as the Host organisation, shall ensure that the LCRN is run in accordance with relevant laws and regulatory requirements, relevant national NHS policies and requirements, and the NHS Constitution.

8. FINANCIAL MANAGEMENT

8.1 The Trust, as Host Organisation, receives, manages and distributes the allocated funding with the LCRN via the Department of Health (DH)-approved standard template sub-contracts, or other forms of agreement with DH-approved text.

8.2 The Trust, as Host Organisation, has an obligation to use the funding solely for development and delivery of LCRN activities as set out in the contract between DH and the Trust. Measures will be developed to provide assurance that LCRN funding provided to partner organisations is used solely for these purposes.

8.3 The Trust, as Host organisation, through the LCRN Executive Group, will draw up an annual financial plan for the LCRN, as part of the LCRN Annual Plan. This plan will be reviewed by the LCRN Partnership Group prior to submission. The plan will be approved by the Trust Board and then submitted for approval to the national CRN

Coordinating Centre.

8.4 The Trust, as Host Organisation, reports to the National CRN Coordinating Centre on financial expenditure including forecast outturn for the financial year, via the NIHR CRN Finance Tool, on a quarterly basis.

8.5 The Trust, as Host Organisation, is required to submit an end-of-year financial return to the National CRN Coordinating Centre in respect of LCRN funding received. The financial return reports on all LCRN funding and expenditure, for all organisations in receipt of that funding and agrees the year-end figures for respective Partner Organisations.

Financial Scheme of Delegation

8.6 The Trust, as Host Organisation, has appointed Martin Maynes as **LCRN Finance Lead** who is responsible for the financial accountability of the network on behalf of the Trust. Martin produces LCRN financial reports for review by the LCRN Executive Group and LCRN Partnership Group.

8.7 Elizabeth Moss, **LCRN Chief Executive Officer**, is responsible for overall LCRN budget oversight and strategic decision making.

8.8 The Trust, as Host Organisation, has appointed Kathryn Fairbrother as **LCRN Business Intelligence Lead** who is responsible for operational management for the infrastructure and central budgets with accountability shared with the LCRN Finance Lead. Kathryn provides oversight of the Service Support budget.

8.9 Debbie Jeffrey (**Primary Care Research Delivery Lead**), Bryony Berridge (**RM&G Manager**) & Kathryn Fairbrother (**Business Intelligence Lead**) are responsible for the operational management of the Service Support budget.

8.10 The Trust has appointed a qualified and experienced finance team to monitor the budget on a day to day basis. The finance team work closely with research finance staff within partner organisations. All members of the finance team are line managed by the LCRN Finance Lead.

8.11 Figure 3, which presents the structure of the finance team, is set out below:

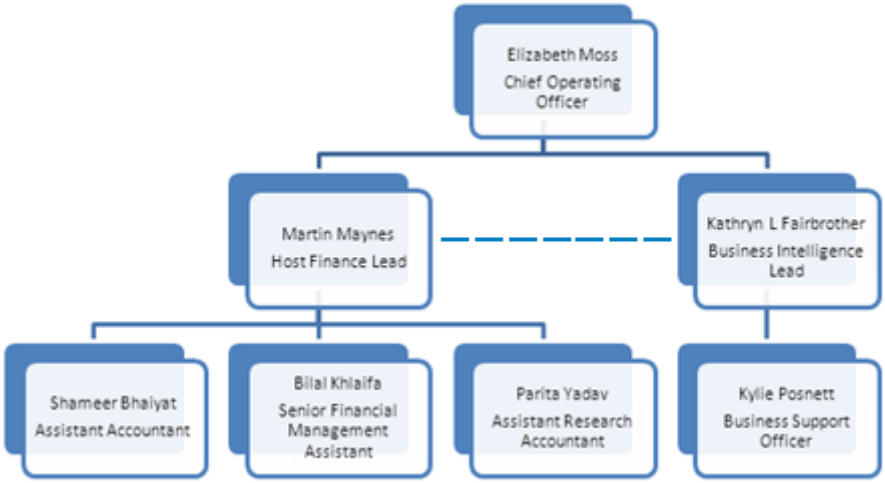


Figure 3 – CRN: East Midlands Finance Support Structure

8.12 The table below provides the LCRN financial cost codes and delegated authorisation allowances.

Table 1

		Authorisers				
		LCRN Chief Operating Officer	LCRN Business Intelligence Lead	LCRN Senior Manager	Workforce Development Lead	RST Team Leader
Cost Code	Description	Up to £600,000	Up to £75,000	Up to £5,000	Up to £5,000	Up to £5,000
O11	CRN EM Non-Primary Care Service Support Costs	Y	Y	N	N	N
O17	CRN EM Research Capability Funding	Y	Y	N	N	N
S18	CRN EM RSI	Y	Y	Y	N	N
S19	CRN EM Clinical and Specialty Leads	Y	Y	N	N	N
S89	CRN EM Primary Care Service Support Costs	Y	Y	N	N	N
S90	CRN EM General Infrastructure	Y	Y	N	N	N
S97	CRN EM UHL Infrastructure	Y	Y	N	N	N
S98	CRN EM LPMS	Y	Y	N	N	N
U08	CRN EM RST	Y	Y	N	Y	Y
U14	CRN EM SSS	Y	Y	Y		N
U89	CRN EM Management Team	Y	Y	Y	N	N
U96	CRN EM Host Services	Y	Y	N	N	N
U97	CRN EM Network Wider Team	Y	Y	Y	Y	N

9 ASSURANCE FRAMEWORK

9.1 The LCRN is committed to supporting safe high quality research and has developed a range of policies, systems and processes to clarify how issues or concerns which may detrimentally impact upon the LCRN are escalated throughout the organisation.

9.2 This section describes the structure and systems through which the LCRN Leadership and Management Groups, and the Trust board receive assurance.

9.3 The assurance framework describes how the LCRN is able to identify, monitor, escalate and manage issues in a timely fashion and at an appropriate level.

Issue Management and Control

9.4 An issue is defined as a relevant event that has happened, was not planned, and requires management action.

9.5 The LCRN has an open and learning culture encouraging monitoring and comments and concerns to be communicated relating to issues that impact on LCRN delivery. The table below provides examples of both internal and external sources of identify issues.

Table 2

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

9.6 It is important that the LCRN has the capability to respond to issues or concerns in a timely fashion. In practice the response required varies considerably according to the nature of the issue or concern. In some cases, immediate action may be required. In other cases, and particularly with more complex or longstanding issues, the commissioning of a full report may be an appropriate response. However the response must always be:

- timely
- proportionate
- comprehensive
- inclusive
- effective.

9.7 The LCRN will follow a five step procedure for issue management and control (table 2). This procedure will be followed by the LCRN Senior Management who comprises the Operational Management Group.

Table 2

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

Internal and External Sources of Assurance

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

Table 3

Internal Sources of Assurance	External Sources of Assurance
Performance review meetings	Patients, carers and the public
Performance reports – Summary, Partner, Division/Specialty, CCG	UHL Audit Programme
Internal audit (review of internal systems and processes)	CRN Coordinating Centre
Executive Group	Partner feedback and engagement
Partnership Group	Partner and public survey results
Operational Management Group	
Staff surveys and exit interviews	
UHL Board feedback	
Executive Performance Board reporting	
LCRN Performance Dashboard	

LCRN Host Organisation Annual Review

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

LCRN Auditing Arrangements

9.10 The Trust is obliged to ensure that LCRN activity is included in the local internal audit programme of work. The LCRN should be audited at least once every three years. The LCRN Clinical Director has instigated these arrangements with the Trust's Interim Director of Finance and PwC UK.

9.11 The LCRN was audited in November/December 2014 and was provided a medium risk rating. There were six findings (5 minor, 1 medium) and the LCRN have prepared and enacted an action plan to ensure all findings were resolved by the end of Quarter 2, 2015/16.

10 BUSINESS CONTINUITY ARRANGEMENTS

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

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

10.3 The LCRN has developed an Urgent Public Health research plan to enable the Trust and the LCRN to support the rapid delivery of urgent public health research, which may be in a pandemic or related situation. The Urgent Public Health Research plan will be immediately activated in the event that the Department of Health requests expedited urgent public health research.

11 RISK MANAGEMENT PROCESS

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

11.2 The LCRN has implemented a risk management framework, which includes a risk register. The risk register is updated regularly and reviewed every 8 weeks by the LCRN Executive Group.

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

			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
Very Low and 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.

12 ESCALATION PROCESS

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

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

1. LCRN Clinical Director – Professor David Rowbotham

2. Nominated Executive Director – Mr Andrew Furlong

3. The Trust Chief Executive Officer – John Adler

4. National CRN Coordinating Centre

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

13 MONITORING OF ACTION PLANS

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

13.2 The LCRN Executive Group will continue to monitor any new action plans created in 2016/17 that develop from the Annual Plan or are required as routine or extraordinary plans throughout the year.

14 REVIEW

14.1 The Governance Framework will be subject to further development as the Trust hosting requirements and LCRN arrangements become embedded.

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

David Rowbotham
Clinical Director, CRN: East Midlands

03 February 2016

Progress in making the UK one of the best places in the world for delivery of clinical research

NHS
National Institute for Health Research

Clinical Research Network
East Midlands

After discussion with UHL Board Chairman, it was agreed that Board reports from the UHL-hosted NIHR Clinical Research Network: East Midlands will include a brief presentation of topics of wider interest with respect to clinical research in the NHS. This is the first presentation.

Background

In the decade preceding the establishment of The National Institute for Health Research (NIHR) in 2006, there was a near terminal decline in clinical trial activity within the NHS. This was caused by a sluggish and unresponsive clinical trial approval process combined with an inability to recruit the required numbers of patients within the funding and timing envelope of individual clinical trials. From a leading position, we had become one of the worst countries in the world for clinical trials delivery. This meant that the national budget for clinical research was being used inefficiently, new treatments were being delayed, and many companies in the life science sector moved out of the UK with serious consequences to the national economy and access of NHS patients to new treatments.

An early strategy of the NIHR was the establishment of clinical research networks tasked with reversing poor clinical research delivery and restoring the UK as one of the best places in the world to perform clinical research. The purpose of this presentation is to show the significant progress in delivering this goal. The NIHR Clinical Research Network (CRN) deals with both non-commercial and commercial trails; this presentation highlights performance in delivering the latter which is associated with early access to new treatments for patients and external investment in the NHS and national economy.

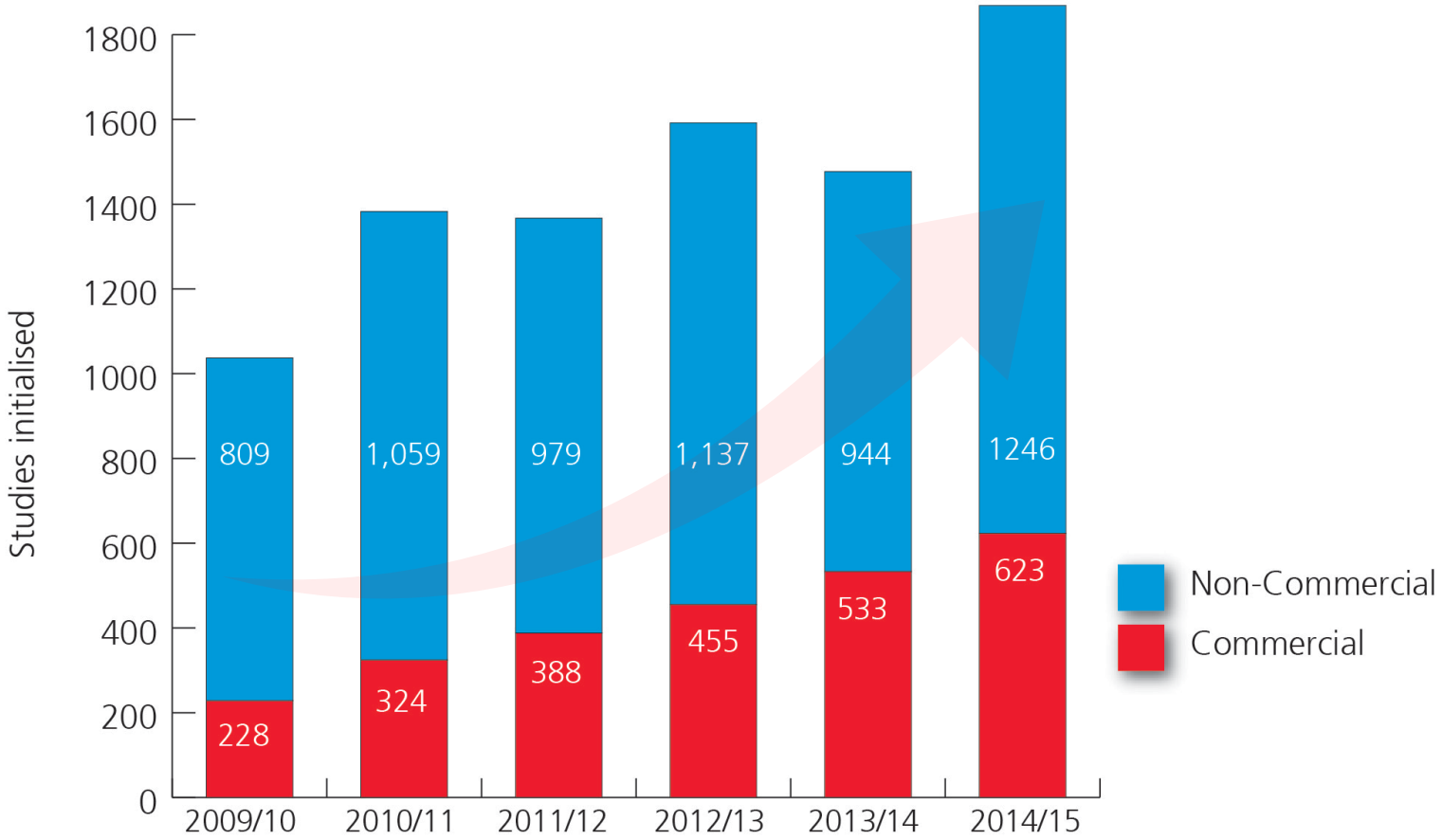
National performance data

These following figures display data from 2010-11 to 2014-15; full data for 2015-16 is not yet available. Page 2 shows a 273% increase in the number of new commercial studies added to the Clinical Research Network portfolio. The number of active trials at any one time is much greater than this. For example, the CRN was managing 16,212 trials (3,319 commercial) at the close of 2015-16. The number of patients recruited into commercial studies has increased by a factor of 2.5 (page 3) and we are beginning to achieve first global recruits in international studies (a recognised measure of ability to deliver compared with others). Also, there has been a remarkable decrease (median 115 to 20 days) in the time taken to obtain NHS permission for new clinical trials (page 4). Page 5 shows how the UK compares with other countries in this regard by comparing the time from the “site selection visit” (when the approval process commences) and the “site initiation visit” (when all approvals are in place). Our position as 2nd in the league table is a considerable improvement and achievement. Similar improvements in delivery to time and target can be demonstrated.

Increased commercial studies

NHS National Institute for Health Research
Clinical Research Network

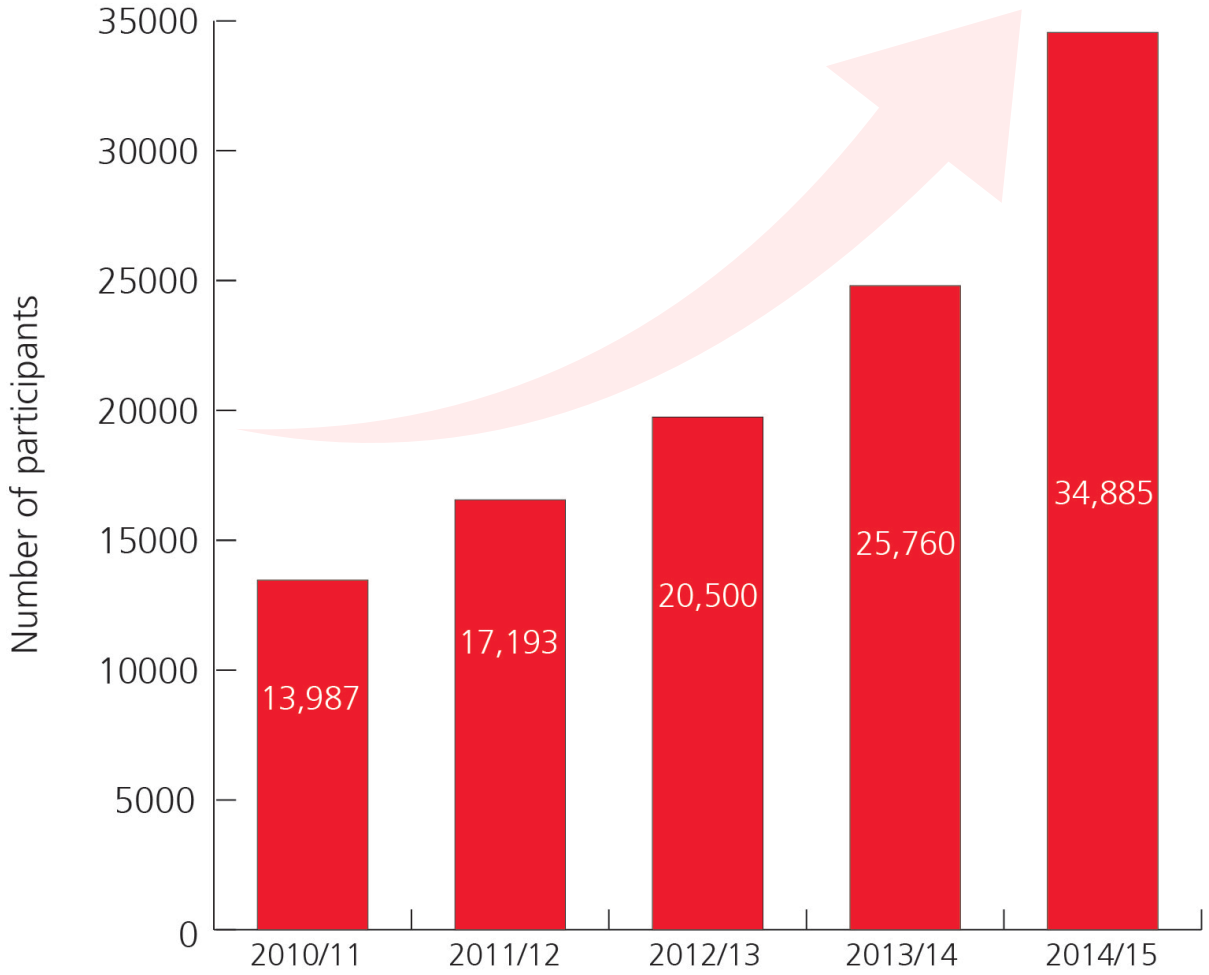
Number of new commercial studies added to the NIHR CRN Portfolio



Increased commercial recruitment

NHS National Institute for Health Research
Clinical Research Network

Number of participants into commercial NIHR CRN Portfolio studies

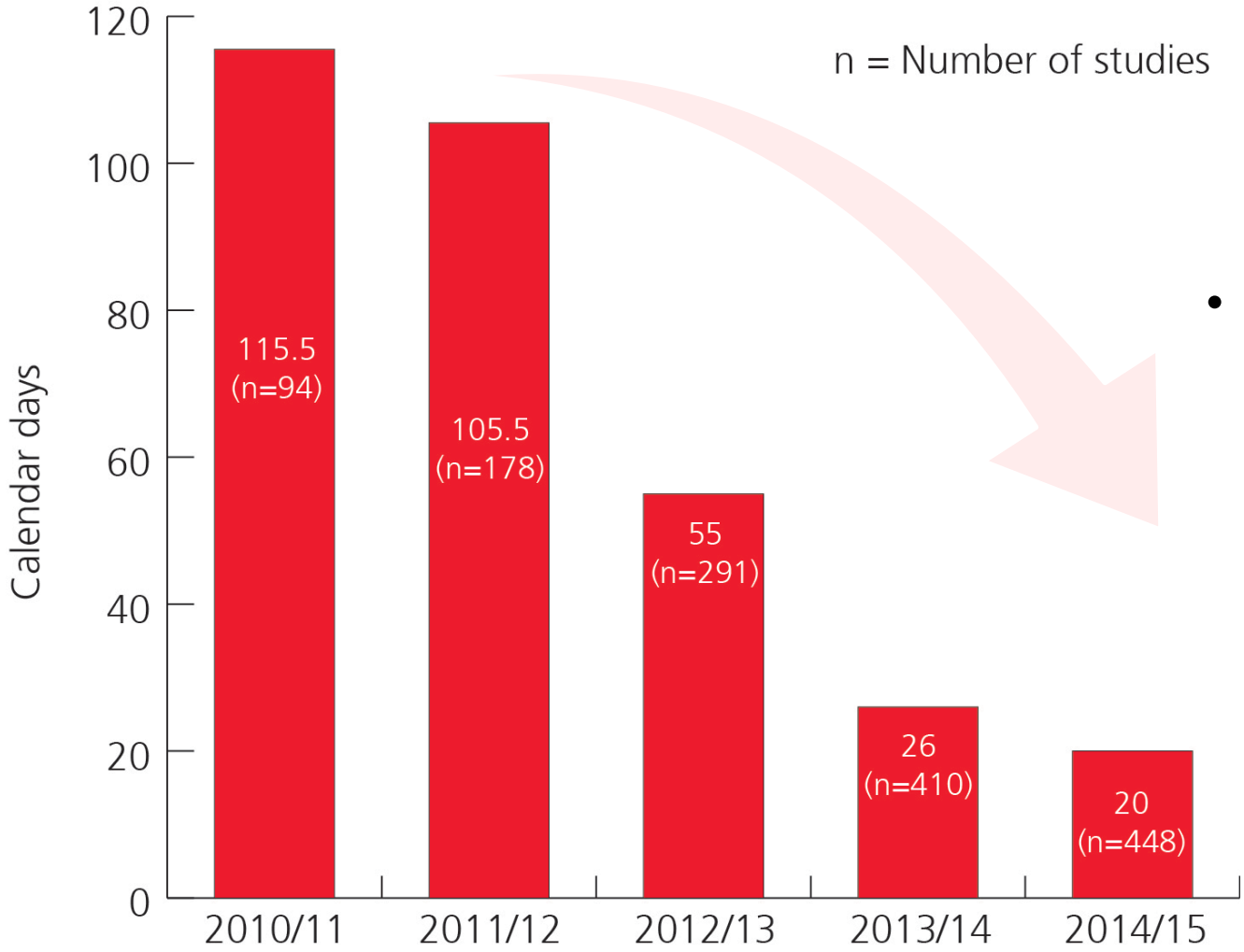


- **112,000+** patients recruited to industry studies over the last 7 years
- **34,500+** patients recruited to commercial contract studies in 14/15
- **17 first global patients** in 2014/15
- **10 first European patients** in 2014/15

Commercial study set-up

National Institute for Health Research
Clinical Research Network

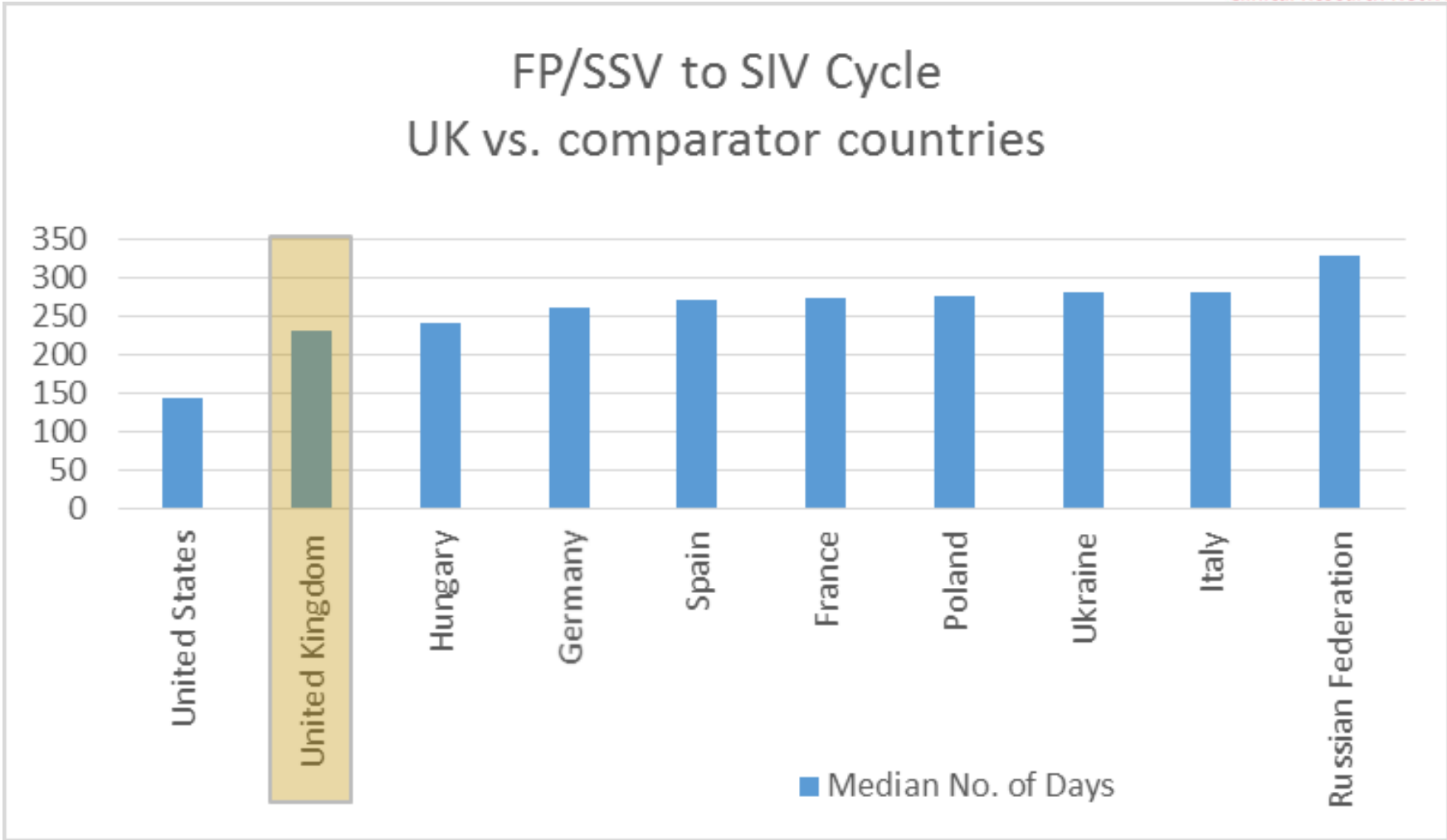
Median calendar days taken to obtain NHS permission (study)



- Over 82% reduction in last 5 years

Set Up

Data source: Global CRO (C)



Number of calendar days between the Site Selection Visit (SSV; or final protocol if later) and the Site Initiation Visit (SIV)