The Royal Wolverhampton
NHS Trust

NIHR CRN West Midlands
26 March 2018

Agenda Item No: 9.4

The Royal Wolverhampton NHS Trust

Trust Board Report

Meeting Date:	26 March 2018
Title:	NIHR CRN West Midlands
Executive Summary:	Under the contract with the DH, RWT as Host Organisation is required to submit an Annual Delivery Plan (ADP) which includes the Annual Financial Plan (AFP) for the Local Clinical Research Network (LCRN). The ADP is based on the Performance and Operating Framework 2018-19 which is part of the DH/LCRN Host Organisation Agreement. This document has been considered and agreed by the CRN West Midlands Partnership Group on 15 March 2018. The RWT Executive Group supported the delivery plan on 15 March 2018 and it is therefore submitted for RWT Trust Board approval on 26 March 2018.
Action Requested:	Receive and note performance report Approve Annual Delivery Plan and Annual Finance Plan
For the attention of the Board	
Assure	CRN West Midlands Annual Delivery Plan and Annual Finance Plan 2018/19 set the strategic direction for the LCRN within the reporting year. It includes specific activities and strategic initiatives to support the achievement of the objectives and targets in the LCRN Performance Indicators as set out in the NIHR CRN Performance and Operating Framework 2018/19.
Author + Contact Details:	Tel 01902 446815 Email Pauline.boyle@nihr.ac.uk Jeremy Kirk, Clinical Director & Pauline Boyle, Acting Chief Operating Officer
Links to Trust Strategic Objectives	1. Create a culture of compassion, safety and quality 2. Proactively seek opportunities to develop our services 3. To have an effective and well integrated local health and care system that operates efficiently 4. Attract, retain and develop our staff, and improve employee engagement 5. Maintain financial health – Appropriate investment to patient services
Resource Implications:	None

CQC Domains	**Effective:** care, treatment and support achieves good outcomes, helping people maintain quality of life and is based on the best available evidence. **Responsive:** services are organised so that they meet people's needs. **Well-led:** the leadership, management and governance of the organisation make sure it's providing high-quality care that's based around individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.
Risks: BAF/ TRR	n/a
Public or Private:	Public session
Other formal bodies involved:	RWT Finance and Performance Committee RWT Executive Group CRN West Midlands Partnership Group
NHS Constitution:	In determining this matter, the Board should have regard to the Core principles contained in the Constitution of: • Equality of treatment and access to services • High standards of excellence and professionalism • Service user preferences • Cross community working • Best Value • Accountability through local influence and scrutiny

Annual Delivery Plan 2018-19	
1	The ADP sets out the strategic direction for the LCRN within the reporting year. It includes the specific activities and strategic initiatives which support the achievement of the NIHR performance objectives. The ADP describes how the CRN West Midlands will contribute to the NIHR CRN Priorities 2018/19: • Deliver against the NIHR CRN Strategies (Business Development and Marketing strategy, Information and Knowledge Strategy, Working with the Life Sciences Industry Strategy, Patient and Public Involvement and Engagement Strategy, NHS Engagement Strategy, Communications Strategy and Workforce Development Strategy) • Deliver NIHR CRN Portfolio Studies to time and target (HLO2B) with a specific focus on commercial contract research (HLO2A) • CRN Digital Programme • Maximise the use of Central Portfolio Management System (CPMS) • Optimise research delivery Other local innovations and initiatives include: • Explore opportunities to conduct research in non-NHS settings • Continuous Improvement • Sustainability of workforce • Supportive and Palliative Care research • Primary Care • Chief Investigator development • Mapping new GP configurations and emerging models of care • Increase links with academic institutions • Exploit business intelligence data • Management of Excess Treatment Costs • Non-medic Principle Investigators • Research in non NHS settings

Finance Update and Annual Financial Plan

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Q3 Reporting:
The final submission for Quarter 3 2017/18 was submitted on January 25th (2018). The CRN reported an under spend of approx. £70k against the full annual allocation of £27.4m this represents 0.26% of the total allocation and is within the guidelines. The £70k has now been allocated and will be fully utilised by the year end.

There was however expenditure related to vacant posts in the Quarter 3 return of £138k, £49k related to the host this will be monitored on a monthly basis and redistributed, as for the remainder (mainly primary care) they have assured us this spend will materialise.

Financial Control Health Check Visit:
Disclosure statements had been sent out in October asking partner organisations to confirm their usage of NIHR funds which was an action requested at the financial control health check visit.

The declaration stated:
"We confirm that the expenditure reported above relates to eligible NIHR CRN activity that has taken place during the last financial year shown. The expenditure has been incurred in accordance with HM Treasury rules.

We confirm that reported CRN resource has not been used to subsidise commercial research within the organisation.

We confirm that the financial return reports on all LCRN funding and expenditure, and reconciles to the figures in the Trust Ledger."

We have received back the majority of these and are awaiting just primary care's return.

Monitoring Visits:
Continue to take place throughout the year and by the end of this year CRN will have visited all the organisations at least once and then the cycle will be repeated.

Annual Financial Plan:
18/19 Plans were drawn up during November and December based on our assessment of income not changing significantly from 17/18. Final allocations were confirmed by NIHR to be £27.6m (17/18 £27.2m). This means we have £564k (£2.0%) to allocate, the guidelines state that we can start the year with a 10% unallocated rate.

However we have several options as to how to utilise that additional funding, we can either fund further strategic bids already identified or we can hold the funding for emerging priorities during the year.

Assessment of Income Distribution based on income received last year		**2018/19**	
		18/19 Median 3 Year -5%/+10%,5% Top slice cap	
PO's	Core	18,003,181	Core
Strategic Funding Modelling	Strategic Funding – GREEN ONLY	1,203,789	SF
Sustainability funding - other		641,633	Other
CRL/CRSL		605,996	CRL/CRSL
GP payments		575,310	GP's
Host budget Pay		4,952,121	Host

	Host budget non pay		1,110,395	
	Host budgets estimated pay award 2% uplift		99,042	Host estimated pay award 2%
	IDENTIFIED ALLOCATIONS		**27,191,468**	
	TO BE ALLOCATED		**563,596**	
			27,364,749	17/18 funding
			273,647	1% increase from last year funding
			19,855	National Speciality Leads
	2018/19 ALLOCATION		**27,658,293**	

Appendices	
3	Annual Financial Plan 2018/19 Annual Delivery Plan 2018/19 Performance and Operating Framework 2018/19

OVERVIEW REPORT TO BOARD

The key headlines/issues and levels of assurance are set out below, and are graded as follows:

Assurance level*	**Colour to use in 'Assurance level*' column below**
Assured	Green – there are no gaps in assurance
Partially assured	Amber - there are gaps in assurance but we are assured appropriate action plans are in place to address these
Not assured	Red - there are significant gaps in assurance and we are not assured as to the adequacy of current action plans If red, commentary is needed in "Next Actions" to indicate what will move the matter to "full assurance"

Key issue	**Assurance level***	**Committee update**	**Next action(s)**	**Timescale**
HLO5: Objective: Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies			Our current performance is comparable with all CRNs. Edge Working Group in place. Training for Partner Organisations	Ongoing
HLO7: Objective: Increase the number of participants recruited into Dementias and Neurodegeneration studies			New Clinical Research Speciality Lead to be appointed.	Ongoing

Key issue	Assurance level*	Committee update	Next action(s)	Timescale
HLO2: Objective: Increase the proportion of studies delivering to recruitment target and time			Forecast is low nationally & locally; reasons including low range targets /data accuracy. Dedicated HLO2 action plan in place.	Ongoing
HLO4: Reduce the time taken for sites to be confirmed, post HRA Approval			Formulation of an Edge Working Group as there are issues with data completion and new systems.	Ongoing
HLO6a: Percentage of Trusts that have reported recruitment to Portfolio studies to date in 2017-18			There is one Partner Organisation which has not yet recruited a patient into a study; negotiations are taking place	May 2018
HLO1: Number of recruits to NIHR Portfolio Studies in 2017-18, as a percentage of agreed pro rata target			Well ahead of target at 109%	
HLO1: Activity Based Funding as a % of target			First place nationally with 9.9% of the ABF pot	
HLO3: Increase the number of commercial contract studies delivered through the NIHR CRN			Exceeded target - 39 studies; 20 ahead of last year	
HLO6b: Percentage of Trusts that have reported recruitment to Commercial studies			Exceeded target with 86% of POs recruiting (target 70%)	
HLO6c: Percentage of GP Practices that have reported			Exceeded target with 31% of GPs recruiting (target	

Key issue	Assurance level*	Committee update	Next action(s)	Timescale
recruitment			25%)	

Section 2: Key Projects					
Ref	**Key project**	**Outcome**	**Lead**	**Milestone**	**Milestone date**
1. Governance and Management					
2.3.3.	Desk top exercise to test the effectiveness of the current business continuity plan	Assurance that the business continuity plan is fit for purpose	Susie Harrison	Desk top exercise complete	Q1
2.5.2. (d)	Video conferencing facilities installed in at least two offices.	More efficient meeting management.	Pauline Boyle	Procurement process completed Facilities installed	Q4
2.8.5.1	Appointment to the post of deputy Chief Operating Officer	Deputy Chief Operating Officer appointed to ensure robust management of the network	Pauline Boyle	Job description development using the national profile Post advertised and recruitment process completed	Q1
2. Financial Management					
3.2.1.	Compliance with new General Data Protection Regulation	Staff names will no longer be reported to the NIHR CC	Alex Howes	Process established in order to report spend on staff without using staff names	Q1
3.1.10.	Finance tool training	Finance information is completed in a timely manner and to a high quality	Alex Howes / Bhavesh Patel	Training delivered upon request	Q1-Q4
3. High Level Objectives					

HLO1	Increase the number of new non NHS studies successfully supported measured on positive feedback using the national survey. This is a new area so any feedback received will be reviewed to determine the usefulness of support provided. Identify what support research teams working in non NHS settings require to set up studies successfully and develop processes for Early Contact Leads to support these. Embed the new national process and crib sheet developed for Early Contact Team. Add specific fields in EDGE to support reporting and performance. Lessons learned from these studies discussed at Early Contact Team meetings. Targeting research related events at non NHS settings (schools, community settings, hospices and care homes).	Increase in the number of studies being delivered in non NHS settings.	Karen Hampshire, Kirsty Hunter and Mobeena Naz Julie Davis	Survey results. Process developed for Early Contact Leads to support sites in non NHS settings. EDGE fields updated. Lessons learnt report. Targeted events at non NHS settings. Investigate opportunities to develop local public health / wellbeing research studies which may be eligible for portfolio in non-NHS setting	Q2
	Explore why researchers are reluctant to use e-digital concepts to increase recruitment as uptake to e-digital during 17/18 was minimal. Continue to review and discuss various e-digital concepts with CIs as part of the Early Contact support. Continue with a E Digital EC Lead to support new ways of working and share with EC Leads. Apply knowledge to conversations with CIs during Early Contact to increase recruitment e.g. PICs, e-digital, Primary Care, Community Pharmacy, other CRN WM PO's	Increased recruitment. More cognisant of e-digital and how it can support research.	Karen Hampshire, Jonathan Forsythe	Potential to use digital to assist with recruitment discussed at every EC meeting Recording of the number of studies using digital to aid recruitment	Q4

	Early Contact Leads to continue to attend events and meetings to raise awareness of the service and added value of linking in as early as possible. Early Contact Leads to continue to highlight benefits ECER during delivery of any SSS training. Develop I&I projects to support this objective e.g. Target all CIs that didn't take up ECER at post PAF stage to understood why the service was not optimised.	Increase the target of 70% of all non-commercial studies supported through Early Contact at the pre-PAF stage.	Karen Hampshire, Kirsty Hunter and Mike Salmon	Events attended. Training delivered. I&I projects completed.	Q4
	Increase the number of local Chief Investigators by: Arranging Sandpit events Developing trainee groups Funding protected time for potential Chief Investigators	Number of local Chief Investigators increased.	Jeremy Kirk	Events arranged. Funding identified and awarded.	Q4
	Continue to work with local Universities to identify potential collaborations.	Number of local Chief Investigators increased.	Pam Devall	Meetings held with each University	Q4
	Ensure that the Business and Marketing Profile is used as a tool to attract new partners / studies to the region, for both commercial and non-commercial research studies	Increase number of research studies within the network.	Julie Davis / Sinead Collinge	Action plan created to fully investigate opportunities to increase the number of research studies in the region based on the new partners and maximise the USPs of the region, the Network and our POs	Q1 - Q4
HLO2	Continue to support Partner Organisations to deliver to time and target by conducting PO Industry Operational Visits	Strengthened relationships between the Industry team and PO's. Maintain realistic target setting for commercial studies and proactive performance monitoring within PO's to achieve 70% of delivering to HLO2a	Catherine Dexter	Conduct PO visits by end of Q2. Ensure strategic suggestions are discussed at Industry Strategy Group and rolled out region-wide as appropriate	Q4
	Divisional Performance Monitoring	Proactive performance monitoring and support with target setting Improved HLO2a across all divisions, and accurate and realistic EOI submissions	Catherine Dexter / Sinead Collinge	Peer review reports completed and reviewed monthly Actions from peer performance reviews implemented	Q2
	Roll out of Closed Study Review Project	An understanding of project failures and successes to ensure lessons learned across the CRN	Catherine Dexter	Process formally launched Documented in LMPS to enable network wide reporting at PO, Division and Specialty Group level. Collection of intelligent data to be utilised to predict future study deliverability	Q1

	To continue on from Annual Plan Objective 17/18 in identifying new ways to deliver the "IRAS/HRA for Sponsors Training" with an emphasis on the sponsors setting realistic recruitment targets with Sites.	Improved recruitment to time and target	Karen Hampshire /Mobeena Naz	Review of past training evaluation forms and identification of new areas to address Identification of specific studies where local Academics were Sponsors for actively recruiting studies and review time to targets performance and speak to Universities directly about how CRN can support their CI/ Research Team in improving RTT	Q2
HLO3	Establishment of the CRN Industry Steering Group	Increase the number of commercial studies delivered in specialties and partner organisations	Sinead Collinge	Engagement with PO's to educate and promote the value of portfolio adoption for all commercial studies including single site studies Identify areas of capacity and patient population through CRSLs and PO's Work nationally and locally to identify appropriate sponsors with study pipelines and introduction to the region and PO's through Specialty Groups	Q4
	Specialty Group Engagement	Utilise specialty groups as an opportunity to discuss regional development and opportunities to deliver commercial research	Sinead Collinge	Engage with CRSL and RDM's to promote the opportunities available in commercial research and look to build relationships with the Life Sciences community Q1 Look at business development opportunities and utilise specialty groups to host the Life Sciences Community and their pipeline	Q4
	See Further details in Life Sciences				
HLO4	Identify a solution to support PO's in identifying studies approaching 40 days from DSS to DSC. The aim of this solution would be to give PO's better oversight of all studies and helps us support delays in a proactive manner	To reach 70% by Q1 and 81% by Q4. If not then ensure all sites have identified reasons for not delivering to this objective.	Karen Hampshire / Mobeena Naz	Review of current trends within PO's regarding performance with HLO04 Liaison with PO's to identify how they currently manage oversight of live studies in Set Up Via the EDGE Working Group identification of possible solutions to provide oversight of live studies.	Q1
	Identify and target active commercial Sponsors who work with CRNWM PO's to attend 'IRAS/HRA for Sponsors' training sessions. There does not seem to be a robust understanding by Commercial Sponsors role in understanding the new HRA processes around capacity and capability.	Increase in the number of sites achieving NHS set up within 40 calendar days (from “Date Site Selected” to “Date Site Confirmed”)	Karen Hampshire / Mobeena Naz	Identification of active commercial/CRO's within the network Identification of which stakeholders require bespoke training	Q4
HLO5	Identify a solution to support PO's in identifying studies approaching 30 days from DSC to FPFV.	To give PO's better oversight of all studies and help the network to support delays in a proactive manner. The aim is to reach 70% by Q1 and 81% by Q4. If not then ensure all sites have identified reasons for not delivering to this objective	Karen Hampshire / Mobeena Naz	Review of current trends within PO's regarding performance with HLO05 Liaise with PO's to identify how they currently manage oversight of live studies in Set Up Via the EDGE Working Group identify possible solutions to provide oversight of live studies Implement the solutions - pilots, testing, training and full implementation	Q1 - Q3

HLO6a	Develop profiles for each PO detailing facilities, population served, patient pathways, and unique selling points. Use prevalence data to place studies where the population is.	Easily identify studies that match the profile of of the population. Studies open to meet the needs of the local population.	Portfolio Managers / Project Management Team	100% of NHS Trusts recruiting to portfolio studies Suite of Trust specific profiles which highlight the USPs for our POs, ensuring that not only commercial but non-commercial research teams bring their studies t to the region	Q4
HLO6b	Increase Partner Organisations delivering commercial research to 90%	Maximise the number of PO's offering commercial research to their patient populations	Sinead Collinge	Continue to support those organisations delivering commercial research successfully Consistently support and work alongside those organisations not currently delivering commercial research to ensure that all available opportunities are highlighted and where possible, delivered	Q4
HLO6c	Mapping new GP configurations and emerging models of care to monitor proportion of general medical practices recruiting into portfolio studies. As the GPs are merging the number of practices available to invite to participate will reduce. Use practice population data to monitor whether the patient population that we have access to is increasing rather than reducing	Ensuring that through the GP configurations we are accessing an increasing patient population, even if this is difficult to show because of the reducing GP practices. As number of GP practices reduces, the percentage will change	Pam Devall	Supporting individual practices and group schemes through the RSI scheme Adapting the RSI scheme to ensure that it remains both attractive to GPs and value for money Evidence that our service and our team to remain relevant in the new landscape	Q4
HLO7	Increase links with academic institutions	Increase the number of local Chief Investigators in Dementia Studies.	Juan Doblado Pavón	Support newly appointed DENDRON CRSL in organising meetings with relevant stakeholders.	Q4
4. LCRN Specialty Activities					

4.1.2.	All CRSL's will attend a joint meeting twice a year. The SSS will attend at least 90% of all CRSL meetings to present the benefits of ECER and Study Support Service . Each CRSL will hold a speciality meeting at least once a year. CRSL's will be provided with prevalence data and will contribute to the feasibility process. The RDM, Portfolio Manager and CRSL will meet regularly to review the portfolio.	CRSL's will be kept up to date, share best practice and monitor Identify CRSL meetings where ECER haven't attended already. Contact Admin support for the Speciality to identify dates for future meetings and ensure ECER attend. Showcase studies where ECER support has made a difference. Identify trends and studies supported through Specialties. Well informed clinical community. Promotion of research and the portfolio as well as what the network can offer researchers. CRSL's will have information required to ensure accurate feasibility is completed. CRSL's in collaboration with the RDM will performance manage the portfolio of studies with particular attention to recruiting to time and target.	Jeremy Kirk Karen Hampshire / Mike Salmon Research Delivery Manager BI team Research Delivery Manager	Register kept of meetings held and attended Meetings attended and feedback obtained Annual event held Information disseminated Performance meetings held	Q1 - Q4 Q3 Q4 Q2 Q1 - Q4
4.1.3.	The CD will continue to ensure each speciality has an appointed lead, through a competitive process.	Appointed lead for each speciality who holds the relevant experience and expertise to lead the speciality.	Jeremy Kirk	All speciality leads appointed through a competitive process	Q1
4.1.4.	Each CRSL will be provided with up to date information on the portfolio, prevalence data, performance data, local intelligence data and profile information for each PO.	Each speciality lead will have all the information required in order to inform accurate feasibility and performance manage studies.	Research Delivery Manager	Information prepared by Portfolio Managers and BI team CRSL's in receipt of information	Q3
4.1.5.	The CC will be informed of changes to CRSL appointments.	Coordinating Centre informed of changes in a timely manner	Andrea Shilton	Process developed and implemented	Q2
4.1.6.	Attendance at local and national meetings will be monitored and included in the annual performance meeting held by the RDM and CRL. All PCNSG meetings will be attended by one or more Primary Care CRSL	Management of performance. Aim to improve role of CRSL to make this more effective in terms of communication and influencing study targets to improve deliverability in the WM	CRL Mark Porcheret	Minimum of 75% of performance meetings attended All PCNSG meeting attended by at least one CRSL PCNSG Minutes will evidence attendance and actions	Q1 - Q4

4.1.7.	The RDM and Portfolio Manager will meet regularly with the CRSL to provide clinical and local intelligence into the early commercial feedback, non-commercial expert review, delivery assessments and performance reviews.	Early clinical engagement to ensure studies deliver to time and target.	Research Delivery Manager	Meetings held at least quarterly	Q1 - Q4
5. Research Delivery					
	Implementation of new WM wide Primary Care Research Site Initiative (RSI) Scheme Implementation of a pilot scheme to test what might be the best approach for groups of practices in terms of value for money and incentive to attract GPs to work with us	Single scheme in place which is equitable and offers all single site GP practices a streamlined and uniform process for sign up In conjunction with new finance forecasting this will allow improvements in budget setting to be made	Sue Elwell	Pilot group practice leadership scheme across all three localities Implementation of a single scheme	Q1 - Q2
	Development of RSI scheme for GP federations / super practices - The primary care landscape is changing and we need to have an RSI scheme that can be adapted to the new care models . Two pilot schemes are in progress and they will be reviewed during the year	Scheme in place that is fit for purpose, allows us to work at scale and best utilises our resources for maximum patient recruitment	Sue Elwell	Pilots complete Scheme in place for GP federations / super practices	Q1 - Q4
	Continue to maintain engagement with community pharmacies which is challenging due to lack of available studies	Maintaining engagement with pharmacies enables us to be flexible and respond to study teams who may wish to utilise pharmacy as a recruiting site	Sue Elwell	Availability of Research Ready Community Pharmacies in readiness for studies that may benefit from support from Community Pharmacy to enhance recruitment	Q1- 4
	Management of Excess Treatment Cost arrangements for Primary Care Studies	Improved equity of access Improved set up time of studies	Mark Stone / David Shukla	Process in place to manage ETC's for Primary Care studies across the network Report on the spend on the spend on ETC's	Q1

	Engagement with emerging GP collaborations In line with working principles 3.1.c,d,f,i,j,k - Inclusivity, equity of access, partnership working, consistency, flexibility and responsiveness to stakeholders -Engagement with the developing 'new care models' (NCM) being established NCM's are still being developed locally and established - they have not currently established clear 'research strategies' and we are going to be continuing to develop this and establish partnerships	The aim is to inform CRN West Midlands on how best to adapt its support for research delivery to ensure that patients being cared for by the New Care Models are given every opportunity to consider and, if desired, participate in research studies. This will also ensure engagement of primary care providers in the delivery of research	Mark Porcheret / Mark Stone / David Shukla	System developed to keep track of NCM - all new WM GP collaborations and emerging Care models mapped on EDGE EDGE used to log which GP practices are in each care model, their research activity, sign up to CPRD, involvement / interest in commercial research and resource as well as payments received WM GP Champions and First 5 GP Champions will be engaged in support of this work Regular reports to the LNMG and SLT will report progress and identify how support for research delivery may need to adapt	Q1 - system developed and first round of data collection Q2 - findings, and suggestions on adapting CRN support, reported to SLT. Second round of data collection Q3 and 4 - third and fourth rounds of data collection and further reports to SLT.
	Assist in the development and review of the Research, Development and Innovation structure across the Staffordshire CCGs The Staffordshire CCGs have come together with a new joint management team and single accountable officer. A new research steering group is required to be developed	Improvement of CCG engagement with research	Mark Stone / David Shukla / Jeremy Dale	Engagement with the Accountable Officer and shared management team of the Staffordshire CCG Steering group established Arrangements replicated in Central and South locality	Q1 - Q4
	Remove duplicates from current Primary Care Early Contact (EC) and Assess Arrange and Confirm (AAC) processes Undertake a pilot to assess the suitability and effectiveness of a combined role	This will aim to: - streamline the function - future proof the RF Team - improve service provision for researchers and Sponsors	Louise Jones / Gail White	Pilot complete Senior Research Facilitators (RF), Senior Research Nurses, two existing RFs and two newly recruited RFs trained to undertake the EC role. .	Q1 - Q2

	Improve Study Support offeried by restructuring the Primary Care team to provide support to the existing EC and RF teams	Improve the capacity in the teams and is also an opportunity for development forming succession planning within the team Primary Care Team will be more cost efficient	Louise Jones	Restructuring of the team complete Introduction of a new Band 5 hybrid role	Q1
	Improve Study Support Offering by continuing to refine and develop the new Primary Care training package that we now offer to stakeholders	Promote the services available and improve communications and engagement with research teams, sponsors and other organisations	Louise Jones / Gail White	Improved face-to-face training delivery package completed Online training material developed and made available to stakeholders	Q3 - Q4
	Improve process for Primary Care forecasting, cost calculation and budget management by centralisation, standardisation and streamlining of current study costing and forecasting process. Process is currently different in each of the three localities	Provide consistency and more accurate forecasting, as well as more stringent monitoring of budgets. In addition, ETCs will be tracked and monitored more effectively enabling CCGs to budget for these accordingly	Pam Devall	Review of current process complete Most efficient process identified New process implemented across the network	Q1 - Q2
	Primary Care Research Nurses working as one team. The Research Nurses have been working in isolation within their own localities often on the same studies. Progress needs to be made so that the nurses are working more collaboratively so that one nurse will be responsible for the running of a study across all three localities. To be able to do this processes need to be put into place: ● Standardised template for nurse working instructions ● SOPs ● Use of clinical templates where appropriate	Nurse team will work more efficiently and maximise recruitment	Jenny Stevens	Standardised template developed for nurses working instructions SOPs developed Clinical templates developed	Q4
	Primary Care Research Nurses to use EDGE as part of the care pathway	Standardised way of running clinics across the area so that locality differences make minimal impact	Jenny Stevens / Ian Thomas	All Primary Care research nurses trained on using EDGE Primary Care nurses have access to appropriate infrastructure to access EDGE Working procedures developed	Q4

	Pan-pathology Research Coordinator Role Awareness	Greater awareness of the importance of Pathology Coordination of research activity (assisting in research staff liaison, accessing pathology expertise, assisting in assessing feasibility, supporting study set up and sample processing) using the existing examples of pathology research coordinator roles in the region.	Dr Owen Driskell	Online webcast of the importance of these roles to the work of the CRN	Q4
	Develop the Pathology research advisory group RAPID	Group established to share best practice and promote pathology in research.	Dr Owen Driskell	Meetings held	Q1-Q4
	A measure of pathology contribution to research	Investigation of methods to generate quantitative evidence for the contribution of pathology to CRN research	Dr Owen Driskell	Establish a measure of research activity	Q4
	Collaboration with East Midlands	Sharing best practice, promote joint working and explore future research and delivery opportunities	Pauline Boyle / Jeremy Kirk	Meetings held	Q1-Q4
	Division 1 Cancer Speciality Meetings	Engagement with Subspeciality Leads (SSLs) to boost the interest, recruitment and knowledge in the specific disease sites. Interest has been received from Gynecological, Lung, Head and Neck and Skin cancers for meeting to be held during 2018/19.	Karen Hylton	3-4 disease speciality events held through the year	Q4
	Clinical Nurses Specialist (CNS) Project revised to East/West Midlands Project	Evaluation of the role of the Multidisciplinary Team (MDT) in supporting equity and access to cancer clinical trials. This has also been registered as an Improvement and Innovation (I & I) project.	Karen Hylton / Julia Locklin	Assessment of the level of engagement in cancer research at MDT time point. For all MDTs to consider potential cancer research for each patient discussed at these meetings.	Q4
	ENRICH	Maintain levels of care home engagement with research by either re-igniting research within care homes not engaged or replacing these care homes with care homes with current capacity to engage.	Andrea Shilton / Sandra Prew	Approximately 100 care homes engaged	Q4
	Continue to develop the Supportive and Palliative Care Specialty Group This year our key areas of focus will include supporting: Qualitative research - Benefits and barriers; Hospice CEO investment; raising awareness at Hospice UK 2018 Conference	Increase the opportunities for local hospices and care homes to become actively involved in research available via the NIHR portfolio Re-ignite research with hospices not engaged or struggling; ensure robust mechanics for identifying Portfolio studies; engaging care homes. Engage with East Midlands to determine the way forward for a nurse S&PC forum.	Andrea Shilton / Supportive and Palliative Care Specialty Group	Hospice CEO investment Raising awareness at Hospice UK 2018 Conference Nurse S&PC forum established	Q4
	Continue to develop and facilitate collaborative working among pharmacy clinical trials staff	Collaborative working among pharmacy clinical trials staff in secondary care	Julie Shenton /Jenny Warmington	Quarterly face to face meetings Established community of practice for pharmacy clinical trials staff across the region	Q1 -Q4

	HRA pharmacy technical assurance Support pharmacy departments involved in the delivery of clinical trials with the implementation of the HRA pharmacy technical assurance process	Pharmacy staff using the HRA pharmacy technical reviews as part of the local pharmacy review process for clinical trials as well as undertaking the reviews as appropriate	Julie Shenton / Jenny Warmington	Pharmacy departments updated upon progress of HRA implementation Review and lessons learnt report completed and disseminated	Dependent upon implementation by HRA
	Explore and scope potential opportunities for pharmacists to be PIs for studies across all sectors including secondary and primary care	Pharmacists undertaking the role of PI	Julie Shenton	Pharmacists expressing interest in undertaking the role of PI Record of the number of Pharmacist taking on the role of PI Forum established to share best practice	Q1 - Q4
	Implement a weekly process to identify data discrepancies within EDGE for PO's around C&C and increase the % at each quarter. Work with PO's where compliance and entering data in near time is an issue. Reinforcing the message via the Effective AAC training session and ROG meetings.	Reach 80% compliance for HLO4 and HLO5	Karen Hampshire / Mobeena Naz	Review of Study Start Up App on a weekly basis. Identify data discrepancies and review Trust Monthly reports to ensure they match. Identify common errors, data issues and trends around poor compliance and ensuring data is entered in real time by PO's.	Q4
	Identify and link in with local NIHR Partners (eg RDS, AHSN, NIHR Trauma Centre, NIHR BRC Birmingham, NIHR Birmingham Liver Biomedical Research Unit).	Raise awareness of the Network particularly around Commercial and and Non Commercial Study Support Service activities. Increase links and referrals to the Network.	Karen Hampshire / Sinead Collinge	Meet and Greet Event with all key Partners. Attend events and deliver presentations that compliment one another.	Q4
	Delivering on the Government Research Priority of Dementia Continue promotion and recruitment through Join Dementia Research. Identify dementia studies that can recruit in acute hospitals. Increase recruitment in care homes. Increase links with local academics.	All opportunities for participants to have the opportunity to be recruited into Dementia research	Juan Doblado Pavon	Increase number of people recruited on JDR to 8%	Q1 - Q4

	Following NHSE consultation for managing ETC's, identify what change is required in terms of resources, capacity and processes to prepare for the management of excess treatment costs. Liaise with other Networks specifically Wessex who already have a model in place. With Cohort 5 SSS Leads consider starting up an informal national SSS support structure to support all LCRNs with this major change in LCRN business if a national group is not developed. Identify a training needs analysis with the current team. Consider capacity issues. Make changes in systems and processes to accommodate management of ETCs.	Process established to manage of ETC's	Karen Hampshire / Kirsty Hunter	When National Guidance is released.	Q4
	AcoRD Moderator to develop and roll out national programme of AcoRD training for AcoRD Specialists across the Midlands (within Network and neighbouring Networks to be confirmed).	To ensure all AcoRD Specialists are trained to a national standard and consistent advice on AcoRD is provided across the Networks.	Karen Hampshire / Kirsty Hunter	AcoRD training delivered Consistent understanding and interpretation of AcoRD across the Networks Standard CRN Support Letter in use across the Networks Stronger community of support for AcoRD Specialists	Q4
6.1.6/7/8	Create strong links between the CRN BI Team, the Host ICT teams and system providers	Ensure that support is provided for all local and national systems	Pat Ryan / Hamid Hussain Linda Smith	Robust process for escalation via the CRN service desk email system Review opportunities to launch Structured Query Language (SQL) server to allow better sharing of data across all geographical and technical boundaries All offices have a Business Continuity Process to support business critical operations	Ongoing Q2 Ongoing

6.2.1/2	Ongoing provision of an LPMS solution that confirms to the requirements of the CRN CC	Support partner organisations to capture the defined minimum data set to measure research activity and allow for robust performance management of Portfolio research	Hamid Hussain / Julie Davis / Pauline Boyle	Review current contract with Edge (current LPMS provider), linking in with the other LCRNs who use EDGE to come up with a common approach and potentially benefit from joint negotiations for contract renewal when the current one expires	Q2
			Andrea Shilton	Ensure that all POs continue to use the system of choice (EDGE); aim is to get all 28 organisations on board (currently 27/28)	Q1
			Hamid Hussain	Review Terms of Reference and membership of Edge Working Group. This Group will take ownership of data quality initiatives and will promote improvements through the wider Research Operational Group, attended by all Trusts.	Q1
6.3.1/2/4	Provision of a specialist, experienced and dedicated BI Team with access to the necessary tools and systems	Provide CRN WM with the business intelligence data and analysis to enable robust performance management to be carried out, spotting trends, sharing best practice and advising partner organisations	Pat Ryan / Hamid Hussain / Julie Davis	Regular reports for CRN WM Executive Team, Partnership Group, Senior Leadership Team, Partner Organisations, research teams; ensure these are reviewed regularly and meet the needs of the organisation and use the official data as issued by the CRN CC	Ongoing
				Develop new Trust reports via Excel, as requested by several Trusts so they will have the ability to copy/paste tables and charts to their own Board reports	Q2
				Succession planning to ensure that there is coverage across the Network in terms of information management and expertise	Q1/2
				Divisional Peer Review form and discussion platform to enable Research Delivery Managers to gain support and tap into the experience of other RDMs in the CRN to ensure that studies have the best chance of delivering to time and target	Q1
				Develop a local business process to routinely investigate and resolve Business Rules Violations via the Data Quality ODP app	Q1
				Work with all Partner Organisations to monitor and resolve data discrepancies via the Study Start-up app: - Develop business process specific to different error types so that both Network and POs have clarify on responsibilities - User guide for POs - Keep West Midlands among the best five LCRNs. - More accurate data in CPMS. - Fewer queries from POs	Q1/2
				Devise method of reporting on the quantifiable specialty-level objectives, relating to objectives 3, 5, 6, 11, 20, 25, 27, 27B, 29, 30 - RDMs will have ongoing information about progress towards achieving targets and early warning of any potential shortfalls. - Several other objectives are about having named leads/champions etc. and do not merit ongoing reporting	Q2

6.3.3	Ensure that the BI Team contribute to the work of the national BI Team and collaborate with other regions	One or both of our BI Managers will attend each meeting of the VBIU and any national meetings which relate to BI	Pat Ryan / Hamid Hussain	Feedback all relevant information to both the Network Senior Leadership Team and the Partner Organisations as appropriate. A member of our BI team will take part in the EDGE-CPMS teleconferences and ensure cover as required.	Ongoing
	Work up a proposal to run a pilot study in Primary Care in the WMs via CPRD	Defined approach to working with CRN and CPRD resulting in improved recruitment, improved range/quantity of studies and improved service offering to study teams	Dr Rebecca Harrison	Feasibility searches improved Confirmation that CPRD searches can be completed across entire LCRN	Q4
	Encouraging GP practices in WM region to sign-up to CPRD WM CRN and CPRD are working closely together to identify opportunities for GP practices and their patients to participate in clinical studies (in line with POF working principle 3.1.d)	Increase in GP CPRD member practice across WMs Increased involvement from large scale organisations e.g. superpractices, GP federations Continue to be leading LCRN for CPRD participation Improve recruitment Increase in the number of studies we can offer practices Improved contribution to the national initiative to increase number of GPs signed up to CPRD (Jonathan Sheffield's letter)	Dr Rebecca Harrison	Relationship building with large scale organisations Feedback acquired from member practices about the value of Quality Improvement reports Proposal worked up to run a pilot study in the WMs via CPRD	Q4
	Development of a West Midlands Wide Research Optimisation Support Team (ROST) group who is responsible for setting and assuring the standards required to help identify patients on GP systems. The group will consist of RFs, manager, nurse, practice manager and GPRF to give a broad view on issues arising.	To quality assure all searches and simple pop-ups to identify patients for research. They will act as the 'expert' for the rest of the team to consult. Part of all members roll will be to educate the rest of the team on how to build effective searches so that the workforce is upskilled.	Jenny Stevens	Provision of a quality assured service to study teams providing a consistent approach to patient identification	Q2
	To support pharmacy departments in Trusts involved in the delivery of clinical trials with EDGE including using EDGE to collect pharmacy set-up and approval times	Facilitate pharmacy departments to assess and plan workload relating to clinical trials	Jenny Warmington	Pharmacy departments in CRN WM POs to collecting and analysing pharmacy approval and set-up times	Q4
7. Stakeholder Engagement and Communications					
7.1.1	Engagement opportunities offered by Join Dementia Research (JDR) and the UK Clinical Trials Gateway (UKCTG) will be communicated to all appropriate stakeholders	Traffic to JDR and UKCTG from the West Midlands will increase	Claire Hall	Signposting to both sites included in all materials and communications where appropriate, including social media posts	Ongoing

7.1.2 (and 7.3.3)	Support for new and emerging NIHR strategies containing stakeholder engagement and communication goals	The CRN Communications Lead will continue to work closely with the Host Organisation Communications Team to provide a joined up approach which sells the successes of the Network to the media and to external organisations eg CQC. All requirements of the Stakeholder Engagement Contract Support Document will be fulfilled.	Claire Hall	Press Releases and Comms publications to highlight RWT as the host, and publicise the successes in year	Ongoing
7.1.3/4	Provision of a sufficient non-pay budget line and resource to deliver PPIE, Engagement & PPIE activities	A dedicated communications budget line and Comms Lead ensures that all potential engagement workstreams are viable and prioritised	Julie Davis	A suite of publications from the Communications Team which market the CRN to internal staff, partner organisations, external companies and partners (eg Industry and Clinical Trials Units etc).	Ongoing
7.1.5	Develop and deliver a local Communications Plan that recognises the LCRNs position as part of a national system	The Communications Lead will deliver a high quality multi-channel communications programme to support: - the implementation of the NIHR CRN NHS Engagement and Communications Strategies and the NIHR Communications Strategy - the implementation of the Communications Contract Support Document - the development and maintenance of the LCRNs positive reputation - transparency of local performance on research delivery - strong internal and external stakeholder relationships - patient, staff, carer and public awareness of local clinical research opportunities - effective working with other parts of the NIHR at local, regional and national level	Claire Hall	Increased use of digital tools, including monthly blogs, videos and social media to implement all Communication Strategies. Recruitment to studies directly influenced by use of social media Increased focus on marketing to Industry - opportunities identified to raise awareness of the Network to potential key commercial partners by working with Industry Operations Manager Run Network Awards for Partner Organisations (Oct) and VIP Awards for Staff (Dec) building on success of last year's events in strengthening internal and external stakeholder relationships Why We Do Research campaign - production of a suite of materials showcasing the changes in practice resulting from research in the WM, for use in raising patient, carer and public awareness Production of an online/hard copy resource created by the NIHR Regional Communications Group set up in 2017/18, showing how we work together. Identification of further opportunities to work together via an online forum. Work with Network's PPIE team to support their action plan where required. Recognise the contributions on those involved in research by 'thanking' patients, research teams, PIs and Support Departments for their input into the CRN WM's objective of increasing the number of patients accessing clinical trials	Ongoing Q2 Q3 Ongoing Q1 Ongoing Ongoing
7.1.6/7	Contribution to delivery of national NIHR campaigns to include NHS 70, I Am Research, JDR and UKCTG	Production of press release, consistent social media activity, staff and patient stories (where applicable) per campaign. Link in with Host Organisation when required Produce four 'Our Stories (three patients and one staff) within the financial year to be published on the NIHR website. Coverage in local media	Claire Hall	Writing and distribution of press releases, patient stories and supporting social media activity: I Am Research NHS 70 JDR & UKCTG Identify, write and submit four 'Our Stories'. Sell in where possible to local/national media and Trust communication channels	Q1-4 (Ongoing) Q1 Q2 Ongoing Q1-4
7.1.8	Ensure that the whole LCRN operates in line with brand guidelines, operational requirements and national messaging	Encourage consistency and brand awareness, and promote a positive reputation by ensuring that all materials produced locally feature the most recent branding and that outdated materials are not in use. Ensure that Network staff are aware of nationally produced branded materials such as specialty leaflets by promoting their use through internal communications channels.	Claire Hall	Updates issued via internal communications channels where required Oversight of all materials produced to ensure adherence to guidelines/messaging	Ongong Ongoing

7.1.9	Ensure that all Partner Organisations or researchers in receipt of funds or support from the NIHR acknowledge this in publications	Encourage acknowledgement by including periodic reminders in our Network Newsletter which is distributed to staff in all Partner Organisations.	Claire Hall	Include quarterly reminders in Newsletter	Ongoing
7.2.1 (and 7.3.1)	Raise awareness of research amongst patients, carers, the public and healthcare professionals. See also 7.2.4, 7.2.7 and 7.2.8.	Patients and the public from the West Midlands wide, diverse community are informed about research, International Clinical Trials Day and national/local initiatives using a range of methods and approaches. Via the CRN WM PPIE Google web page there is an established systematic process for patients and the public, CRN WM staff, NHS partner organisations and community health organisations to access CRN WM PPIE information and support e.g. PPIE advice, training, study support and collection of patient stories. CRN WM has a visible presence online utilising social media frameworks.	Mary-Anne Darby - Head of PPIE	Promote, implement and coordinate annual/ongoing NIHR campaigns, initiatives and projects within the CRN WM e.g. 'I Am Research' and Join Dementia Research (JDR). Work with and support Network Partners to host Research Awareness Events including the annual celebration of International Clinical Trials Day on 20th May 2018. Work with the Network's Communications Lead and Divisional Research Delivery Managers to organise and support activities to celebrate Health Awareness Weeks/Days throughout the year. Collaborate with Partner Organisations, NIHR partners and voluntary organisations to raise awareness of dementia research in the Care Home/ Retirement Village/ Live at Home Scheme settings using a play about dementia. Support staff working in Hospices in the West Midlands to raise awareness of research by appointing Research Champions/ PRAs and hosting research displays and engagement events. Promote the use of NIHR CRN / CRN WM PPIE resources such as: - Leaflets e.g. 'I Am Research' and 'Join Dementia Research' and Banners and Postcards e.g. Local Patient Stories. Promote the UK Clinical Trials Gateway (UKCTG). Launch and promote the use of the CRN WM PPIE Google webpage amongst patients, the public, CRN WM staff, NHS partner organisations and community health organisations. Communicate with patients, carers and the public via social and digital media e.g. Twitter and Facebook regarding CRN WM PPIE activities.	Q1 Q1-Q4 Q1-Q4 Q4 Q3-Q4 Q1-Q4 Q1-Q4 Q1 Q1-Q4
7.2.2	Development and Implementation of a PPIE Action Plan	A CRN WM PPIE Action Plan aligned and cross referenced to the CRNCC PPIE Strategy is produced. Choice, equality and diversity is evident in the PPIE Action Plan.	Mary-Anne Darby	Produce the PPIE Action Plan Implementation of the PPIE Action Plan	Q1 Q1-Q4

7.2.3	Development of meaningful patient and public representation and involvement at all levels and in all activities across the CRN WM. See also 7.2.4.	There will be evidence of increased and meaningful patient and public representation and involvement in CRN WM activities across Divisions and Specialties.	Mary-Anne Darby / Carly Greene	Work with/support staff in the Divisions to develop PPIE plans and implement PPIE initiatives. Following the successful appointment of a new adult lay member on the Partnership Group, work with all the lay members and Patient Research Ambassadors (PRAs) to increase their involvement in helping to achieve the Network's objectives e.g. HL02. Following the successful appointment of seven Network Patient Research Ambassadors, ensure that they are involved in the activities of the Divisions/Specialties where they have a particular interest, expertise or experience. Continue to review the membership of the Young Person's Steering Group (YPSG) to ensure there is representation from different communities and across all the age groups i.e. 11 years plus. Facilitate and support the YPSG in their activities including: - further developing their working relationship with MidTECH and commercial organisations e.g. GSK - conducting a research study – Mental Health in Schools - challenging the language used in Palliative Care - planning an event to celebrate '10 Years of the YPSG and raise awareness of research' - developing further links with schools across the West Midlands. Continue to support and develop the role of the Network's Join Dementia Research (JDR) Champions. Establish lay members as part of the Hospices' Research Governance Groups. Inform Research Delivery Managers and CRSLs/CRLs of the PPIE support available from the CRN WM PPIE Team and Patient Research Ambassadors. Ensure Network Patient Research Ambassadors and Lay Members are informed of the opportunities for involvement in Network activities e.g. via the PPIE Google Community.	Q1- Q4
7.2.4	Implementation of the Patient Research Ambassador Initiative (PRAI) across the CRN West Midlands	There is an increased number of Patient Research Ambassadors (PRAs) across partner organisations. Communities of best practice are cultivated, good practice is shared and PRA activities are celebrated. There is a process to systematically measure the impact of the local PRAI.	Mohammed Shaikh - PPIE Cross Cutting Theme Lead	Produce a local Patient Research Ambassador Initiative (PRAI) Delivery Plan 2018/19 with support from local PRAs and the West Midlands Patient Research Ambassadors' Regional Forum. Support all Trusts and NHS organisations, particularly in primary care, across the Network to establish and further develop the Patient Research Ambassador role. Share best practice of PRA activities and experiences across the region using the West Midlands Patient Research Ambassadors' Regional Forum e.g. Collation of PRA case studies and PRA tweet engagement. Develop a system to measure the impact of the PRA initiative in the region. Host a PRA Annual Networking and Celebration Event in the West Midlands.	Q1 Q1-Q4 Q1-Q4 Q1-Q2 Q4

7.2.5 (and 7.3.2)	Continued membership and participation in the West Midlands Public Involvement and Lay Accountability in Research (PILAR) Group	There is collaboration and sharing of best practice in PPIE amongst NIHR partners. There is information about research and opportunities for involvement for patients and the public available from research organisations across the West Midlands.	Mary-Anne Darby	Attendance at bimonthly PILAR meetings. Participate in collaborative work streams. Sharing of good practice.	Ongoing
7.2.6/7	Collation of feedback from participants about their experience of being involved in research. See also 7.2.7.	Patients' stories about their experiences of being involved in research are accessible to and shared with patients, the public and staff. An annual Patient Research Experience Survey will be undertaken. A written report, showing analysis of results with a set of recommendations will be produced and fed into the CRN WM PPIE Annual Plan 2019/20.	Mohammed Shaikh / Carly Greene	Collate patient stories and ensure these stories are shared via the CRN WM website and other media. Using the 'lessons learnt'/recommendations from the 2017/18 Patient Research Experience Survey (PRES) review the survey methods (including questionnaire) to plan for the 2018/19 PRES. Undertake the PRES in the Mental Health setting and in Care Homes. Input and analyse the data. Produce PRES reports. Develop recommendations and an action plan following the 2018/19 PRES to improve delivery. Feedback findings to the CRN Coordinating Centre	Q1-Q4 Q1 Q2 – Q3 Q3 Q3 Q3- Q4 Q4
7.2.8	Development and provision of learning and development opportunities for patients, carers, the public, lay representatives and staff.	There is a comprehensive programme of PPIE training available for patients, the public and staff across the CRN WM. Network PRAs are involved in the review, development, planning and delivery of PPIE training. There is an increased awareness and knowledge of research, PPIE initiatives and PPIE training available (face to face and online) amongst patients, carers and staff.	Mary-Anne Darby / Mohammed Shaikh	Review the Building Research Partnerships Training programme and resources following feedback from programme participants. Develop the 'Research Familiarisation' workshop to use at NHS partner organisations and community health organisations in the West Midlands. Work with Network PRAs in the development and delivery of the 'Research Familiarisation' workshop and Building Research Partnerships Training Programme. Promote and encourage patients, the public, PRAs and staff to register and undertake the Massive Open Online Course (MOOC): Improving Healthcare through Clinical Research. In collaboration with members of the West Midlands Public Involvement and Lay Accountability in Research (PILAR) Group continue to deliver a range of PPIE in research training.	Q1 Q1 Q1-Q4 Q1-Q4 Q1-Q4
7.2.9	Further development of the CRN WM PPIE Google Community.	A PPIE Google Community is created. PRAs, Lay Members and PPIE staff from across the West Midlands are able to communicate, share best practice and opportunities for participation and involvement in research.	Mary-Anne Darby	Ensure all PRAs, Lay Members and PPIE staff in the CRN WM are invited to join the community. Provide guidelines, training and ongoing support in the use of the google community. Post information e.g. opportunities for participation and involvement in research. Monitor and evaluate the use of the community.	Q1 Q1-Q4 Q1-Q4 Q1-Q4

	Identify and implement a business process to review the missing and inaccurate data in the Study Start Up app and EDGE on a weekly basis and ensure it has kept below 5%. Update the current EDGE SOP regarding the EDGE data points to support PO's in completing EDGE data accuracy. Support PO's with direct training on the SOP. Review the current compliance of the unresolved errors with our PO with the App on weekly basis. Identify any key trends with the errors and introduce solutions. Randomly identify errors to ensure they have been included in the Trust Monthly Data Compliance Reports, if not investigate why not. Liaise with BI and DPM's to ensure missing sites are added to CPMS where CRNWM are lead and participating when other LCRNs have followed due process. Contact the National BI Team where unresolved errors are their responsibilities.	Missing and inaccurate data below 5% .	Karen Hampshire / Mobeena Naz	Business process implemented SOP updated Training delivered Compliance reviewed weekly	Q4
7.2.10	Further development of the PPIE Database.	Up to date information about contact with patient/carer/public groups and organisations is held and can be made available in a timely manner.	Mohammed Shaikh	Record details of contact with patient/carer/public groups and organisations on the PPIE database. Provide information about this as requested.	Ongoing
7.2.11	Identification of a Senior Leader with responsibility for PPIE.	There is participation in both national and local PPIE initiatives and an integrated approach to PPIE is delivered.	Mary-Anne Darby	Ongoing	Ongoing
7.3 (and 4.14.6)	Include PPIE representation in membership of Improvement and Innovation Steering Group	To have a lay member as a member of the Improvement and Innovation Steering Group	Carly Craddock / Julie Shenton	PPIE representative included in the Improvement and Innovation Steering Group Terms of Reference	Q1 - Q2

7.3 (and 4.14.6)	Engage with local LCRN partners to explore opportunities to collaborate with regards to embedding a culture of continuous improvement	Identify potential opportunities for collaboration with local LCRN partners e.g. other parts of the NIHR based in the region, the local AHSN and other external organisations to embed a culture of continuous improvement	Carly Craddock / Julie Shenton	Engagement with other local LCRN partners and identification of initiatives to embed a culture of continuous improvement with these organisations; if these organisations are found to be looking to embed a culture of continuous improvement also, look for ways to work collaboratively with them to achieve this	Q3
7.3 (and 4.14.6)	Share impact of continuous improvement projects with other LCRNs in our regional LCRN-cluster collaboration i.e CRN EM and CRN Eastern	Share impact stories of continuous improvement projects delivered in CRN WM with CRN EM and CRN Eastern with the intention that all three LCRNs promote and showcase the impact stories simultaneously. Likewise to share impact stories in CRN WM that CRN EM and CRN East Midlands have identified.	Carly Craddock / Julie Shenton	Continuous improvement impact stories from CRN WM shared with CRN EM and CRN Eastern and the impact stories shared simultaneously with staff across all three LCRNs; likewise CRN WM to share impact stories from CRN EM and CRN Eastern simultaneously with the respective networks	Q2 and ongoing
7.3 (and 4.14.6)	Joint event with other LCRNs in our regional LCRN-cluster collaboration i.e CRN EM and CRN Eastern to showcase Improvement and Innovation projects	Hold a joint event with CRN EM and CRN Eastern to showcase Improvement and Innovation projects including projects delivered by those on the ALP programme	Carly Craddock / Julie Shenton	Joint event held for staff to share Improvement and Innovation projects across the three LCRNs in our regional LCRN-cluster collaborative	Q3 - Q4
7.3 (and 4.14.6)	Continue to deliver CRN WM Continuous Improvement Strategy 2016-19	CRN WM Improvement and Innovation steering group members to continue to lead and deliver ongoing strategic projects identified from CRN WM Continuous Improvement Strategy 2016-19	Carly Craddock / Julie Shenton	Completion of ongoing strategic projects	Q4
7.3 (and 4.14.6)	Review of CRN WM Continuous Improvement Strategy 2016-19	Undertake a review of the CRN WM Continuous Improvement Strategy 2016-19 as midway through 3-year lifespan and update as necessary	Carly Craddock / Julie Shenton	CRN WM Improvement and Innovation Steering Group away day to review the strategy and update as necessary	Q2/Q3
7.3 (and 4.14.6)	Work collaboratively with other LCRNs to implement the Improvement and Innovation Framework when available	When available, work collaboratively with other LCRNs in our regional LCRN-cluster collaboration i.e CRN EM and CRN Eastern as well as other LCRNs if appropriate to implement the Improvement and Innovation Framework	Carly Craddock / Julie Shenton	Local implementation of the Improvement and Innovation Framework	dependent upon availability of the framework
	Develop and implement an engagement plan to support engagement with all POs in relation to Early Contact. Specifically focus on strategies to improve engagement with POs unlikely to signpost to the Early Contact Service.	Increase the number of POs that would signpost to the Early Contact service from 80% to 90%.	Karen Hampshire / Kirsty Hunter / Mike Salmon	Engagement plan to be completed. Strategies to work with POs suited to support required. PO involvement in I&I projects to improve engagement. Revisit PO who will signpost to maintain positive engagement.	Q4

	Identify POs that deliver ECER themselves. Invite them to an event with CRNWM ECER Team (SSS and PC) to support best practices and ensure a consistent service is delivered to our Chief Investigators and Study Teams.	Increase the level of current knowledge and joint working around ECER with those delivering Early Contact. This will include SSS ECER, PC ECER and those POs who deliver this work.	Karen Hampshire / Kirsty Hunter	Joint meeting.	Q3
	Identify and link in with West Midlands NIHR Partners (RDS, AHSN, NIHR Trauma Centre, NIHR BRC Birmingham, NIHR Birmingham Liver Biomedical Research Unit, CLAHRC) to discuss and raise awareness of the Network in relation to added value of the Study Support Service for Commercial and Noncommercial Research. Identify where there is best practices or signposting can occur.	Increase links and referrals to the Network and especially the service from other NIHR Partners. Attending events and delivering presentations that compliment one another.	Karen Hampshire / Sinead Collinge	Meet and Greet Event with all key NIHR Partners.	Q4
	Develop a training session. Contact our local Academic and PO's Sponsors regarding the Training. Review feedback to see whether it was a successful and further training is required.	Support our local Academic and PO Sponsors with a new training session on UK Policy Framework for health and social care.	Karen Hampshire / Mobeena Naz	Develop and deliver training. Review and act upon feedback from the training.	Q2
	Identify non eligible studies for 17/18 and see whether a trend exists eg students being signposted to the NIHR for research management and governance support. Identify a solution to decrease the number of studies utilizing the PAF process as well as ECER support inappropriately eg training with local Academic Sponsors.	Review 17/18 Non Eligibility studies to see whether local Academic Sponsors are signposting inappropriate researchers to the CRN. This will ensure that ECER Leads are supporting potential eligible studies only. If a trend is identified then implement a solution with the local Academic Sponsors.	Karen Hampshire / Mobeena Naz	Identify trends, develop action plan.	Q3
	Liaise with the local NIHR accredited CTUs to discuss improvements to joint working relationships around ECER.	Follow on from the success of PO engagement with ECER activities during 17/18 this will be rolled out to CRNWM CTUs to improve joint working.	Karen Hampshire / Kirsty Hunter	QJoint meetings held.	Q2

	Regional alignment with NIHR RDS West Midlands	Joint meeting to develop collaborative working	Dr Kirsty Hunter / Dr Owen Driskell	Joint Meeting	Q4
	Further develop links with the NIHR IVD Cooperatives	Working with the IVD cooperatives and Regional Laboratory Networks (eg WMLMRG) to promote regional laboratories as sites for IVD Cooperative pipeline studies (Important areas include genetics, microbiology and biochemistry).	Dr Owen Driskell	Site Identification Protocol	Q4
	Further development of the Primary Care Participate Newsletter	- Aim is to improve the recently streamlined (West Midlands Wide) newsletter to acheive further joined up communication between CRN, universities, study teams and GP practices. This form of communication highlights new studies which GPs may participate in to enable them to offer their patients the opportunity to get involved in research. - Widen the scope of interest to on-line readership - Developing themed editions: Spring 2018 commercial edition with articles from Industry team.	Jenny Oskiera	E-Participate: We aim to add links to other publications, websites, podcasts etc The forthcoming edition will include a link to Keele CTU courses and we anticipate WMS CTU following suit in the summer. We are exploring the value of a link to WMS Academic Primary Care and equivalents at other universities Themed editions will raise awareness in selected key areas, increase activity in practices already engaged and encourage others	Q1/Q2 - Progress under way with link to Keele CTU re courses/ their newsletter; WMS CTU to follow later in the year. 1st theme in Spring - Q1 2nd theme Q3/4 tbc
	Cancer Patient Research Ambassador Role (Cancer PRA)	To pilot the use of NIHR Cancer PRA's to promote cancer research and trials within the CRN WM. Attendance at the NCRI Cancer Conference.To contribute to educational events such as Division 1 Annual general meeting (AGM).	Ivanna Baker/Ami Salter (Division 1)	Mystery Shopper exercise. Attendance at West Midlands Patient Research Ambassador regional forum (PRA). NIHR PPIE Cancer PRA Our Stories video. Providing cancer specific PRA support to Early Contact and Engagement team for cancer protocols.	Q4
8. Organisational Development					

8.1.3	Ongoing strategic leadership and operational management of the CRN WM Research Training Collaborative (WMRTC) - a region wide reciprocal initiative which aims to ensure that research staff and clinical teams supporting research can access high quality locally-provided training which is fit for purpose and consistent between host organisation/facilitator.	Locality based programme planning and delivery of training in GCP and other research-related topics which are aligned to the three NIHR CRN priority areas for organisational and workforce development.	Emily Linehan (WFD Training Manager)	Maintain and build on the success of our newly established locality-based training collaboratives to encourage PO participation in research-related learning and development initiatives. Use established WFD trainer roles (3 x 0.2 WTE delivery staff released to support WFD activities) to continue to support the delivery of strategic programmes including PI Essentials workshops and 'Fundamentals..' across our POs and embed these within the WMRTC model / region-wide programme. Plan and deliver an annual stakeholder event for clinical research delivery professionals Provide regional facilitator development opportunities to retain experienced facilitators and maintain their competence and credibility.	Q1 - Q4
		Development of a WMRTC strategy for 2018-2022 aligned to and complementing the CRN WM comprehensive workforce plan (see 8.1.5)	Hannah Reay (WFD Lead)	Identify representative stakeholders to draft a WMRTC strategy document Consult with relevant PO and HEI representatives including Trust-based learning and development departments (not specifically research related) Finalise a Strategy document aligned to local, regional and national workforce planning initiatives	
	'Clinical Research is Everyone's Future' (CRIEF) promotion project (I&I project linked to 8.1.3, 7.2.2 and 7.1.6)	Use of CRIEF materials in Trust-wide corporate induction programmes and research staff induction	Jane Willcocks (WFD Facilitator)	Plan project and engage POs via Partnership Board and R&D managers Identify pilot sites and process to gain approval to add materials to corporate Trust-wide induction programmes Embed CRIEF video 1 into Trust-based face-to-face Induction programmes and evaluate over a 3 month period Identify opportunities to embed CRIEF materials to support awareness initiatives within POs and other potential/research-active organisations in the West Midlands	
8.1.4	Workforce profile project	Establish a profile of research staff in the West Midlands who are directly and indirectly funded by CRN WM	Hannah Reay (WFD Lead)	Plan project in consultation with PO/WFD representatives and to reflect regional and national priority areas for workforce development initiatives (e.g. clinical research practitioners) Identify sources of existing information / gaps in regional intelligence Gather and collate workforce data Analyse data to understand local capacity and capability within priority groups (aligned to Specialty Objectives regarding numbers of trainees / 'new' PIs / early career CIs and ongoing regional I&I projects e.g. non medical PIs and clinical research practitioners)	Q1 Q1 Q1 - Q2 Q2 - Q4
		Establish a regional community of non-registered patient facing delivery staff (Clinical Research Practitioners)	Kerri Mason (CRP, North Staffs Combined Trust; NIHR CRN ALP Alumni)	Negotiate time/funding to release CRP within a PO to lead the regional CRP initiative Identify the regional clinical research practitioner workforce and gather profile data Plan and deliver a regional event for CRPs	Q1 Q1-2 Q3-4
8.1.5	Development of a comprehensive workforce plan	Engage all relevant stakeholders in formulating a workforce plan for 2018-20	Hannah Reay (WFD Lead)	Establish a profile of CRN WM funded staff (see 8.1.5) Undertake a listening exercise with research workforce leads within POs (lead nurses / R&D managers) to gather information about workforce availability, requirements, existing PO-based strategies for sustainability and local priority areas Collate information and draft workforce plan for PO consultation Finalise and submit workforce plan to NIHR CRN Implement the CRN WM workforce plan	Q1 - 2 Q1 - 2 Q2 Q3 Q3 onwards

8.1.6	Supporting the delivery of an integrated approach to WFD across NIHR CRN	Leader identified to coordinate workforce planning, recruitment, development and retention	Hannah Reay (WFD Lead)	Leader Identified Ongoing implementation of the CRN WM Vacancy process project (streamlining and improving consistency in internal CRN WM recruitment/induction processes) Actively contribute to WFD Leads community See also 8.1.3 and 8.1.5 Ongoing implementation of a competency framework for research delivery staff in patient-facing and non-patient facing roles building on regional and national frameworks (existing and in development)	 Q1 - Q4 Q1 - Q4 Q1 - Q4
8.1.7	WMRTC learning resource development and review to increase blended learning opportunities	Complete ongoing review of WMRTC learning programme to ensure it is responsive to current and anticipated learning needs Offer blended learning opportunities within our established programme	Emily Linehan (WFD Training Manager) Jane Willcocks (WFD Facilitator) Project Team	Milestones within ongoing initiatives include: - Piloting the 'bundling' of training sessions (offering multiple topics on the same day) - Introducing blended learning through the use of pre-course reading/resources/e-learning and pilot webinar of Governance topics - Existing sessions - topic specific content review (paediatric consent & communication; intro to valid informed consent) - Create continued learning opportunities for Network staff in Google Hub platform, prioritising Kanbanchi and Hangouts, to promote effective ways of working	 Q1 - Q2 Q1 - Q4 Q1 - Q4 Q1
8.1.8	Primary care context-specific training materials	Complete pilot of adapted national course materials and share with CRN by applying for adoption on the National Directory	Jane Willcocks (WFD Facilitator)	Building on the successful adaptation of materials to create the 'Fundamentals of Clinical Research Delivery in Primary Care' in 2017/18 the materials will be piloted in collaboration with primary care colleagues in CRN Yorkshire & Humber. Pilot data will be collated and a final version agreed Application for adoption onto the National Directory Similar adaptation & piloting of GCP materials for delivery in a primary care context will be complete by the start of this plan; application for adoption onto the National Directory for this course will be made	Q1 Q2 Q2 Q1

8.1.9/10	Finalise a wellbeing strategy that enables the CRN to create the conditions that contribute towards a fulfilling employee experience resulting in high levels of productivity which in turn contributes to organisational success.	Extended roll out and evaluation of the 'Wellbeing Pick and Mix', a wellbeing programme designed to ensure that all of our staff benefit from a range of opportunities that suit their personal needs, learning styles and work life arrangements - helping them to self manage their own wellbeing. Offer to all LCRN funded staff	Julie Davis	Monthly workshops with a focus on healthy body, healthy mind and work life balance Monthly Blogs on wellbeing linked to the workshops, complete with signposting for further information Google site for staff so we have a single point of contact for all wellbeing initiatives Standing desks rolled out across the region with evaluations on impact Walking meetings or lunchtime strolls being encouraged. Regular 'step challenges' arranged to encourage increased activity and an in house fitness intervention trialled VIP Awards to reward and recognise staff contributions. Talent Management Strategy to make the most of the skills we have in the Network Fix It Friday - encouraging everyone to do one thing, of their choice, that makes a difference to the CRN Team lunches, meetings, notice boards and events Coaching and Mentoring Scheme to support development Staff suggestion box linking in with Innovation and Improvement initiatives Pay it Back - volunteer for one day with a health related organisation and raise the profile of research in the CRN Wellbeing Library - sharing books on personal development and wellbeing in the offices Relaxed Dress Code to encourage people to be more active and creative in the workplace Career Progression Pathway to demonstrate a commitment to personal development Access to Apps and surveys to self manage wellbeing Access to host organisation Wellbeing package to include staff benefits pages, counselling, bereavement support, smoking cessation, one-to-one health trainer, advice on alcohol and substance misuse and salary sacrifice schemes for health care. Launch Line Managers Away Day to ensure that all managers, regardless of level, are trained and developed appropriately and in turn offer the same level of performance reviews (100% compliance) and personal development opportunities to their teams Revisit the HLOs and You document to make it more personal and less about the HLOs, but instead highlights how all LCRN funded staff can engage with, and help achieve, the strategic initiatives of the CRN WM	Ongoing initiatives - to be trialled in Q1 with intended wider roll out in Q1/2
	Fundamentals of Clinical Research Delivery (FoRD) for Laboratory Staff Webcaste	Online webcast provision of the FoRD for Lab Staff Training	Dr Owen Driskell	Online webcast of the FoRD Lab Staff Training	March 2019
	Raise awareness of the PI role among pathology staff (including Histology, Microbiology, Biochemistry and Immunology).	Increased number of PIs from pathology staff	Dr Owen Driskell	PIs from Pathology	Q4

	Design and development of a national register/directory for pathology staff operating in research delivery without a professional registration option	Supporting the CRN lead for Pharmacy and AHPs in engaging the AHCS in exploring the generation of a registry/directory for this laboratory workforce.	Dr Owen Driskell	Registry developed	Q4
	Primary Care Leadership work - Implementation of a work package to support the Primary Care Delivery Support Team to improve how they work in terms of consistency, flexibility and agility	Further progress of the work undertaken with Gillian Felton from the CC to get the WM Primary Care Team working better as one team to address the challenges that we face. Team have identified challenges, set up five workstreams and started to work together on possible solutions - A project lead role will be developed to oversee all projects - A forum will continue to enable team members to identify and work together to resolve any future issues	Pam Devall / Jess Graysmark	All projects registered as I & I projects and progressed in this format A process to enable this work to continue will be implemented WM Primary Care Team will work seamlessly across the region and will identify themselves and be viewed as one team	Q4
	Primary Care Research Nurses	Primary Care Nurses will be given the opportunity to work in Secondary Care for 3-6 months. A pilot will run in the north locality where one nurse will work in secondary care for 3 days a week This will help nurses gain experience of CTIMPs and learn the standards that are required to run a drug trial. It . all these standards are transferable into the Primary Care setting and should be used as the gold standard. Secondary to this is the opportunity to upskill the nursing workforce making it more flexible	Jenny Stevens	Nurses will gain experience of CTIMPs and learn the standards that are required to run a drug trial. It . Upskilled nursing workforce making it more flexible	Q2
	Evaluate the ACROSS system	To have a six - twelve month review/audit of the ACROSS system for requesting nursing support within CRN Generic nursing team.	Karen Hylton / Kelly Hollier	To evaluate that various PO within CRN WM are utilising the new system. To ensure that the approval and turnaround time meets the 2 week deadline. To ensure that the capacity of the nurses are able to meet the demands of requests. We plan also to include Dementia and Mental Health requests onto the request system to include all six divisions.	Q4
	Clinical Research Project Assistants (CRPA)	To appoint six new CRPA's to support data collection at Partner Organisations (PO)	Karen Hylton	Reduction in data collection burden via feedback from PO.	Q4
	Training for pharmacy staff delivering clinical trials	Continue to promote and support the implementation of the 'Delegation and Training Decision Tool and associated training resources to pharmacy staff involved in IMP management	Julie Shenton / Jenny Warmington	Pharmacy departments in CRN WM POs involved in clinical trials delivery adopting and using the decision aid and associated training resources	ongoing

	Senior leadership culture re I&I	Work with the senior leadership team to ensure support for embedding a culture of improvement by allowing staff time to deliver projects including looking at ways to develop an agile approach to undertaking projects in a timely manner	Carly Craddock / Julie Shenton	Embedded culture in the senior leadership team re supporting staff to undertake projects encouraging an agile approach to project management where appropriate to ensure that projects are delivered in a timely manner.	Ongoing
9. Business Development and Marketing					
9.1.1	Engage with both local SMEs and the national team to market CRN WM to local and national companies	Build a small number of key collaborations to highlight the opportunities of working with industry	Sinead Collinge	Develop the Life Sciences Steering Group to include all local stakeholders and meet the needs of the companies, the CRN and our partners	Q1 and ongoing
9.1.2	Engage with commercial partners to ensure all patient populations have access to research	Scope untapped patient populations and specialties that are commercially under active and engage with commercial companies to assess pipelines, promote our capabilities and bring research into the West Midlands. Thus increasing the number of commercial studies and ensuring all specialties are active and offering research opportunities to all patients	Sinead Collinge	Assess needs of Partner Organisations, build Trust profiles and national pipeline assessments to identify appropriate commercial collaborators and build new relationships.	Q1 and ongoing
9.1.3	Promote the importance of both the Industry agenda and the USPs of the Network to attract new business	Increase the number of commercial and non-commercial research teams wanting to work with the Network	Sinead Collinge / Julie Davis	Produce an action plan that links with the Business Development and Marketing Profile (in appendices)	Q1-2
10. Life Sciences					
	Working in collaboration with East Midlands CRN and Midlands Health Innovation to promote our regional offerings to SME's to assist in research delivery	A clear service offering available for SME's and a support network to enable research delivery within the Midlands	Sinead Collinge	Collate regional capabilities across the NHS and Universities within the Midlands - Q1. Identify a service offering and collaboration pathway to ensure a streamlined and efficient cross-organisational service is provided to SME's	Q4
	Build upon relationship with University of Birmingham Business Enterprise to ensure CRN offerings are known. Expand and engage with other University Business Enterprises - Keele, Warwick, Wolverhampton	Be a known organisation for SME's wanting to conduct research in the NHS	Sinead Collinge	Continue to work with University of Birmingham to promote CRN services - Q4. Identify other regional Business Enterprise Organisations and promote CRN offerings	Q2
	Set up and deliver an educational and promotional event to our local SME community to showcase the support available within the West Midlands to enable research delivery	Build relationships regionally with other organisations and support bodies (AHSN, Medilink, NOCRI, Innovate UK etc). Establish a regional service offering for SME's	Sinead Collinge	Identify stakeholders to work and collaborate with Q1. Organise an event to ensure SME's are aware of the pathway from innovation, research to NHS adoption. Deliver Event in Q2	Q2

	Establishment of the CRN Industry Steering Group	To promote the national Life Sciences agenda, identify PO's strategic Life Science Objectives and ensure they are met regionally. Utilise this group to drive the Life Sciences agenda locally	Sinead Collinge	Ensure representation of all Trust types across the region, Industry Community and SME community Q1 Identify the strategic aims and objectives for 18/19, and how they will be delivered to meet PO and NIHR objectives Q4	Q4
	Research Engagement with IVD companies	West Midlands Laboratory Medicine Research Group meetings. Follow up Scientific Conference Meeting to showcase IVD diagnostics and further develop themes of IVD development.	Dr Owen Driskell	Scientific Meeting & Study Proposal	Q4
	To engage with three new models of care across the West Midlands to embed commercial research activity within these organisations	Meet with new models and leadership practices across WM and promote commercial research and better understand how the Network can support engagement Develop a working group within each practice to support commercial research activity Provide training on submitting feasibilities and study set up Identify 'new roles' which can support commercial research at the practice to reduce GP burden Look at wider portfolio - can organisation deliver 'secondary care studies' Measure: To increase number of EOI's from these new models/leadership practices	Raj Gill	Ability to offer commercial sponsors newer formations in which to deliver commercial studies set up fewer sites with competitive recruitment numbers. Number of portfolio commercial studies run in primary care increased New organisations remaining research active with CRN and also engaging with commercial research (HLO3)	Q4
	To develop and maintain lines of communication between pharmaceutical and medical technology companies in the West Midlands to promote our CRN WM Primary Care Service, new models of care and drive in new business	We aim to host a networking event for pharmaceutical and medical technology companies to promote West Midlands and primary care as a setting to set up and conduct studies. Research Design Service/ AHSN PC SSS / ECER /Practices	Raj Gill	Improved relationships with Commercial sponsors Awareness of WM Primary Care willingness, readiness and capability to deliver commercial research raised to companies Awareness of WM Primary Care willingness, readiness and capability to input into the design of commercial research raised to companies	Q1
	To streamline the PC SSS and PCIM service offered to commercial sponsors	Review and improvement of PC SSS process and PCIM service to ensure that the process for supporting practices to set up commercial studies is efficient, streamlined and demonstrates WM as an attractive region to conduct research especially within primary care. This will improve set up of commercial studies at sites (HLO4) and attract new and repeat business from commercial sponsors. (HLO1, HLO3)	Raj Gill	Improved study support service process for Primary Care industry studies Increase in number of commercial sponsors approaching and returning to the WM to deliver Primary Care studies GPs better supported to deliver commercial research	Q4

Financial Plan/Payment summary 2018/2019 as at 16.02.18

Sum of Financial Funding Agreed £	Funding Stream							
Partner Organisations	Core	CRL/CRSL	GP Payments	Other	National Specialty Lead funding	Strategic	TBC	Grand Total
BIRMINGHAM AND SOLIHULL MENTAL HEALTH NHS FOUNDATION TRUST	247,009							247,009
BIRMINGHAM COMMUNITY HEALTHCARE NHS FOUNDATION TRUST	148,332					21,102		169,434
BIRMINGHAM WOMENS & CHILDRENS HOSPITAL NHS FOUNDATION TRUST	1,480,198	34,691		62,518		76,692		1,654,099
BLACK COUNTRY PARTNERSHIP NHS FOUNDATION TRUST	85,603					38,343		123,946
BURTON HOSPITALS NHS FOUNDATION TRUST	353,633			0				353,633
COVENTRY AND WARWICKSHIRE PARTNERSHIP NHS TRUST	348,700					4,023		352,723
DUDLEY AND WALSALL MENTAL HEALTH PARTNERSHIP NHS TRUST	70,486					38,545		109,031
GEORGE ELIOT HOSPITAL NHS TRUST	152,895	18,419		15,035		70,711		257,060
Group1			575,310					575,310
HEART OF ENGLAND NHS FOUNDATION TRUST	1,848,162	30,900				107,100		1,986,162
John Taylor Hospice						6,000		6,000
Marie Curie Hospice						7,717		7,717
NORTH STAFFORDSHIRE COMBINED HEALTHCARE NHS TRUST	103,193					4,875		108,068
SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST	803,779	17,826				51,277		872,882
SHREWSBURY AND TELFORD HOSPITAL NHS TRUST	572,118					55,114		627,232
SHROPSHIRE COMMUNITY HEALTH NHS TRUST	8,759							8,759
SOUTH STAFFORDSHIRE AND SHROPSHIRE HEALTHCARE NHS FOUNDATION TRUST	206,154					56,065		262,219
SOUTH WARWICKSHIRE NHS FOUNDATION TRUST	173,386	15,010		65,035		38,550		291,981
St. Giles Hospice						3,400		3,400
St. Mary's Hospice						7,989		7,989
STAFFORDSHIRE AND STOKE ON TRENT PARTNERSHIP NHS TRUST	224,229			50,000		51,102		325,331
THE DUDLEY GROUP NHS FOUNDATION TRUST	497,716	5,658		63,157		70,932		637,463
THE ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST	215,033							215,033
THE ROYAL ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST	215,860	9,270						225,130
THE ROYAL WOLVERHAMPTON NHS TRUST (DELIVERY)	1,034,070	54,816						1,088,886
THE ROYAL WOLVERHAMPTON NHS TRUST (Host)	6,161,558			21,669	2,500			6,185,727
THE ROYAL WOLVERHAMPTON NHS TRUST (Host) Consultants		6,891						6,891
THE ROYAL WOLVERHAMPTON NHS TRUST (Host) Stipend		24,720						24,720
THE ROYAL WOLVERHAMPTON NHS TRUST (HOST) TBC		58,710						58,710
THE ROYAL WOLVERHAMPTON NHS TRUST (UNIVERSITY OF BIRMINGHAM)	784,126	17,358						801,484
THE ROYAL WOLVERHAMPTON NHS TRUST (UNIVERSITY OF BIRMINGHAM) NON PRIMARY		74,183		50,369				124,552
THE ROYAL WOLVERHAMPTON NHS TRUST (UNIVERSITY OF KEELE)	1,566,867	25,752		100,000				1,692,619
THE ROYAL WOLVERHAMPTON NHS TRUST (UNIVERSITY OF WARWICK)	707,727	14,832						722,559
THE ROYAL WOLVERHAMPTON NHS TRUST (UNIVERSITY OF WARWICK) NON PRIMARY		12,360		38,788				51,148
TO BE ALLOCATED							472,751	472,751
UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST	2,096,071	60,585			17,317	153,889		2,327,862
UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST	1,667,249	61,301		85,062		76,296		1,889,908
UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST	1,630,267	42,897				21,267		1,694,431
WALSALL HEALTHCARE NHS TRUST	158,158							158,158
WEST MIDLANDS AMBULANCE SERVICE NHS FOUNDATION TRUST	46,061					152,865		198,926
WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST	309,467			50,000		76,350		435,817
WORCESTERSHIRE HEALTH AND CARE NHS TRUST	70,425					9,485		79,910
WYE VALLEY NHS TRUST	177,448					38,175		215,623
Grand Total	**24,164,739**	**586,179**	**575,310**	**601,633**	**19,817**	**1,237,863**	**472,751**	**27,658,293**

LCRN HOST ORGANISATION CONTRACT
UPDATED FROM 1 APRIL 2018

APPENDIX A

PERFORMANCE AND OPERATING FRAMEWORK

Part A: Context

1. Structure and Purpose of the NIHR CRN

1.1. The NIHR CRN provides world-class health service infrastructure to support clinical research in the NHS in England.

1.2. The NIHR CRN comprises 15 Local Clinical Research Networks (LCRNs) and the National CRN Coordinating Centre working together with shared principles, values and behaviours. The LCRN Host Organisation and the LCRN Partners together form the single system that is the LCRN.

1.3. The purpose of the NIHR CRN is to provide efficient and effective support for the initiation and delivery of funded research in the NHS. Some of this research is funded by the NIHR but most of it is funded by NHS non-commercial partners and industry. This activity makes an important contribution to improve the health of the population and to support economic growth; and the NIHR CRN features in the government's Strategy for UK Life Sciences.

1.4. The NIHR CRN allocates and manages funding to meet NHS Support and other specified costs for eligible studies, as defined by the Authority's Eligibility Criteria for NIHR CRN Support (which can be found at: https://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/). These comprise randomised controlled clinical trials of interventions (including prevention, diagnosis, treatment and care) and other well designed studies for commercial and non-commercial sponsors.

2. Aims of the NIHR CRN

2.1. The aims of the NIHR CRN are defined by the Department of Health and are set out in the NIHR Briefing Document for the NIHR CRN, available at: https://www.nihr.ac.uk/about-us/documents/4.01-Clinical-Research-Network.pdf

2.2. The aims of the NIHR CRN are to:

(a) Promote equality of access, ensuring that wherever possible, patients have parity of opportunity to participate in research

(b) Improve the quality, speed and co-ordination of clinical research by removing the barriers to research in the NHS

(c) Streamline and performance manage NHS Support for eligible studies to ensure the NHS Service Support Costs of these studies are met in a timely and efficient manner

(d) Work in partnership to unify and streamline administrative procedures associated with regulation, governance, reporting, and approvals

(e) Meet the research delivery needs of the life sciences industry including: pharmaceutical; biotechnology; diagnostic; medical technology; and contract research organisations (CROs)

(f) Further integrate health research and patient care

(g) Engage the providers of NHS services in research in line with the NHS Constitution to promote research participation and a research culture.

3. Working Principles

3.1. The work of the National CRN Coordinating Centre and the LCRNs is guided by a set of principles:

(a) Patient-centred: We never lose sight of the fact that the research we help to carry out is for patient benefit. Patients are at the core of what we do

(b) Good Governance: We are an organisation with clear accountability arrangements, in control of things for which we will be held to account

(c) Inclusive: We welcome everyone within the NHS, including all providers of NHS services, who are committed to the delivery of high-quality clinical research

(d) Equity of access: We work to ensure patients, carers, the public, and healthcare professionals, from all parts of England and from all areas of healthcare, have opportunities to participate in and benefit from the widest range of high-quality clinical research studies.
LCRNs should seek to offer a balanced portfolio of research, giving opportunity according to local population needs.
LCRNs should monitor and where appropriate influence their portfolio of research, taking into consideration the principle that patients should have the opportunity to participate in studies relevant to their health condition and conducted in accessible locations. Therefore the placement of studies should take into account where the greatest burden of a particular health condition is found.
LCRNs should monitor and give consideration when conducting studies to the following dimensions:

- Health burden (prevalence/incidence)
- Study setting (primary care, secondary care, tertiary care, palliative care, social care)
- Geographical scope (international multi-site, UK multi-site and single site)
- Primary study design (interventional/observational/both)
- Randomisation status (randomised/non-randomised)
  Study type (commercial/non-commercial)

(e) Patient involvement: We are committed to engaging patients, carers and the wider public as partners in all aspects of our activity to improve research quality and ensure the experience of involvement and participation in clinical research is positive and fulfilling

(f) Partnership working: We are committed to working with all partners across the Network, facilitating collective decision making that supports national strategy. The Network is a collective endeavour and collaborative working is key to our success. The LCRN Host Organisation and all LCRN Partner organisations should work with integrity and mutual respect, recognising that the success of the Network is measured by the success of the LCRN Partner organisations

(g) Collaborative national working: The LCRN leadership team and management staff, including Research Delivery staff, will work closely with counterparts in other LCRNs and in the National CRN Coordinating Centre. These will form national, function-specific teams with direction, guidance and support provided by the relevant lead in the National CRN Coordinating Centre

(h) Transparency: We are open and transparent, sharing information freely at all levels of the organisation, with all partners and with the public. It is clear how and why decisions are made

(i) Consistency: We aim to provide a consistent, excellent service to researchers in all studies, in all parts of the country, for all clinical Specialties, and across all NHS sectors

(j) Flexibility: We work flexibly, promoting integration, working across boundaries and conducting work at the right level (national or local). We find flexible and pragmatic solutions to ensure success and minimise bureaucracy

(k) Responsive to stakeholders: We have strong and responsive relationships with our stakeholders. We listen to feedback and use it to improve the way we do business

(l) Efficiency: We use our money for the purposes intended. We understand the importance of increasing efficiency and demonstrating value for money to the taxpayer

(m) Effectiveness: We improve the quality, speed and cost-effectiveness of clinical research by continuous review and improvement of all our structures and systems

(n) Research Culture: Research is our core business. Our organisation promotes a research culture ensuring research is embedded within clinical care

(o) Workforce Development: Our workforce has a shared sense of purpose and the skills and understanding to meet the changing needs of the organisation. We are committed to developing and supporting our staff and those patients and carers actively contributing to the delivery of research

(p) Evidence based: We will make informed decisions guided by effectively utilising timely, accurate and reliable data and other information.

4. NIHR CRN Priorities 2018/19

4.1. Context

4.1.1. The National CRN Coordinating Centre and the Department of Health Science, Research and Evidence Directorate agree a set of national priorities for the CRN on an annual basis.

4.1.2. These priorities are set in pursuance of the vision, goals and aims of the CRN. These priorities should be reflected in the Annual Business Plan for the National CRN Coordinating Centre and for each LCRN.

4.2. NIHR CRN Strategies

4.2.1. The NIHR CRN has seven high-level strategies for the National CRN Coordinating Centre contract period 2015-20, for the following areas:

(a) Business Development and Marketing

(b) Communications

(c) Information and Knowledge

(d) NHS Engagement

(e) Patient and Public Involvement and Engagement

(f) Workforce Development

(g) Working with the Life Sciences Industry.

4.2.2. These strategies were a Department of Health contract requirement, and were approved by the Department of Health through the Department of Health / National CRN Coordinating Centre Contract Management Board. Each strategy set out a work plan of projects and deliverables for each National CRN

Coordinating Centre contract year; these annual work plans are incorporated in the National CRN Coordinating Centre Annual Business Plan.

4.2.3. It should be noted that typically 2018/19 will be the final full year of implementation of these strategies, entering a review phase in 2019/20.

4.3. 'One NIHR' Programmes

4.3.1. The five NIHR National Coordinating Centres shall from April 2018 collaborate to deliver a number of work programmes in areas that 'cut across' the five centres and that will benefit the NIHR as a whole ('One NIHR' programmes).

4.3.2. These programmes will be managed through the NIHR Centres Executive Board.

4.3.3. The NIHR Centres Executive Board has agreed the following One NIHR programmes for the contract year 2018/19:

(a) NIHR Digital Programme – this programme shall implement the approved NIHR Digital Strategy

(b) NIHR Communications Programme – this programme shall implement the approved NIHR Communications Strategy

(c) 'Push the Pace' Project

(d) NIHR Standard Application Form Project

(e) Global Health Research Programme

(f) Research Charity Engagement Programme

4.3.4. The Annual Plan for each of these programmes - the 'NIHR Programmes Joint Annual Plan' - will be submitted for Department of Health approval through the NIHR Centres Executive Board. Once approved, it will be included in each Coordinating Centre's Annual Business Plan.

4.4. Further optimisation of the NIHR CRN

4.4.1. The Department of Health has requested that the NIHR CRN undertakes a number of service development and continuous improvement activities in 2018/19, which typically form part of wider NIHR advancement initiatives.

4.5. NIHR CRN High Level Objectives

4.5.1. The purpose of the NIHR CRN is to provide efficient and effective support for the initiation and delivery of funded research in the NHS. The performance of the NIHR CRN in meeting this purpose is measured against the CRN High Level Objectives (HLOs). The priority for the NIHR CRN is to meet and if possible exceed the HLO targets set on an annual basis by the Department of Health.

4.5.2. For 2018/19 a primary focus will remain on all LCRNs meeting the target that 80% of NIHR CRN Portfolio studies are delivered to recruitment target and time

(HLO 2A relating to commercial studies and HLO 2B relating to non-commercial studies).

4.6. Optimisation of CRN study data integration

4.6.1. The programme of work for data integration between the NIHR CRN Central Portfolio Management System (CPMS) and the Local Portfolio Management Systems (LPMS) of the 15 LCRNs will bring multiple benefits, including:

- Enabling an efficient and coordinated way of exchanging research study performance and research management data, removing the need to enter recruitment data and study information into multiple systems;
- Driving the efficient provision and best use of intelligence for NIHR research studies;
- Supporting the government view that providing better information about public organisations will deliver better value for money in public spending, drive growth and inform choice;
- Supporting the UK Information Strategy which applies to all aspects of the NHS, including research.

4.6.2. This initial data integration is formed of three elements:

(1) "Get Study", this being the functionality to exchange core details of NIHR CRN studies between CPMS and LPMS'; this element has been fully implemented;

(2) "Capacity and Capability", this being the functionality to exchange information on the readiness of research sites to conduct a NIHR CRN study; implementation of this element is in progress;

(3) "Research Activity", this being the functionality to exchange information on participation and participants in a NIHR CRN study; implementation has not commenced.

4.6.3. Element (2) will be delivered by March 2018. Element (3) is being developed in 2017/18 and will be completed in 2018/19.

4.7. CRN Funding Model

4.7.1. The Department of Health and the National CRN Coordinating Centre have identified a number of potential changes to the CRN Funding Model as part of wider NIHR initiatives. These are:

- Moving towards a better geographical match between disease burden and NIHR CRN participant recruitment;
- Incentivising Trusts and Principal Investigators for involvement and performance in industry studies;
- Incentivising LCRNs to maintain a 'balanced portfolio' of studies.

4.7.2. The National CRN Coordinating Centre has undertaken substantial work on each of these three topics in the course of the contract year 2017/18, however further development and validation is required in order for these factors to be reflected in the NIHR CRN Funding Model. The intention is that these factors will be included in the NIHR CRN Funding Model that will determine LCRN funding allocations from the financial year 2019/20 onwards.

4.8. CRN staff skills development in new sciences, technologies and methodologies

4.8.1. The rapidly changing clinical research landscape is both an asset and a challenge. It has generated the need for many more practitioners and patients throughout the Health and Social Care system to have a better understanding of new types of science, new innovations in application of technologies and new methodologies associated with research.

4.8.2. This demand, coupled with a tight economic environment in the NHS, Public Health and Social Care setting, has seen a significant reduction in the investment in skills development through continuing professional development. There is a need for the NIHR to take a more assertive approach to the upskilling of front line staff and the investigator community.

4.8.3. The NIHR CRN has had significant experience and success through the delivery of the GCP programme, ensuring high quality skills development using online learning and we would wish to be more active in this space. This could be through the more timely development of easily accessible "bite size" learning using NIHR funded staff, but also through the curation and signposting of high quality materials from other sectors. This would then ensure that time-poor front line staff are clearly supported to use their learning time to best effect. The NIHR CRN has well-established reach and reputation to ensure this is achievable.

4.8.4. The National CRN Coordinating Centre, using digital learning resources to best effect, will support the development of understanding and confidence in the NIHR CRN funded workforce to deliver new, novel and innovative clinical research.

4.9. Implement Optional Services as required

4.9.1. Under clause 7.5 (“Optional Services”) of the Department of Health contract for the National CRN Coordinating Centre, “…the Authority may require the Supplier to provide any Optional Services at any time by giving notice to the Supplier in writing and following the procedure in paragraph 6.1 of Schedule 21 (Governance)”. The implementation and commencement of any additional Optional Services would be a priority activity should additional Optional Services be required by the Authority.

Part B: Performance Framework

1. Introduction

1.1. This Part B of Appendix A sets out the NIHR CRN Performance Framework effective from 1 April 2018.

1.2. Performance management in the NIHR CRN is built on four principles:

(a) **Transparency** – that the NIHR CRN openly publishes and reports performance information

(b) **Collaboration** – that the LCRN Host Organisation and LCRN Partner organisations put in place effective partnership working arrangements to ensure that all stakeholders work collaboratively to develop and deliver against objectives

(c) **Information Integrity** – that national and local information systems are managed and utilised consistently across the NIHR CRN to enable accurate and up to date information to be available to support effective performance management

(d) **Continuous Improvement** - that LCRN Host Organisations and LCRN Partners embed a culture of continuous performance improvement, delivered for the benefit of patients whilst maximising value for money.

1.3. The purpose of the current NIHR CRN Performance Framework is to set out the objectives, measures and targets for the NIHR CRN which will be used to measure the success of the LCRN.

1.4. The NIHR CRN Performance Framework will be supported by a series of LCRN Contract Support Documents which will specify the data points and methodology used for all objectives and measurements, and will also provide details of the NIHR CRN annual reporting cycle.

2. LCRN Performance Indicators - Background

2.1. The following sets of indicators will be used by the National CRN Coordinating Centre and Department of Health to assess LCRN performance:

No.	Indicators	Aspect of LCRN performance
1	NIHR CRN High Level Objectives (HLOs)	The performance of the LCRN in the delivery of NIHR CRN Portfolio studies
2	NIHR CRN Clinical Research Specialty Objectives	The contribution of the LCRN to the delivery of the national objectives for the NIHR CRN Clinical Research Specialties

3	LCRN Operating Framework Indicators	The performance of the LCRN in operating in compliance with mandated operational structures and processes
4	Initiating and Delivering Clinical Research Indicators	The performance of individual providers of NHS services in initiating and delivering clinical research as set out in Section 3A of the Contract between the LCRN Host Organisation and the Department of Health
5	LCRN Partner Satisfaction Indicators	The performance of the LCRN Host Organisation and LCRN Leadership/Management Team in delivering an inclusive and effective LCRN
6	LCRN Customer Satisfaction Indicators	The performance of the LCRN in delivering a responsive and flexible service that meets the needs of our customers
7	LCRN Patient Experience Indicators	The performance of the LCRN in delivering excellence in patients' experience of research

2.2. Some specific indicators will require LCRN-level targets. As part of the LCRN annual planning process, LCRNs will propose LCRN-level targets for these indicators. These proposals will be considered by the National CRN Coordinating Centre and the National CRN Coordinating Centre will confirm the final LCRN-level targets. The annual performance of the LCRN will be measured against these final LCRN-level targets.

Set 1 – NIHR CRN High Level Objectives (HLOs)

2.3. The HLOs are the national, overarching objectives for Clinical Research Network research delivery, and constitute the most important set of NIHR CRN Performance Objectives. The HLOs are collective objectives for the whole NIHR CRN system.

2.4. The LCRN Host Organisation will plan and report on the LCRN's contribution to these national HLOs.

2.5. The NIHR CRN HLOs are presented in Table 1 below.

Set 2 – Clinical Research Specialty Objectives

2.6. The Clinical Research Specialty Objectives are the development and performance objectives for the 30 NIHR CRN Clinical Research Specialties. Each Specialty ordinarily has a single objective each year. The NIHR CRN National Specialty Groups propose the objectives on an annual basis, for

approval by the National CRN Coordinating Centre and the Department of Health.

2.7. The LCRN Host Organisation will plan and report on the LCRN's local contribution to these national Clinical Research Specialty Objectives and targets.

2.8. Although each Specialty has its own objective, these should not be taken in isolation, and LCRNs are expected to promote cross-Specialty working in order to maximise the overall performance of the LCRN and network as a whole. Recognition and support should be provided to Specialties which are contributing to the objectives of other Specialties in line with the NIHR CRN's "one Network" approach to delivery.

2.9. All Specialty Groups must also focus on delivering against the HLOs from a Specialty perspective. There is an NIHR CRN wide focus on delivery of clinical research to time and target (HLO 2).

2.10. The Clinical Research Specialty objectives are presented in Table 2 below.

Set 3 – LCRN Operating Framework Indicators

2.11. The NIHR CRN Operating Framework (Section C of this document) defines the organisational requirements, operational systems and processes that LCRNs are required to implement in order to ensure consistency across the LCRN infrastructure and, where necessary, standards for locally defined arrangements and systems.

2.12. The NIHR CRN Operating Framework is a comprehensive document with a substantial number of provisions. On an annual basis, the National CRN Coordinating Centre selects a number of provisions, typically provisions in respect of key operational arrangements, which form the set of indicators. These indicators are used by the National CRN Coordinating Centre in order to assess each LCRN's compliance with the Operating Framework provisions.

2.13. The LCRN Operating Framework Indicators are presented in Table 3 below.

Set 4 – Initiating and Delivering Clinical Research Indicators

2.14. The Plan for Growth, published by the Government in March 2011, and which can be found at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/31584/2011budget_growth.pdf, announced the transformation of incentives at local level for efficiency in initiation and delivery of research which includes the publication of clinical trial start-up times against public benchmarks.

2.15. The definitions in relation to the Performance in Initiating and Delivering Clinical Research exercise have evolved since its original implementation. The latest information on the current requirements can be found on the NIHR website at https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/performance-in-initiating-and-delivering-research/ : with data points

definitions as described here: https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm

2.16. The LCRN Host Organisation Agreement and the "flow down" agreement between the LCRN Host Organisation and Category A LCRN Partner include - at Clause 3A - the standard NIHR contract clauses implementing the Government's Plan for Growth provisions and requirements relating to the Performance in Initiating and Delivering Clinical Research; which involves the reporting of achievement against the initiation benchmark for all clinical trials and delivery of recruitment to time and target for commercial contract clinical trials.

2.17. The Authority will hold the LCRN Host Organisation and each Category A LCRN Partner individually accountable for its performance with respect to Clause 3A. Additional wording has been added to the standard text in the LCRN Host Organisation Agreement to ensure there are no grounds for confusion over the LCRN Host Organisation's responsibilities in this domain.

2.18. The LCRN Host Organisation and Category A LCRN Partner will each submit their data directly to the Authority via the national system as advised by the Authority. The Government's aims in introducing these clauses were to see a dramatic and sustained improvement in the performance of providers, to increase the number of patients that have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research. The Authority effects any changes to funding as a result of poor performance, via the Research Capability Funding allocations to Trusts, not via NIHR CRN funding.

2.19. Other providers of NHS services, including Category B LCRN Partners, shall not be required to report against the Performance in Initiating and Delivering Clinical Research exercise. Nevertheless, it is important they understand that they have an important part to play in increasing performance in the initiation and delivery of research.

Set 5 – LCRN Partner Satisfaction Survey Indicators

2.20. The effective operation of the LCRN is dependent upon all LCRN Partner organisations working together in a mutually supportive and collaborative way – i.e. as a network. It is the contractual responsibility of the Host Organisation to ensure the provision of LCRN leadership, management, resources, systems, governance and operational arrangements to achieve this.

2.21. Therefore it is of primary importance that LCRN Partners are content with this provision by the Host Organisation, that the National CRN Coordinating Centre seeks direct assurances of this from LCRN Partners, and that the National CRN Coordinating Centre is sufficiently informed in order to address any material issues with the LCRN Host Organisation and leadership.

2.22. In order to gain this assurance, the National CRN Coordinating Centre will undertake an annual survey of LCRN Partners, referred to as the 'LCRN Partner Satisfaction Survey'. The survey will elicit LCRN Partners' views on the range of

LCRN Host Organisation responsibilities, these forming a set of indicators of LCRN Partner Satisfaction.

Set 6 – LCRN Customer Satisfaction Indicators

2.23. The 'customers' of the NIHR CRN are research funders – both commercial and non-commercial – and the investigators and research teams conducting that research. As the primary purpose of the NIHR CRN is to provide NHS support services to these customers, it is self-evident that NIHR CRN customers need to be content with the provision of LCRN services, including systems, processes, facilities, staff, communication, and the general relationship and interactions.

2.24. In order to gain this assurance, the National CRN Coordinating Centre will undertake an annual survey of LCRN customers, referred to as the 'LCRN Customer Satisfaction Survey'. The survey will elicit LCRN customers' views across the dimensions of LCRN service provision, these forming a set of indicators of LCRN Customer Satisfaction.

Set 7 – LCRN Patient Experience Indicators

2.25. The research that the NIHR CRN helps to carry out is for patient benefit and patients are at the core of what we do.

2.26. The LCRN Host Organisation will coordinate an annual survey of patients, referred to as the 'Patient Research Experience Survey'. The survey will elicit patients' views of their experience of taking part in research. Each LCRN will include a number of standard questions which will form a set of indicators of LCRN Patient Experience.

3. Performance Management Processes

Annual Plan and Annual Report

3.1. The LCRN Host Organisation will adhere to the requirements of the annual business planning cycle as defined by the National CRN Coordinating Centre. This will include the preparation and submission to the National CRN Coordinating Centre of LCRN plans and reports, including an LCRN Annual Plan and an LCRN Annual Report, following the specification set by the National CRN Coordinating Centre in respect of structure, content, quality and submission timelines.

3.2. The LCRN Annual Plan will set the direction for the LCRN for that contract year. It must include the initiatives, projects and activities, including milestones and targets, where applicable, to support the achievement of the LCRN Performance Indicators as set out in this Part B of Appendix A.

3.3. The LCRN Annual Plan will include a financial plan. The financial plan will include the annual funding allocations to the LCRN Host Organisation and LCRN Partners.

3.4. The LCRN Annual Report will provide an assessment of the LCRN's delivery against the Annual Plan, and it will report LCRN performance against the LCRN Performance Indicators.

3.5. The LCRN Annual Report will include a year-end financial report.

3.6. The LCRN Annual Plan and LCRN Annual Report should be supported and agreed by the LCRN Partnership Group and formally approved by the LCRN Host Organisation board.

3.7. These plans and reports should be developed in collaboration with the governance, management and influencing groups set out in Part C of this Appendix A (including but not limited to the LCRN Operational Management Group and the LCRN Partnership Group).

Performance management by the National CRN Coordinating Centre

3.8. The detailed arrangements for the performance management of the LCRN by the National CRN Coordinating Centre are set out in the CRN Performance Management Framework document, which shall be provided to the LCRN Host Organisation.

3.9. The LCRN leadership team, as defined in Part C of this Appendix A, will attend two performance review meetings per year with senior representatives from the National CRN Coordinating Centre (a Mid-Year Review meeting and an Annual Review meeting).

3.10. The Mid-Year review meetings will be attended by members of the National CRN Coordinating Centre Executive team and the LCRN Clinical Director(s) and LCRN Chief Operating Officer. The LCRN Host Organisation Nominated Executive Director and Partnership Group Chair are invited to attend but attendance is not mandatory. Up to two additional LCRN observers may also attend.

3.11. The annual performance review meetings will be attended by members of the National CRN Coordinating Centre Executive team and the LCRN Clinical Director(s) and LCRN Chief Operating Officer. The LCRN Host Organisation Nominated Executive Director and Partnership Group Chair are expected to attend.

3.12. The LCRN Annual Report will be reviewed at the Annual Review meeting in the second quarter of each contract year.

3.13. The National CRN Coordinating Centre will monitor compliance of LCRN Host Organisations in respect of the DH/LCRN Host Organisation Agreement, including the Performance and Operating Framework via a Contract Compliance Framework.

3.14. Where issues in the performance of the LCRN in respect of the LCRN Performance Indicators are identified, the LCRN Host Organisation shall put in

place a remedial action plan, to be agreed with the National CRN Coordinating Centre. The issue(s) should be documented in the LCRN's Risks and Issues Log.

3.15. If the performance of the LCRN against the remedial action plan fails to improve within a period specified by the National CRN Coordinating Centre and to the levels agreed with the National CRN Coordinating Centre, the Agreement may be terminated, as set out in Clause 19.1 of the Agreement.

Performance management by the LCRN Host Organisation

3.16. The overall performance of the LCRN will be determined by measuring the performance of the LCRN Host Organisation and its LCRN Partners. The LCRN Host Organisation will therefore need to ensure robust performance management processes are in place across the LCRN.

3.17. LCRN Partner organisations and Specialty Groups will set and agree their performance goals on an annual basis with the LCRN Host Organisation. The LCRN Host Organisation will provide this information to the National CRN Coordinating Centre on request.

3.18. The LCRN Host Organisation will actively manage and monitor performance against the LCRN Annual Plan and provide reports, including LCRN performance reports, to the National CRN Coordinating Centre as required.

3.19. The LCRN Host Organisation will promote active local performance management approaches within the LCRN in relation to achievement of the LCRN Performance Indicators set out in this Part B of Appendix A.

3.20. In order to support the production of high quality performance data and reporting, the LCRN Host Organisation must ensure all NIHR CRN Portfolio recruitment data is recorded on NIHR CRN information systems in a timely and efficient manner, in line with guidance set out by the National CRN Coordinating Centre.

3.21. The LCRN Host Organisation will be responsible for ensuring all LCRN Partners have access to timely LCRN performance data.

3.22. The LCRN Host Organisation should encourage LCRN Partner organisations to maintain Board level scrutiny of NIHR CRN key performance indicators via appropriate local Board reports.

3.23. The LCRN Host Organisation will support local performance improvement projects which address underperformance against the NIHR CRN objectives.

3.24. The LCRN Host Organisation will engage the LCRN Partnership Group as a key forum for driving LCRN performance, challenging underperformance, supporting increased participation and improved delivery, and sharing best practice.

3.25. The LCRN Host Organisation and its LCRN Partner organisations will actively contribute to national programmes for development, performance review and support.

3.3. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of the LCRN Performance Indicators which are accessible on the NIHR Hub:

Ref	Title
PM/002	NIHR CRN High Level Objectives Data Point Grid
PM/041	NIHR CRN Specialty Objectives Data Point Grid
PM/031	NIHR CRN Performance Management Framework
PM/033	Requirements for LCRN Annual Delivery Planning
PM/034	Requirements for LCRN Annual Delivery Reporting
PM/035	Risks and Issues Log Requirements
PM/060	NIHR CRN Annual Reporting Cycle

4. LCRN Performance Indicators - Tables

Table 1 – NIHR CRN High Level Objectives

Objective		Measure	2018/19
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
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%
		B: Proportion of non-commercial studies achieving or surpassing their recruitment target during their planned recruitment period	80%
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	700
		B: Number of new commercial contract studies entering the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies	75%
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%
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%

Objective		Measure	2018/19
		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%
6	Increase NHS participation in NIHR CRN Portfolio Studies	A: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies	99%
		B: Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio commercial contract studies	70%
		C: Proportion of General Medical Practices recruiting each year into NIHR CRN Portfolio studies	45%
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	25,000

Table 2 – Clinical Research Specialty Objectives

#	Specialty	Objective	Measure	Target
1	Ageing	Increase early career researcher involvement in NIHR CRN Portfolio research	Number of LCRNs that have evidenced increased early career researcher involvement in NIHR CRN Portfolio research	15 LCRNs
2	Anaesthesia, Perioperative Medicine and Pain Management	Increase the number of NIHR CRN Portfolio studies led by trainees as Chief Investigator or co-Chief Investigator	Number of LCRNs with a study/studies led by a trainee (Chief Investigator or co-Chief Investigator)	5 LCRNs
3	Cancer	Increase patient access to Cancer research studies across the breadth of the Cancer subspecialties	Number of LCRNs achieving on-target recruitment into at least 8 of the 13 Cancer subspecialties, where "on-target" means either improving recruitment by 10% from 2017/18 or meeting the following recruitment targets per 100,000 population served: a) Brain: 0.2 b) Breast: 10 c) Colorectal: 3 d) Children and Young People: 3 e) Gynae: 3 f) Head & Neck: 1.5 g) Haematology: 7 h) Lung: 4 i) Sarcoma: 0.1 j) Skin: 0.5 k) Supportive & Palliative Care and Psychosocial Oncology: 4 l) Upper GI: 3 m) Urology: 12	15 LCRNs

#	Specialty	Objective	Measure	Target
4	Cardiovascular Disease	Develop the research workforce in cardiovascular surgery	LCRNs will identify the cohort of investigators who work on cardiovascular-led NIHR CRN Portfolio studies at cardiothoracic surgery centres in their geography. In consultation with this cohort the LCRN will make a written plan on how it will help those who are interested become Principal Investigators.	15 LCRNs
5	Children	Increase NHS participation in Children's studies on the NIHR CRN Portfolio	Proportion of NHS Trusts recruiting into Children's studies on the NIHR CRN Portfolio	90%
6	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%
7	Dementias and neurodegeneration	Increase early career researcher involvement in NIHR CRN Portfolio research	Number of LCRNs that have evidenced increased early career researcher involvement and provided the names of at least two new early career researchers that have become local Principal Investigators for DeNDRoN studies on the NIHR CRN Portfolio during 2018/19	15 LCRNs
8	Dermatology	Develop the Dermatology Principal Investigator (PI) workforce	Number of new Nurse PIs for managed or supported Dermatology studies entering the NIHR CRN Portfolio	1 new Nurse PI per LCRN
9	Diabetes	Improve primary-secondary care collaboration in the delivery of Diabetes research	Increase recruitment into studies that require collaboration between primary and secondary care	Overall national increase of 5% from baseline
10	Ear, nose and throat	Increase trainee involvement in NIHR CRN Portfolio research	Establish links with the relevant professional organisations involved in research for patients with Ear, nose and throat, Hearing and Balance conditions to encourage and support trainee involvement in NIHR CRN Portfolio studies	15 LCRNs
11	Gastroenterology	Improve recruitment to NIHR CRN Gastroenterology studies	Recruitment of 40 participants per 100,000 population to Gastroenterology studies on the NIHR CRN Portfolio	15 LCRNs

#	Specialty	Objective	Measure	Target
12	Genetics	Increase early career researcher involvement in NIHR CRN Portfolio research	Number of LCRNs that have evidenced increased early career researcher involvement in NIHR CRN Portfolio research	15 LCRNs
13	Haematology	Establish links with the relevant professional organisations to encourage and support trainee involvement in NIHR CRN Portfolio studies	Number of LCRNs that have evidenced increased trainee involvement in NIHR CRN Portfolio research	15 LCRNs
14A	Health Services Research	Develop research infrastructure (including staff capacity) in the NHS to support clinical research in Health Services Research	Number of LCRNs with a lead for Health Services Research	15 LCRNs
14B	Health Services Research	Increase the number of recruitment sites for NIHR CRN Portfolio studies funded by the Health Services and Delivery Research programme	Number of new sites for existing and new studies on the NIHR CRN Portfolio funded by the Health Services and Delivery Research programme	1 new site per LCRN
15	Hepatology	Increase access for patients to Hepatology studies on the NIHR CRN Portfolio	Number of LCRNs recruiting to Hepatology studies on the NIHR CRN Portfolio in the disease areas of: cirrhosis and its complications; and/or non alcoholic fatty liver disease (NAFLD) or non alcoholic steatohepatitis (NASH)	15 LCRNs
16	Infection	Develop research infrastructure (including staff capacity) in the NHS to support clinical research	Named champion for sexually transmitted infection	15 LCRNs
17	Injuries and Emergencies	Increase participation in pre-hospital studies via Ambulance Trusts	Number of LCRNs that have recruited via Ambulance Trusts to two or more pre-hospital care managed or supported Injuries and Emergencies studies on the NIHR CRN Portfolio	15 LCRNs

#	Specialty	Objective	Measure	Target
18	Mental Health	Increase participation in Mental Health studies involving children and young people	Increase the number of NIHR CRN Portfolio studies recruiting participants aged 16 years or under	5% increase from 2017/18
19	Metabolic and Endocrine Disorders	Understand and develop the research workforce that work in Metabolic and Endocrine-led studies	Accurately record the Principal Investigators and recruitment staff (nurses and trial coordinators) working on Metabolic and Endocrine-led studies, on the NIHR CRN Portfolio open during the 2018 calendar year	Submission of data by 15 LCRNs
20	Musculoskeletal Disorders	Increase engagement of orthopaedic champions to support the delivery of Musculoskeletal Disorders studies on the NIHR CRN Portfolio	A: Named orthopaedic champion identified in each LCRN	15 LCRNs
			B: Increase the number of participants recruited into orthopaedic studies on the NIHR CRN Portfolio	10% increase from 2017/18
21	Neurological Disorders	Increase early career researcher involvement in NIHR CRN Portfolio research	Number of LCRNs that have evidenced increased early career researcher involvement in NIHR CRN Portfolio research	15 LCRNs
22	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	70%
23	Oral and Dental health	To develop the Oral and Dental research workforce in order to meet the demands of the expected growth in the portfolio following the JLA Priority Setting Partnership	LCRNs to survey dentists and dental care professionals within their geographies to identify their research readiness and interests in order to gain an understanding of the local capacity and capability	15 LCRNs
24	Primary Care	Increase engagement of GP registrars and First Five GPs with NIHR CRN Portfolio research	LCRNs to identify and fund a minimum of two named individuals in a GP registrar/First Five nurturing role to undertake Research Champion activities	15 LCRNs
25	Public health		A: Number of LCRNs with a lead for Public Health	15 LCRNs

#	Specialty	Objective	Measure	Target
		Develop research infrastructure (including staff capacity and working with local authorities) to support research in Public Health	B: Number of LCRNs recruiting to at least five studies on the NIHR CRN Portfolio managed by Public Health	15 LCRNs
26	Renal Disorders	Increase the number of 'new' Principal Investigators (PIs) engaged in commercial Renal Disorders studies on the NIHR CRN Portfolio	Number of LCRNs with one or more 'new' PIs (defined as researchers who have not engaged as PI in any commercial study in the last 3 years)	15 LCRNs
27	Reproductive Health and Childbirth	Increase the proportion of NHS Trusts recruiting into Reproductive Health and Childbirth studies on the NIHR CRN Portfolio	A: Proportion of acute NHS Trusts, which provide maternity services, recruiting into Reproductive Health and Childbirth studies on the NIHR CRN Portfolio	70%
			B: Recruitment within the LCRN geography as a proportion of infant mortality data for that region	Establish baseline to determine appropriate level of growth for 2019/20
28	Respiratory Disorders	Increase access for patients to Respiratory Disorders studies on the NIHR CRN Portfolio	Number of LCRNs recruiting participants into respiratory rare disease studies on the NIHR CRN Portfolio (e.g. pulmonary fibrosis, pulmonary hypertension, cystic fibrosis, lymphangioleiomyomatosis, pulmonary alveolar proteinosis).	At least 10 LCRNs
29	Stroke	CRN recruitment to Stroke RCTs should be at least 8% of the 2017/18 Sentinel Stroke National Audit Programme (SSNAP)-recorded hospital admissions	CRN Stroke RCT recruitment as a % of SSNAP-recorded admissions	8% national target

#	Specialty	Objective	Measure	Target
30	Surgery	Increase patient access to Surgery research studies on the NIHR CRN Portfolio across the breadth of the surgical subspecialties	Number of LCRNs recruiting into at least 12 of the 14 surgical subspecialties (breast, cardiac, colorectal, general, head & neck, hepatobiliary, neurosurgery, orthopaedics, plastics and hand, transplant, trauma, upper GI, urology, vascular) AND at least 2 patients/100,000 population into at least 6 of the 14 surgical subspecialties	15 LCRNs

Table 3 – LCRN Operating Framework Indicators

ID	Domain	Indicator	Assessment Approach
1.1	Governance and Management	LCRN provides an Annual Plan, Annual Report and other documents as requested by the National CRN Coordinating Centre	Monitoring of provision of key documents requested by the National CRN Coordinating Centre
1.2	Governance and Management	LCRN Clinical Director and/or LCRN Chief Operating Officer attend all National CRN Coordinating Centre/LCRN Liaison meetings	Attendance registers for National CRN Coordinating Centre/LCRN Liaison meetings
1.3	Governance and Management	LCRN Host Organisation and LCRN Category A Partners submit an NHS Information Governance Toolkit annual assessment to NHS Digital and attain Level 2 or Level 3	Analysis of information on the NHS Digital Information Governance Toolkit website which provides open access to attainment levels for all submitting organisations
1.4	Governance and Management	Category A LCRN Partner flow down contract templates used to contract with all Category A LCRN Partners	LCRN Annual Report
1.5	Governance and Management	Category B LCRN Partner flow down contract templates used to contract with all Category B LCRN Partners	LCRN Annual Report
2.1	Financial Management	Internal audit in respect of LCRN funding managed by the LCRN Host Organisation, undertaken at least once every three years and which meets the minimum scope requirements specified by the National CRN Coordinating Centre	Monitoring of audit reports provided by the LCRN Host Organisation to the National CRN Coordinating Centre
2.2	Financial Management	Deliver robust financial management using appropriate tools and guidance	• Monitoring by the National CRN Coordinating Centre of percentage variance (allocation vs expenditure) quarterly and year-end (target is 0%)

ID	Domain	Indicator	Assessment Approach
			• Monitoring by the National CRN Coordinating Centre of proportion of financial returns completed to the required standard and on time (target is 100%) • Monitoring of financial management via LCRN financial health check process
2.3	Financial Management	Distribute LCRN funding equitably on the basis of NHS support requirements	Comparison by the National CRN Coordinating Centre of annual LCRN Partner funding allocations and NHS Support requirements
3.1	CRN Specialties	LCRN has an identified Lead for each NIHR CRN Specialty	The LCRN Host Organisation shall: (1) Provide the National CRN Coordinating Centre with access to a list of LCRN Clinical Research Specialty Leads, which includes each individual's start/end dates and contact information (2) Notify the National CRN Coordinating Centre if there are changes within the financial year (3) Provide a narrative to justify intentional vacancies or the expected timeframe to fill vacancies
3.2	CRN Specialties	Each LCRN Clinical Research Specialty Lead attends at least 2/3 of National Specialty Group meetings	Attendance registers for National Specialty Group meetings
3.3	CRN Specialties	Each LCRN provides evidence of support provided to their LCRN Clinical Research Specialty Leads to enable them to undertake their role in contributing to the NIHR CRN's nation-wide study support activities, specifically in respect of commercial early feedback and non-commercial expert review for the eligibility decision and including where applicable, local feasibility activities, delivery assessments and performance reviews	Review by the National CRN Coordinating Centre of evidence of support provided in LCRN Annual Plan and Report

ID	Domain	Indicator	Assessment Approach
4.1	Research Delivery	Each LCRN consistently delivers the local elements of the CRN's nation-wide Study Support Service as specified in the latest version of the Standard Operating Procedures produced by the National CRN Coordinating Centre and available as part of the LCRN Contract Support Documents	Monitoring by the National CRN Coordinating Centre of provision of the individual components of the Service via the study progress tracker application on Open Data Platform where the LCRN is assigned as the Lead LCRN and/or Performance Lead
4.2	Research Delivery	Each LCRN provides near time Minimum Data Set data items as specified by the National CRN Coordinating Centre, which have been quality assured to accurately reflect research activity measures and enable collaborative delivery of studies across the NHS	• Monitored via Open Data Platform reports, the single research intelligence system and the Research Delivery Assurance Framework • Analysis of percentage of missing and inaccurate data points from each LCRN
5.1	Information and Knowledge	LCRN provides an LPMS to capture for their region the required Minimum Data Set data items as specified by the National CRN Coordinating Centre, and enables timely sharing of information as one element of the single research intelligence system	Monitoring by the National CRN Coordinating Centre of system integration, usage and data transfer as part of the single research intelligence system
5.2	Information and Knowledge	LCRN provides support for ongoing provision of an LPMS solution	Review of budget line for provision of an LPMS in LCRN Annual Financial Plan
5.3	Information and Knowledge	Each LCRN has a nominated representative in attendance at all national NIHR CRN Virtual Business Intelligence meetings	Attendance registers for national NIHR CRN Virtual Business Intelligence meetings
5.4	Information and Knowledge	Each LCRN has a nominated representative in attendance at all national CPMS-LPMS meetings where either a) strategic sign off is required or b) an operational working perspective is required	Attendance registers for national CPMS-LPMS meetings

ID	Domain	Indicator	Assessment Approach
6.1	Stakeholder Engagement and Communications	LCRN has an experienced and dedicated communications function	● Individual's name and contact details provided to the National CRN Coordinating Centre ● Non-pay budget line for communications identified in LCRN Annual Plan
6.2	Stakeholder Engagement and Communications	Each LCRN has a defined approach to communications and action plan aligned with both the NIHR CRN and NIHR strategies	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report ● Evidence of joint work with local NIHR infrastructure reviewed
6.3	Stakeholder Engagement and Communications	The LCRN has in place a senior leader with experience and identified responsibility for PPIE	Individual's name and contact details provided to the National CRN Coordinating Centre
6.4	Stakeholder Engagement and Communications	The LCRN records metrics of research opportunities offered to patients	● The LCRN will hold information on its reach with patients and the public (metrics may include local website usage, leaflet distribution, social media reach etc) ● Evidence of local patient evaluation system ● Progress discussed at national PPIE meetings and reported in LCRN Annual Report
6.5	Stakeholder Engagement and Communications	The LCRN has collaborative PPIE workplans across CRN and partners with measurable outcomes for delivery of learning resources	● LCRN Annual Plan includes PPIE workplan with clear outcomes, milestones and measurable targets ● Non-pay budget line for PPIE and WTE for PPIE role(s) identified in LCRN Annual Plan ● Progress reported in LCRN Annual Report
6.6	Stakeholder Engagement and Communications	Each LCRN supports awareness of, engagement with and delivery of National CRN Coordinating Centre-managed services, such as Join Dementia Research (JDR) and the UK Clinical Trials Gateway (UKCTG)	● Review of outcomes as reported within LCRN Annual Report ● Review of performance on JDR
6.7	Stakeholder Engagement and Communications	Each LCRN delivers the Patient Research Ambassadors (PRAs) project	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report

ID	Domain	Indicator	Assessment Approach
6.8	Stakeholder Engagement and Communications	Each LCRN delivers the patient experience survey, as specified by the National CRN Coordinating Centre	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report
6.9	Stakeholder Engagement and Communications	Each LCRN develops and implements a plan to deliver the CRN NHS Engagement Strategy	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report
7.1	Workforce, Learning and Organisational Development	The LCRN has in place a senior leader with identified responsibility for the wellbeing of all LCRN-funded staff	● Individual's name and contact details provided to the National CRN Coordinating Centre ● Implementation of the local action plan to support the wellbeing framework and action plan
7.2	Workforce, Learning and Organisational Development	Each LCRN has an active programme of activities that engage the wider workforce to promote clinical research as an integral part of healthcare for all	● Evidence of programme of learning opportunities provided in LCRN Annual Plan and Report ● Increased engagement of local partners in promoting the work of the NIHR
7.3	Workforce, Learning and Organisational Development	The LCRN has in place a senior leader with identified responsibility for driving a culture of Continuous Improvement (Innovation and Improvement) supported by an action plan aligned to local and national initiatives and performance metrics	● Evidence of programme of activities provided in LCRN Annual Plan and Report ● Effective approaches shared by Continuous Improvement Leads at national meetings
8.1	Business Development and Marketing	Each LCRN has an up to date business development and marketing Profile using the template provided by the National CRN Coordinating Centre	● Profile template submitted as part of LCRN Annual Plan ● Contact details provided for assigned LCRN Profile lead in LCRN Annual Plan
8.2	Business Development and Marketing	The LCRN has an action plan for promoting the industry agenda aligned with the national business development strategy	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report
8.3	Business Development and Marketing	The LCRN actively contributes to the intelligence gathering process from NIHR CRN Customers using the template provided by the National CRN Coordinating Centre	● LCRN reports interactions with NIHR CRN Customers at the Life Sciences Industry Forum meetings

Part C: Operating Framework

1. Introduction

1.1. This Part C of Appendix A sets out the NIHR CRN Operating Framework effective from 1 April 2018.

1.2. The Operating Framework defines the organisational requirements, operational systems and processes that LCRNs are required to implement in order to ensure consistency across the LCRN infrastructure and, where necessary, standards for locally defined arrangements and systems.

2. Governance and Management

2.1. General Principles

2.1.1. In accepting the Authority's contract for the LCRN, the LCRN Host Organisation will need to:

(a) work to ensure the success of the LCRN and to secure a vibrant local NHS research environment within the LCRN's area and as part of a national system

(b) ensure the terms of the contract with the Authority are fully met

(c) ensure resources allocated to support clinical research activity are properly utilised, through the LCRN.

2.1.2. The LCRN Host Organisation board is accountable for the effective governance of the LCRN. The Board shall apply, in a proportionate and appropriate way, the principles of good governance and thereby promote:

(a) robust, transparent and accountable LCRN governance

(b) effective and supportive LCRN hosting arrangements

(c) effective and proportionate contracts with LCRN Partners and other organisations in receipt of LCRN funding or resources

(d) governance arrangements that ensure effective local performance management, LCRN Partner participation and engagement, research delivery and value for money.

2.1.3. The LCRN Host Organisation board will put in place governing structures, systems, terms of reference and local policies for the LCRN. As a minimum these shall include the specific governance requirements detailed in this contract in respect of:

(a) key personnel

(b) the Scheme of Delegation and LCRN Host Organisation board controls and assurances

(c) assurance framework and risk management system

(d) escalation process

(e) LCRN Partners

(f) The LCRN Partnership Group.

2.1.4. NHS patients, carers and the public are the key stakeholders in NIHR CRN research, and are to be included in LCRN governance arrangements.

2.1.5. LCRN governance arrangements should be documented in a single, up-to-date document and formally agreed by the LCRN Host Organisation board and by the National CRN Coordinating Centre.

2.2. Scheme of Delegation and Host Board Controls and Assurances

2.2.1. The LCRN Host Organisation shall have agreed a specific delegation of authority to the LCRN leadership team. This should be by a documented decision by the LCRN Host Organisation board.

2.2.2. As part of the delegation to the LCRN leadership team, the LCRN Host Organisation shall identify and agree appropriate board level controls and assurances around LCRN activities including:

(a) receipt of an LCRN Annual Plan, from the Nominated Executive Director, for approval

(b) receipt of an LCRN Annual Report, from the Nominated Executive Director, for approval

(c) submission of the LCRN Annual Plan and LCRN Annual Report to the National CRN Coordinating Centre for approval

(d) provision of the approved LCRN Annual Plan and LCRN Annual Report to all members of the LCRN Partnership Group.

2.2.3. The LCRN Host Organisation shall ensure the proper management of the LCRN in terms of compliance with the governance framework and processes of the LCRN Host Organisation, including human resources, standing financial, audit and standards of business conduct instructions. The LCRN Host Organisation shall ensure internal policies and standing financial instructions, as they affect the LCRN, do not unreasonably diminish the efficient management of the LCRN.

2.2.4. The LCRN Host Organisation shall ensure the LCRN is run in accordance with relevant laws and regulatory requirements, relevant national NHS policies and requirements, and the NHS Constitution.

2.3. Assurance Framework and Risk Management System

2.3.1. The LCRN Host Organisation shall maintain an assurance framework including a risk management system in respect of the LCRN.

2.3.2. The LCRN assurance framework will be scrutinised by the LCRN leadership team at their regular meetings, and shared with the LCRN Partners at LCRN Partnership Group meetings.

2.3.3. The LCRN Host Organisation will ensure robust and tested local business continuity arrangements are in place for the LCRN. This is to enable the LCRN Host Organisation 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 to return to "business as usual". Business continuity arrangements should be in line with guidance set out by the National CRN Coordinating Centre.

2.3.4. Annually, the LCRN Host Organisation must review its role in discharging the Authority contract for hosting the LCRN and must provide a report on this within the LCRN Annual Report. This report shall be shared with the LCRN Partnership Group and provided to the National CRN Coordinating Centre.

2.3.5. The LCRN Host Organisation must ensure LCRN activity is included in the local internal audit programme of work.

2.4. Escalation Process

2.4.1. The LCRN Host Organisation shall set out, implement and maintain a documented LCRN escalation process, which is in line with the accountability arrangements.

2.4.2. There will be identified points of contact within the LCRN management structure, the LCRN Host Organisation, and the National CRN Coordinating Centre for concerns and issues to be escalated.

2.4.3. Escalation routes and levels shall include:

(a) LCRN Clinical Director and/or Chief Operating Officer

(b) LCRN Host Organisation Nominated Executive Director for the LCRN

(c) LCRN Host Organisation Chief Executive Officer

(d) Chief Operating Officer, National CRN Coordinating Centre

(e) Chief Executive Officer, National CRN Coordinating Centre.

2.5. Corporate Support Services

2.5.1. The LCRN Host Organisation shall act as an effective steward of LCRN resources and ensure all management processes, facilities and support services

necessary for the effective leadership and management of the LCRN are provided.

2.5.2. These management processes, facilities and services shall include:

(a) governance, risk and assurance arrangements, including information governance

(b) financial management and reporting

(c) Human Resources (HR) services for LCRN staff, provided in a timely and expedited manner; this is to include streamlined HR and site access arrangements so that LCRN staff can work flexibly across all research sites

(d) Information and Communications Technology equipment as necessary and access to information systems as specified by the National CRN Coordinating Centre

(e) good-quality, modern office space, facilities and equipment for LCRN staff. The office for LCRN leadership and management staff is the de facto 'head office' of the LCRN, and it is important that it has the identity and is recognised as the local office of the NIHR CRN. The office must be provided by the LCRN Host Organisation to the satisfaction of the LCRN Clinical Director and LCRN Chief Operating Officer. The office should:

- be in an area accessible and welcoming to external visitors, including patients and members of the public
- include an allocation of private office space
- display appropriate NIHR CRN signage
- include separate reception arrangements; or, if this is impractical, shared reception arrangements agreed with the LCRN Clinical Director and LCRN Chief Operating Officer
- be clearly defined and demarcated from the space occupied by other LCRN Host Organisation departments if the LCRN space is within an open-plan environment.

(f) legal and contracting support, including sub-contracting administration.

2.5.3. An annual funding allocation will be made available to the LCRN Host Organisation to support the provision of these services. Support should be provided by suitably qualified and experienced staff commensurate with the level of funding.

2.6. Information Governance

2.6.1. The LCRN Host Organisation and LCRN Partners shall comply with the legal framework for information storage and access, and the information governance standards specified in the Authority's Information Governance Toolkit, and shall

complete the annual return in the timeframe specified by NHS Digital, with an attainment of Level 2 or above on all requirements.

2.6.2. In the event the LCRN Host Organisation receives any NHS Information Governance Toolkit scores of Level 1 or 0 in any financial year, it must investigate whether these deficiencies arise from or impact on NIHR CRN-funded activities. If so, the LCRN Host Organisation shall propose remedial actions. Remedial actions taken must be reported by the LCRN Host Organisation to the National CRN Coordinating Centre as part of the LCRN Annual Report.

2.6.3. The LCRN Host Organisation must put in place measures to assure itself that LCRN Partners are compliant with information governance requirements as set out in section 2.6.1 in respect of LCRN funded activities. The LCRN Host Organisation may be required to provide confirmation of information governance compliance of LCRN Partners in respect of LCRN funded activities, as part of the National CRN Coordinating Centre annual information governance audit.

2.6.4. The LCRN Host Organisation must ensure a process exists to report all information security incidents arising from LCRN-funded activities to the National CRN Coordinating Centre in a timely manner. Information governance incidents should be notified to crncc.ig@nihr.ac.uk.

2.6.5. The LCRN Host Organisation must ensure that, where there is a requirement to share data relating to the management and performance of research related activities, either within the LCRN and/or its LCRN Partner organisations, any such data are shared across LCRN boundaries/information systems in accordance with information governance best practice.

2.6.6. The LCRN Host Organisation will ensure any third party commercial information received by itself or LCRN Partner organisations from the NIHR CRN or accessed via NIHR CRN hosted information systems in support of any research related activities which is deemed commercially sensitive or marked as confidential will be treated as such, only used for the purpose for which it was provided and will be distributed as required only to those LCRN Partner organisations in agreement of the disclosure terms.

2.6.7. The LCRN Host Organisation must actively promote and enable good information governance within the LCRN Host Organisation and LCRN Partner organisations and make available someone with specialist knowledge of information governance to respond to queries raised relating to LCRN-funded activities. The LCRN Host Organisation must report this information to the National CRN Coordinating Centre within the LCRN Annual Plan.

2.7. Accountable Officer

2.7.1. The Chief Executive Officer of the LCRN Host Organisation is the Accountable Officer for this Agreement.

2.8. Leadership Team

2.8.1 Overview

2.8.1.1. The LCRN Host Organisation shall appoint an LCRN leadership team, including as a minimum:

(a) the Nominated Executive Director

(b) the LCRN Clinical Director

(c) the LCRN Chief Operating Officer.

2.8.1.2. The core responsibilities of the LCRN leadership team are to:

(a) provide leadership across the range of LCRN activities

(b) ensure LCRN activities are delivered in line with the governance requirements within this contract

(c) carry out such activities as may be necessary for the proper governance of the LCRN

(d) ensure a proper and auditable process is executed for the fair and effective distribution of LCRN funding

(e) be available for regular meetings as a core leadership team

(f) support scrutiny and transparency, e.g. by providing any information as required for the internal auditors, and attending the audit committee of the LCRN Host Organisation as requested

(g) ensure the timely delivery of performance and other reports

(h) support the LCRN Host Organisation by adhering to any local governance requirements, such as the local standing financial instructions and all relevant national NHS requirements

(i) convene regular LCRN Partnership Group meetings

(j) make freely available to the LCRN Host Organisation and all LCRN Partner organisations, as requested, any information that is not commercial and/or in confidence and in line with national NHS policies

(k) manage the LCRN so as not to compromise either the LCRN Host Organisation or LCRN Partner organisations through reasons of conflicting issues such as competition law or data protection.

2.8.1.3. LCRN Host Organisations must inform the National CRN Coordinating Centre in writing and at the earliest opportunity of any changes in personnel or long-term absence of any member of the LCRN leadership team, including the Deputy Chief Operating Officer.

2.8.1.4. The LCRN Clinical Director and the LCRN Chief Operating Officer will participate in LCRN support and development programmes developed by the National CRN Coordinating Centre.

2.8.2 The Nominated Executive Director

2.8.2.1. The LCRN Host Organisation Chief Executive Officer shall nominate an executive director, who is a voting member of the LCRN Host Organisation board, to act as the Board Director responsible for the LCRN (the "Nominated Executive Director").

2.8.2.2. The Nominated Executive Director will be the line manager for the LCRN Clinical Director.

2.8.2.3. The Nominated Executive Director may be the LCRN Host Organisation's Board level lead for research; however the nominated Executive Director should not be the organisation's R&D Director or equivalent. There must be a clear separation between accountability for the LCRN and accountability for the LCRN Host Organisation's own research activities.

2.8.2.4. The Nominated Executive Director role will include:

(a) where the LCRN Host Organisation is not the employer of the LCRN Clinical Director, ensure that all necessary contractual arrangements are in place between the LCRN Host Organisation and the employer in order that the LCRN Clinical Director can fulfil the duties of the role in full and with delegated authority equivalent to a substantive employee of the LCRN Host Organisation

(b) meet regularly with and generally support the LCRN Clinical Director and LCRN Chief Operating Officer in the delivery of the LCRN Work Programme, and be assured that this is being delivered

(c) ensure the LCRN assurance framework and risk management system are being properly managed

(d) be part of the escalation process for issues and concerns

(e) be available to members of the LCRN Partnership Group as part of the escalation process

(f) have the right to attend the LCRN Partnership Group meetings

(g) produce the annual review of the LCRN Host Organisation's role in discharging the Authority contract for hosting the LCRN, which will include details of LCRN Host Organisation Board oversight around controls and assurances, any relevant audit committee and internal audit activity, and statements of compliance in respect of the required Board approvals.

2.8.2.5. The LCRN Host Organisation Nominated Executive Director will delegate responsibility to the LCRN Clinical Director and LCRN Chief Operating Officer for the day-to-day leadership, management and oversight of the LCRN.

2.8.3 Clinical Director

2.8.3.1. The LCRN Clinical Director shall be the senior officer responsible for overall leadership and management of the LCRN.

2.8.3.2. The LCRN Clinical Director will be the line manager for the LCRN Chief Operating Officer.

2.8.3.3. The Clinical Director may be employed by the LCRN Host Organisation or by one of the LCRN Partner organisations, on condition that the provision of the Clinical Director and authority and lines of reporting and accountability are clearly set out in a documented agreement between the LCRN Host Organisation and the Clinical Director's employer.

2.8.3.4. The LCRN Clinical Director should have an annual appraisal meeting with the LCRN Host Organisation Nominated Executive Director, to monitor performance and identify opportunities and need for continuing professional development, including the NIHR leadership programme. The Nominated Executive Director must advise the National CRN Coordinating Centre in advance of the appraisal meeting in order to enable Coordinating Centre involvement in the appraisal.

2.8.3.5. At the discretion of the LCRN Host Organisation, the post of LCRN Clinical Director may be filled as a job-share; in this situation, however, one individual must be nominated as the senior post-holder who reports to the LCRN Host Organisation Nominated Executive Director.

2.8.3.6. LCRN Clinical Director posts should be reappointed every three years, with a possible extension of no more than two years.

2.8.3.7. The LCRN Host Organisation shall ensure that the National CRN Coordinating Centre is involved in the selection process for LCRN Clinical Directors. All LCRN Clinical Director appointments must be ratified by the National CRN Coordinating Centre.

2.8.4. Chief Operating Officer

2.8.4.1. The LCRN Chief Operating Officer will be responsible for the operational delivery of the contract and overall operational management of the Network. The Chief Operating Officer must be employed by the LCRN Host Organisation. The line management report must be to the LCRN Clinical Director.

2.8.4.2. The LCRN Chief Operating Officer should have an annual appraisal meeting with the LCRN Clinical Director, to monitor performance and identify opportunities and need for continuing professional development, including the NIHR leadership programme. The LCRN Clinical Director must advise the National CRN

Coordinating Centre in advance of the appraisal meeting in order to enable Coordinating Centre involvement in the appraisal.

2.8.4.3. The LCRN Host Organisation shall ensure the National CRN Coordinating Centre is involved in the selection process for Chief Operating Officers.

2.8.5. Deputy Chief Operating Officer

2.8.5.1. It is a requirement that there is in place a named deputy for the LCRN Chief Operating Officer, by means of either (a) a substantive post of 'Deputy Chief Operating Officer' or (b) another LCRN senior manager who is the named deputy in the absence of the Chief Operating Officer.

2.9. Management Team

2.9.1. The arrangements for the management of LCRN activities will be critical to LCRN success and delivery of the contract requirements. The LCRN Host Organisation will implement management arrangements in line with the management structures and staffing set out in this Part C of Appendix A.

2.9.2. The LCRN Host Organisation shall appoint an LCRN management team that is sufficiently resourced to provide:

(a) effective management of the delivery of the LCRN portfolio of studies across all Clinical Research Specialties; and

(b) effective management of all necessary supporting activities; and

(c) effective engagement with the National CRN Coordinating Centre and other LCRNs in the continuous improvement of the nation-wide NIHR CRN systems and processes.

2.9.3. The LCRN management team must include identified managers for the following functions as a minimum:

(a) Study Support Service (including management of Divisional Research Delivery, Cross-divisional Research Delivery, and Industry Operations)

(b) Workforce Development

(c) Business Intelligence

(d) Patient and Public Involvement and Engagement

(e) Communications

(f) Information and Communications Technology

(g) Finance

(h) Human Resources

(i) General administration.

2.9.4. The core responsibilities of the LCRN management team are to:

(a) deliver the management and operational (i.e. non-clinical) activities of the LCRN

(b) ensure LCRN activities are delivered in line with the governance requirements within this contract, and raise any non-compliance issues with the LCRN Leadership Team

(c) support the LCRN leadership team to ensure activities are carried out as may be necessary for the proper governance of the LCRN

(d) ensure CRN Portfolio studies, including life sciences industry research, are delivered in accordance with any specific agreed governance requirements.

2.9.5. Members of the LCRN management team may be employed by the LCRN Host Organisation, or by any LCRN Partner organisation, by agreement between the LCRN Host Organisation and the LCRN Partner organisation.

2.9.6. The LCRN Host Organisation will ensure all appointments to the LCRN management team are conducted in line with good human resources practice and in an open and competitive manner, and appointments do not favour those employed by the LCRN Host Organisation over other candidates.

2.10. Standard Role Outlines

2.10.1. The LCRN Host Organisation shall adopt the standard role outlines provided by the National CRN Coordinating for the following roles, ensuring all responsibilities listed in the role outlines are fully supported:

(a) Clinical Director

(b) Chief Operating Officer

(c) Clinical Research Specialty Lead

(d) Divisional Research Delivery Manager

(e) Industry Operations Manager.

2.11. Management Groups

2.11.1. The LCRN Leadership Team shall put in place the following LCRN management groups as a minimum:

(a) Executive Group

(b) Clinical Research Leadership Group

(c) Operational Management Group.

2.11.2. The Nominated Executive Director shall convene the LCRN Executive Group, whose membership shall include, as a minimum, the Nominated Executive Director, LCRN Clinical Director and LCRN Chief Operating Officer.

2.11.3. The LCRN Clinical Director shall convene the LCRN Clinical Research Leadership Group whose membership shall include the Clinical Director (Chair) and the Clinical Research Specialty Leads. The role of the Clinical Research Leadership Group is to advise the LCRN Executive Group, with particular respect to:

(a) clinical implications of national policy at the local level

(b) the balance of the LCRN portfolio across Specialties, sites, patient groups and study composition, seeking opportunities to expand research participation

(c) resource allocations

(d) other clinical intelligence and advice to support LCRN research delivery.

2.11.4. The LCRN Chief Operating Officer shall convene the Operational Management Group. The role of the group will be to ensure effective LCRN management and performance, acting as the forum to address cross-divisional and operational issues. The group will liaise with the Clinical Research Leadership Group and LCRN Clinical Research Specialty Groups regarding performance issues, resource allocation, the balance of the LCRN portfolio and availability of opportunities in the LCRN area for all patients to participate in research. The Operational Management Group will monitor the day-to-day operational performance of the LCRN, in particular delivery of objectives, and work with the National CRN Coordinating Centre at an operational level on national work relating to the LCRN. This includes managing performance of NIHR CRN Portfolio studies by Specialty and Division and identifying ways to address underperformance. The Operational Management Group membership shall consist of the Chief Operating Officer (Chair) and the LCRN senior operational managers who comprise the LCRN management team, including Research Delivery Managers and the Industry Operations Manager.

2.11.5. The LCRN Leadership Team shall ensure that Terms of Reference are in place for each of these groups, in line with the LCRN Contract Support Documents provided by the National CRN Coordinating Centre.

2.11.6. The LCRN Leadership Team may convene other management groups as deemed necessary, such as meetings of Research and Development Directors and Managers.

2.12. LCRN Partners

2.12.1. Organisations in receipt of LCRN funding to support NIHR CRN Portfolio research will be known as the LCRN Partners.

2.12.2. LCRN Partners will be of two types, of equal importance:

(a) Providers of NHS services with substantial levels of research activity, such that the organisation will receive a planned annual allocation of LCRN funding ("Category A Partners")

(b) Providers of NHS services with relatively low levels of research activity, typically ad hoc or intermittent in nature, involving low numbers of patients and/or low numbers of research studies, such that the organisation will not require a planned annual allocation of LCRN funding and instead will be reimbursed as required for costs incurred; this category is likely to include most primary care service providers, and other non-NHS organisations providing NHS services ("Category B Partners").

2.12.3. LCRN Host Organisations shall use the Category A LCRN Partner and Category B LCRN Partner flow down contract templates to contract with LCRN Partners, or any other sub-contract arrangements as instructed by the National CRN Coordinating Centre from time to time.

2.12.4. The LCRN Host Organisation will inform the National CRN Coordinating Centre in writing of the dissolution, merger or change of name of any LCRN Partner organisation.

2.13. LCRN Partnership Group

2.13.1. The LCRN Host Organisation will constitute a formal forum for LCRN Partners. This forum may also include those commissioning organisations that have contracts with such providers of NHS services. This forum shall be known as the LCRN Partnership Group. The LCRN Partnership Group should be formed of delegates with authority to represent and make decisions on behalf of their organisation. The LCRN Partnership Group will include lay representation.

2.13.2. The LCRN Host Organisation will agree an appropriate process that enables less research-active providers, primary care and independent contractors to the NHS, to be represented on the LCRN Partnership Group. Options for this might include, but are not limited to, representatives from NHS Clinical Commissioning Groups, NHS England regional teams and Directors of Public Health, as well as research-active independent contractors.

2.13.3. Where an LCRN has a large number of LCRN Partnership Group members, an arrangement for representation may be adopted, provided the LCRN Partner organisations within that arrangement delegate responsibility in writing from their Chief Executive Officer (or equivalent) to their representative organisation on the LCRN Partnership Group.

2.13.4. The LCRN Partnership Group must be chaired by a Chief Executive Officer from an LCRN organisation; either from the LCRN Host Organisation or from an LCRN Partner organisation.

2.13.5. The LCRN Host Organisation should be considered an LCRN Partner in its capacity as a recipient of NIHR CRN funding to support clinical research, a capacity separate to the LCRN hosting role. The LCRN Host Organisation therefore should be represented on the LCRN Partnership Group as an LCRN Partner, in order to represent the interests of the LCRN Host Organisation outwith the LCRN hosting function.

2.13.6. Expected frequency of meetings is four times each year as a minimum.

2.13.7. The Terms of Reference of the LCRN Partnership Group will include:

(a) reviewing and agreeing LCRN business plans and reports, including annual financial and business plans, development plans and the Annual Report, in advance of approval by the LCRN Host Organisation board

(b) informed by financial and activity data, active oversight and constructive mutual challenge of LCRN activity and performance, including delivery performance compared to funding allocated, in order to raise ambition and improve performance in each LCRN Partner organisation (or group of organisations, for less research-active LCRN Partners)

(c) monitoring of any compliance requirements of LCRN Partner organisations.

2.13.8. As a condition to receiving LCRN funding, and as set out in the Agreement between the LCRN Host Organisation and the LCRN Partner, 'Category A' LCRN Partner organisations will be required to support the LCRN Host Organisation in effective governance by:

(a) identifying an individual who has authority to represent and act on behalf of the organisation, preferably a voting member of the Organisation's Board, or alternatively a member of the Organisation's executive or senior management team. Regardless of position, in all cases the representative must have full authority to act and vote on behalf of the Partner Organisation. Should the representative be unable to attend a Partnership Group meeting, and where the Terms of Reference of the Partnership Group permit deputies, the deputy should have the same authority to act for the purposes of that meeting

(b) ensuring activities and funding in LCRN Partner organisations are managed in accordance with good governance

(c) ensuring any relevant governance or compliance matters, such as research governance or information governance or internal audits, are properly attended to and relevant details shared with the LCRN leadership team

(d) facilitating all NIHR CRN related internal audit reviews and investigations

(e) receiving the LCRN Annual Report at the Organisation's Board, to include details of their local involvement in the LCRN via a supplementary report from the organisation's LCRN Partnership Group representative

(f) reviewing and scrutinising LCRN business and funding plans, and performance against these, in order to maintain assurance around LCRN activities.

2.14. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Governance and Management which are accessible on the NIHR Hub:

Ref	Title
PM/003	NIHR Clinical Research Network Governance, Leadership & Management
PM/036	Notification of Absence of LCRN Host Organisation Nominated Executive Directors, LCRN Clinical Directors or LCRN Chief Operating Officers
PM/037	Process for Notification of Changes to LCRN Host Organisation Nominated Executive Directors, LCRN Clinical Directors or LCRN Chief Operating Officers
M/009	Representation on LCRN Partnership Groups of primary care and independent contractors to the NHS

3. Financial Management

3.1.1. The LCRN Host Organisation will receive, manage and distribute the allocated funding within the LCRN via the Department of Health-approved standard template sub-contracts as instructed by the National CRN Coordinating Centre.

3.1.2. The LCRN Host Organisation will use the funding solely to support the delivery of research activities as set out in this contract. The LCRN Host Organisation will put in place measures to provide assurance that LCRN funding provided to LCRN Partners is used solely for these purposes.

3.1.3. The LCRN Host Organisation will ensure that national 'top-sliced' funding is spent specifically on the purpose intended and underspends are not redistributed within the LCRN. Any national 'top-sliced' funding underspends should be reported, at the earliest opportunity to the National CRN Coordinating Centre where reallocation decisions will be made.

3.1.4. The LCRN Host Organisation, through the LCRN Executive team, will set out an annual local funding allocation model which will clearly describe the basis on which funding is allocated to LCRN Partner organisations. The local funding allocation model will be publicly available. Further detail regarding the required controls can be found in the Funding Allocations section of the LCRN Minimum Controls.

3.1.5. The LCRN Host Organisation will ensure that all payments made to distribute allocated funding are valid, complete, accurate, appropriately authorised and made promptly and within 30 days (as per Clause 6.2 of the DH/Host contract). Further detail regarding the required controls can be found in the Payments section of the LCRN Minimum Controls.

3.1.6. The LCRN Host Organisation, through the LCRN Executive team, will draw up an Annual Financial Plan for the LCRN as part of the LCRN Annual Plan. The LCRN Partnership Group will review and comment on the Annual Financial Plan. The plan shall be approved by the LCRN Host Organisation board and submitted to the National CRN Coordinating Centre for approval.

3.1.7. The LCRN Host Organisation will implement a budgetary control system to monitor actual expenditure to the Annual Financial Plan to ensure a full year forecast is produced at least quarterly. This forecast will be managed to ensure a breakeven position. Further detail regarding the required controls can be found in the Budgetary Control section of the LCRN Minimum Controls.

3.1.8. The LCRN Host Organisation will implement a system to ensure that financial reports provided to the National CRN Coordinating Centre are accurate, complete and up to date. Further detail regarding the required controls can be found in the Reporting section of the LCRN Minimum Controls.

3.1.9. The LCRN Host Organisation will report to the National CRN Coordinating Centre:

(i) a forecast outturn for the financial year which agrees to the Annual Financial Plan together with quarterly financial returns, via the NIHR CRN Finance Tool or any other system specified by the National CRN Coordinating Centre, to agreed deadlines. Further detail regarding the required controls for the NIHR CRN Finance Tool can be found in the Finance Tool section of the LCRN Minimum Controls.

(ii) an end-of-year financial return to the National CRN Coordinating Centre in respect of all LCRN funding received. The financial return must report on all LCRN funding and expenditure, for all organisations in receipt of that funding, and agree to the year-end figures in the respective Trusts' or other organisations' accounts by the deadlines specified by the National CRN Coordinating Centre.

(iii) the end-of-year financial return to the National CRN Coordinating Centre must include a signed disclosure statement from the LCRN Host Organisation Director of Finance and LCRN Chief Operating Officer. Disclosure statement Version 1.0 can be found as an appendix of the LCRN Minimum Controls.

3.1.10. The LCRN Host Organisation must obtain assurance that the financial information provided by the LCRN Partner Organisations is accurate and complete and that all costs are valid and appropriately authorised. Further detail

regarding the required controls can be found in the Monitoring of LCRN Partner organisations section of the LCRN Minimum Controls.

3.1.11. The LCRN Host Organisation will obtain a signed disclosure statement from each Partner organisation signed by the Director of Finance of the Partner organisation. The disclosure statement can be found as an appendix of the LCRN Minimum Controls.

3.1.12. The LCRN Host Organisation must ensure the financial management, budgeting and reporting of LCRN funding is managed by suitably qualified and experienced finance staff both within the LCRN Host Organisation and in LCRN Partners, commensurate with the level of funding.

3.1.13. The LCRN Host Organisation must obtain assurance from the Host and LCRN Partner organisations that NIHR funding is not used to subsidise commercial research. A cost recovery basis as stated in HSG(97)32 "Responsibilities for meeting patient care costs associated with research and development in the NHS" and reiterated in "Attributing the costs of health and social care Research and Development" (AcoRD) guidance issued by the Authority and its eligibility criteria for NIHR CRN Support, which is available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/140054/dh_133883.pdf should be adopted within the LCRN Host Organisations and Partner organisations standard operating procedures. Further detail regarding the required controls can be found in the Commercial Cost Recovery section of the LCRN Minimum Controls.

3.1.14. LCRN funding cannot be used to meet redundancy costs.

3.1.15. CRN funding must be treated as a ring-fenced budget. Therefore, CRN funding must not be subject to spending restrictions that might be applied to other budgets in LCRN Host or Partner organisations, e.g. restrictions on recruitment of staff or non-pay spend. CRN funding cannot be used for the purposes of contribution to an organisation's Cost Improvement Programme or similar cost saving exercises. It is expected that LCRN funding is held within ring-fenced accounts in the financial ledgers of the LCRN Host Organisation and LCRN Partner organisations to facilitate financial management and reporting.

3.1.16. The LCRN Host Organisation shall comply with any other financial guidance from the National CRN Coordinating Centre in respect of LCRN funding.

3.2. NIHR CRN Finance Tool Data Protection

3.2.1. The National CRN Coordinating Centre processes personal data consisting of information provided by LCRN Host Organisations relating to staff funded in part or in whole by the NIHR Clinical Research Network, including name, employer and salary details.

3.2.2. These data are processed for the following purposes:

(a) in order to ensure public funds are spent appropriately

(b) in order to aid in financial audit

(c) to provide aggregated anonymised information on numbers, types and grades of staff funded by the NIHR CRN

(d) for resource management activity for which the National CRN Coordinating Centre has responsibility.

3.2.3. The National CRN Coordinating Centre processes these personal data in order to exercise its function as the managing agent for the Authority. The Authority is the Data Controller for these data.

3.2.4. The National CRN Coordinating Centre processes all data fairly and lawfully in accordance with the Data Protection Act.

3.2.5. Access is granted solely to those with responsibility for carrying out these activities.

3.2.6. Only relevant data are collected and there is no further processing other than for those reasons noted in section 3.2.2. above.

3.2.7. All data are saved on a secure network that is regularly backed-up.

3.2.8. Data are retained for seven years post contract end date and are then destroyed via secure means.

3.2.9. The LCRN Host Organisation is responsible for informing its CRN-funded staff that their data will be shared with the National CRN Coordinating Centre, including the nature of the data and why it is shared.

3.3. Audit

3.3.1. The LCRN Host Organisation must undertake an internal audit at least once every three years in respect of LCRN funding.

3.3.2. The internal audit must cover the Minimum Control standards specified by the National CRN Coordinating Centre.

3.3.3. The LCRN Host Organisation shall provide a report of each internal audit to the National CRN Coordinating Centre (crn.finance@nihr.ac.uk) within a month following receipt of the final audit report, including the summary, recommendations and implementation plan.

3.3.4. Further updates regarding the implementation of the audit recommendations should be provided to the National CRN Coordinating Centre, timings as agreed with the NIHR CRN Finance team. The LCRN shall provide additional information in respect of the internal audit request by the National CRN Coordinating Centre.

3.3.5. An Internal audit in respect of LCRN funding managed by Partner organisations should be undertaken in the event of a material or reputational risk being identified by the LCRN Host Organisation through the monitoring visits or by any other means. Further detail on the monitoring visits is contained in the Minimum Controls document. It is our expectation that the audit is undertaken by the Partner organisations internal audit provider and any areas of concern related to

NIHR funding are highlighted to the Host Organisation and the National CRN Coordinating Centre.

3.3.6. The costs incurred by the LCRN Host Organisation or the Partner organisations in undertaking an internal audit can be charged against LCRN funding.

3.4. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Financial Management which are accessible on the NIHR Hub:

Ref	Title
F/004	CRN Funding Reporting Guidance
F/007	LCRN Minimum Controls

4. CRN Specialties

4.1.1. 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 Portfolio of research studies.

4.1.2. The LCRN will engage with local patient and clinical research communities through local Clinical Research Specialty Groups that provide the structure through which those working in Specialties within the LCRN area are able to network and engage with study delivery. Each LCRN Clinical Research Specialty Group will maintain an overview of the Specialty research portfolio, ensuring it is balanced, where possible, includes both non-commercial and commercial contract research, and includes clinical trials (including prevention, diagnosis, treatment and care) and other well designed studies relevant to the needs of the local patient population. The LCRN Clinical Research Specialty Groups will promote consistent delivery to time and target of the local research portfolio, underpinned by robust feasibility, and contribute to the Study Support Service, as appropriate. It will be essential for the LCRN Clinical Research Specialty Groups to seek opportunities to expand participation in relevant studies on the NIHR CRN Portfolio and those progressing through the funding pipeline. It is expected that these groups will have representation from the full range of clinical professionals.

4.1.3. Each LCRN Clinical Research Specialty Group will be led by an appointed LCRN Clinical Research Specialty Lead. The LCRN Clinical Research Specialty Leads will report to the LCRN Clinical Director or Clinical Research Leads (Divisional), and to the relevant National Clinical Research Specialty Lead. LCRN Clinical Research Specialty Leads will be responsible for the clinical leadership of their research communities within the LCRN area, development of LCRN Clinical

Research Specialty Groups and clinical oversight of the performance of the Specialty portfolio of studies.

4.1.4. The LCRN Host Organisation will ensure that support is provided to the LCRN Clinical Research Specialty Leads to enable them to undertake their role in contributing to the NIHR CRN's nation-wide study support activities, specifically in respect of commercial early feedback and non-commercial expert review for the eligibility decision and including where applicable, local feasibility activities, delivery assessments and performance reviews.

4.1.5. The LCRN Host Organisation must inform the National CRN Coordinating Centre of any changes to LCRN Clinical Research Specialty Leads.

4.1.6. LCRN Clinical Research Specialty Leads will be expected to play an active role in the national Clinical Research Specialty Group for each Specialty, which comprises the Clinical Research Specialty Leads from all the LCRNs. Each national Clinical Research Specialty Group is led by a National Clinical Research Specialty Lead who reports to a Specialty Cluster Lead within the National CRN Coordinating Centre. Together with other LCRN Clinical Research Specialty Leads and the communities of practice within that Specialty, they will constitute national networks of Specialty expertise.

4.1.7. The LCRN Clinical Research Specialty Leads will provide clinical intelligence and advice, particularly to the Divisional Research Delivery Manager(s) and through the nation-wide Study Support Service elements including commercial early feedback, non-commercial expert review, delivery assessments and performance reviews to support research delivery across the LCRN, addressing resource allocations and the balance of the LCRN portfolio across Specialties, sites, patient groups and study composition, as well as providing guidance on the clinical implications of national policy at the local level.

4.1.8. LCRN Clinical Directors and LCRN Clinical Research Specialty Leads may be employed by the LCRN Host Organisation or one of the LCRN Partner organisations within the LCRN area through a formal agreement between the LCRN Host Organisation and the relevant organisation.

4.2. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of CRN Specialties which are accessible on the NIHR Hub:

Ref	Title
PM/039	Process for the Management and Escalation of Issues Relating to Local Specialty Performance
M/014	NIHR CRN Urgent Public Health Research: Urgent Public Health Champion role outline

5. Research Delivery

5.1. Research Delivery Divisions

5.1.1. Operational management and delivery of the LCRN portfolio of studies will be organised through Research Delivery Divisions. These Divisions are determined nationally and each will manage research delivery for a cluster of Clinical Research Specialties.

5.1.2. The 30 Clinical Research Specialties are grouped into 6 Divisions for operational management purposes, typically as follows:

(a) Division 1: Cancer

(b) Division 2: Cardiovascular disease; Diabetes; Metabolic and endocrine disorders; Renal disorders; Stroke

(c) Division 3: Children; Genetics; Haematology; Reproductive health and childbirth

(d) Division 4: Dementias and neurodegeneration (DeNDRoN); Mental health; Neurological disorders

(e) Division 5: Ageing; Dermatology; Health services and delivery research; Oral and dental health; Musculoskeletal disorders; Primary care; Public health

(f) 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.

5.1.3. This grouping may be amended locally at the discretion of the LCRN Leadership Team in order to reflect local circumstances and operational efficiency. Each Specialty must be able to map to a Division detailed in 5.1.2 to support national oversight and clinical engagement.

5.1.4. Each local Division will have a nominated Research Delivery Manager to provide operational leadership. In each Division, Research Delivery Managers will also form national networks of operational expertise for Divisional groupings of Specialties, led by the Research Delivery function at the National CRN Coordinating Centre. A local Research Delivery Manager may provide operational leadership for more than one Division.

5.1.5. Research Delivery Managers will be responsible for the local management and delivery of all NIHR CRN Portfolio studies (commercial, collaborative and non-commercial), through nation-wide processes as defined by the Study Support Service, relating to the grouping of Specialties within their Division. They will work with the LCRN Operational Management Group to manage Divisional resources, identifying innovative and flexible approaches where appropriate. Effective interfaces with the Industry Operations Manager are essential. Each Research Delivery Manager will be the local single point of initial contact for all matters related to their respective portfolio of studies. The LCRN single point of

contact for commercial studies will triage to the Research Delivery Manager or other appropriate person. The LCRN single point of contact is used by the national Research Delivery function for feasibility requests and portfolio management, and external industry partners for study site queries, issues and escalation. Study level matters relating to commercial research studies will be initially channelled to the national single point of contact and cascaded to LCRNs, as appropriate.

5.1.6. Research Delivery Managers will work closely with all LCRN Clinical Research Specialty Leads to support clinical research within those Specialties.

5.1.7. Research Delivery Managers will work closely with the LCRN Industry Operations Manager to ensure an effective Study Support Service is delivered for commercial research in each of the LCRN Research Delivery Divisions.

5.1.8. Research Delivery Managers may be employed by the LCRN Host Organisation or other LCRN Partner organisations through a formal agreement between the LCRN Host Organisation and the relevant organisation.

5.2. Cross-divisional Research Delivery Team

5.2.1. The LCRN will have a cross-divisional research delivery team to undertake activities that support all clinical Specialties. This will include the LCRN Industry Operations Manager. The core functions of the cross-divisional team will include provision of the Study Support Service as defined by the National CRN Coordinating Centre adhering to the relevant Standard Operating Procedures and LCRN Contract Support Documents. This includes:

(a) industry operations activities, working closely with the Research Delivery Managers to include provision of a single point of contact service for the life sciences industry

(b) support for local confirmation of capacity and capability under the Health Research Authority (HRA) Approval process.

5.2.2. LCRNs should continue to drive and support arrangements that streamline and simplify these functions, such as “mutual recognition” and “single sign off” arrangements.

5.2.3. Members of the cross-divisional research delivery team may be employed by the LCRN Host Organisation or LCRN Partner organisations within the LCRN area through a formal agreement between the LCRN Host Organisation and the LCRN Partner organisation. These members are considered as LCRN staff working to deliver NIHR CRN support activities to the nation-wide standards defined by the Study Support Service.

5.3. Delivery of Research

5.3.1. The LCRN Host Organisation shall ensure all LCRN Partners adhere to national systems, Standard Operating Procedures and operating manuals in respect of research delivery as specified by the National CRN Coordinating Centre.

5.3.2. The LCRN Host Organisation shall ensure the LCRN management team provides effective study performance management, in line with Standard Operating Procedures and LCRN Contract Support Documents issued by the National CRN Coordinating Centre, in order to ensure all NIHR CRN Portfolio studies recruit to agreed timelines and targets; this is an organisation wide priority.

5.3.3. The LCRN Host Organisation will scope out appropriate mechanisms for engaging with and optimising performance in primary care to improve delivery of all studies.

5.3.4. The LCRN Host Organisation will ensure the LCRN develops and implements a local engagement and communication strategy with stakeholders involved in the research delivery pathway (to include patients, carers and the public, other NIHR Infrastructure such as NIHR Research Design Services, Clinical Trials Units, Sponsors (industry/HEI) and Academic Health Science Networks). The strategy should promote a shared understanding of NIHR CRN processes and develop a culture that encourages early contact between the parties to facilitate the successful set-up and delivery of research.

5.3.5. The LCRN Host Organisation will demonstrate a “one Network” approach to delivery, supported by engagement with and implementation of the Study Support Service, and will ensure that duplication of nation-wide support activities is avoided.

5.3.6. The LCRN Host Organisation will ensure the LCRN carries out its appropriate role in delivering all support activities throughout the research delivery pathway in line with the AcoRD guidance. Where the LCRN or any LCRN Partner determines it cannot carry out the role set out in this policy for any ‘high priority’ CRN Portfolio study (as defined in the CRN Eligibility Criteria) on grounds other than non-feasibility, the LCRN must advise the National CRN Coordinating Centre in advance of communication of this decision to the investigator. Any such refusal of a high-priority study must be reported in the LCRN Annual Report to the National CRN Coordinating Centre. Use of national standard templates referenced in the AcoRD guidance are mandatory for the presentation, negotiation and agreement of study costing and/or attribution, for example the NIHR CRN Industry Costing Template.

5.3.7. The nation-wide support activity areas are defined below. They include a number of sub-activities as described by the Study Support Service to ensure consistent support for researchers:

(a) Early contact and engagement

(b) Early Feedback

(c) Site Identification

(d) Study optimisation

(e) Effective Study Set-up

(f) Study Performance.

5.3.8. The LCRN Host Organisation will ensure the LCRN involves patients, carers and the public in its activities at all stages of the research delivery pathway as part of a documented patient, carer and public involvement plan.

5.3.9. The LCRN Host Organisation must ensure appropriate arrangements are in place to support the rapid delivery of urgent public health research, which may be in a pandemic or related situation. It shall ensure the LCRN has an urgent public health research plan which can be immediately activated in the event the Authority requests expedited urgent public health research. The LCRN Host Organisation must also appoint an active clinical investigator as the LCRN's public health champion to act as the key link between the LCRN and the National CRN Coordinating Centre and support the Urgent Public Health Research Plan in the event of it being activated.

5.4. Life Sciences Industry

5.4.1. The LCRN Industry Operations Manager will work closely with the LCRN Chief Operating Officer to enable the implementation of the NIHR CRN Working with the Life Sciences Industry Strategy within the LCRN. The Industry Operations Manager will lead the oversight of the Study Support Service for commercial research, including the single point of contact service, within the LCRN. The Industry Operations Manager will work closely with the Research Delivery Managers to deliver an effective and responsive local service which improves delivery to time and target and increases the number of commercial studies delivered within their LCRN. The Industry Operations Manager will liaise with the Study Start Up & Feasibility Research Delivery and Research Operations functions within the National CRN Coordinating Centre to ensure consistency of feasibility, study performance and national delivery of the Study Support Service for commercial research across the LCRNs. The Industry Operations Manager will be responsible for the promotion of the industry agenda to LCRN Partner organisations and investigators, delivering aspects of the NIHR CRN Working with the Life Sciences Industry Strategy and the NIHR CRN Business Development and Marketing strategy.

5.5. Delivering on the Government Research Priority of Dementia

5.5.1. In line with the Government's priority, the LCRN Host Organisation will ensure the LCRN will prioritise dementia research and will work with the National CRN Coordinating Centre and the office of the NIHR National Director for Dementia Research to deliver the NIHR CRN response to the Prime Minister's challenge on dementia.

5.5.2. The High Level Objective for dementia for the NIHR CRN is to increase the number of people participating in Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio (Table 1: HLO 7). To achieve this, the LCRN will deliver activities to increase the number of Dementias and

Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio that are conducted within the LCRN and improve how they are delivered across different healthcare settings.

5.5.3. The dementias and a range of other neurodegenerative diseases are increasingly understood to have commonalities both in terms of their underlying mechanisms, and in patient presentation, experience and management. It is recognised that advances in understanding of these diseases and new treatments are likely to come from inter-disciplinary research. Measuring the number of people recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio, as opposed to recruitment into dementia-specific studies, will reflect the commonality across the dementias and other neurodegenerative diseases. The LCRN Host Organisation will ensure the LCRN supports this strategy by:

(a) engaging with local patient and clinical research communities at a disease level, in particular Dementias and Neurodegeneration (which includes Parkinson's disease, Huntington's disease and motor neurone disease)

(b) identifying and nominating a clinical research lead in each of these two disease areas to support the delivery of the Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio through local clinical leadership and participation in national activities, including national feasibility review.

5.5.4. To support recruitment to dementia studies, the NIHR, in partnership with the Alzheimer's Society and Alzheimer's Research UK, manages a nationally consistent consent-for-approach system: (known as the "Join Dementia Research" system) for implementation by the NIHR and wider NHS. The LCRN will promote and support use of this system as advised by the National CRN Coordinating Centre and ensure its staff supporting the delivery of dementia studies are trained and equipped to use it.

5.5.5. The LCRN Host Organisation will ensure the LCRN works to increase access to research for people living in care homes and improve the delivery of dementia research in care homes by establishing a network of research-ready care homes.

5.5.6. The NIHR CRN has created a web-based toolkit, as part of the Healthcare Professionals section of the Join Dementia Research website, to support NHS organisations to improve recruitment to dementia studies on the NIHR CRN Portfolio. The LCRN Host Organisation will promote use of the toolkit in its LCRN Partner organisations and encourage them to share learning through it.

5.5.7. The LCRN Host Organisation will ensure the LCRN identifies resources at appropriate levels and sites to underpin the implementation of the CRN National RATER Programme required to support dementia research delivery.

5.6 LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Research Delivery which are accessible on the NIHR Hub:

Ref	Title
RD/021	Confidential information arrangements for the Life Sciences Industry feasibility services - Confidential Disclosure Agreement (CDA process)
RD/023	Provision of good practice in assessing, arranging and confirming local capacity and capability for participating organisations delivering NIHR CRN Portfolio studies
RD/024	Provision of good practice for sponsors to enable assessing, arranging and confirming local capacity and capability for participating organisations delivering NIHR CRN Portfolio studies
RD/040	Eligibility criteria for NIHR CRN support - Implementation document
RD/027	Eligibility criteria for NIHR CRN support - Annex A-Frequently Asked Questions
RD/042	NIHR CRN Study Support Service: Principles and Process for Setting and Amending Study Site Targets
RD/043	Principles for Local NIHR CRN Site Identification Process for commercial studies SOP
RD/044	Research Delivery Meeting Structure SOP
RD/045	Eligibility criteria for NIHR CRN support. Annex B - Overview of non-commercial eligibility review process
RD/046	Eligibility criteria for NIHR CRN support. Annex C - Overview of the self declaration process for NIHR non-commercial partners
RD/048	Eligibility criteria for NIHR CRN support. Annex D - Assessing the need for NIHR CRN support
RD/049	NIHR CRN Study Support Service: for Activity Attribution Support and Review SOP
RD/050	NIHR CRN Study Support Service: Early Contact & Engagement with Researchers SOP
RD/051	NIHR CRN Study Support Service: Industry Costing Template Validation SOP

RD/052	NIHR CRN Study Support Service: Study Performance Monitoring SOP
RD/053	National Study Delivery Assessment
RD/054	Effective Study Start-up
RD/055	Commercial Study Milestone Schedule Process
RD/056	Study Support Service Helpdesk SOP
RD/057	Commercial Eligibility and Feasibility Process SOP
RD/010	NIHR CRN Urgent Public Health Research: Set Up
RD/011	NIHR CRN Urgent Public Health Research: Initiation
RD/012	NIHR CRN Urgent Public Health Research: Delivery
RD/013	NIHR CRN Urgent Public Health Research: Reporting
M/014	NIHR CRN Urgent Public Health Research: Urgent Public Health Champion role outline
M/022	Provision of infrastructure support for research delivery in primary care settings
F/006	Income distribution from NIHR CRN Industry Portfolio Studies

6. Information and Knowledge

6.1. Information Systems

6.1.1. The LCRN Host Organisation must ensure appropriate, reliable and well maintained information systems and services are in place and fully operational.

6.1.2. The LCRN Host Organisation must adhere to the National CRN Coordinating Centre's Information Security Policy and the Acceptable Use Policy for the NIHR Hub issued by the Department of Health.

6.1.3. In order to ensure the safe, secure and legal management of public finances the LCRN Host Organisation must provide, or secure access to, a system to ensure robust financial management. This system should have the ability to undertake audit and provide financial reports as required.

6.1.4. The LCRN Host Organisation should ensure a suitable staff management system is in place to be able to provide (but not exclusively) mandatory HR returns on staffing levels and ethnicity. The system should also be capable of enabling the LCRN Host Organisation to conduct staffing audits and ensure effective workforce planning.

6.1.5. Where the LCRN Host Organisation undertakes any new or incremental development of local Information Systems that support LCRN activities, the LCRN Host Organisation must ensure the new or changed system interface aligns with existing NIHR CRN Information Systems.

6.1.6. Where the LCRN Host Organisation has procured information systems or applications to support LCRN activities (e.g. a Local Portfolio Management System) it is the responsibility of the LCRN Host Organisation (in association with the third-party provider) to ensure service management support is provided, as detailed in the National CRN Coordinating Centre LCRN Contract Support Documents.

6.1.7. For information systems or applications which support LCRN activity (e.g. research delivery), the LCRN Host Organisation must, in association with any third-party provider, ensure service management support is provided, as detailed in National CRN Coordinating Centre LCRN Contract Support Documents.

6.1.8. Where an issue with a national system cannot be resolved locally (e.g. an issue with the NIHR Hub), the LCRN Host Organisation must ensure the issue is escalated to the national NIHR CRN Service Desk, as detailed in National CRN Coordinating Centre LCRN Contract Support Documents. The LCRN Host Organisation must ensure information systems utilised in LCRN activities comply with the 2015-17 NIHR Information Strategy v2.0.

6.1.9. LCRN Host Organisations and LCRN Partner organisations must ensure business-critical information and associated information systems are of sufficient quality so that they are fit for purpose, accurate and trusted to support the business operations.

6.2. Local Portfolio Management System (LPMS)

6.2.1. The LCRN Host Organisation must ensure LCRN research delivery is supported by an LPMS solution that conforms to the requirements of the National CRN Coordinating Centre. This system should support all LCRN Partner organisations to capture the defined nation-wide minimum data set to support HLO reporting, research activity and local performance management of NIHR CRN Portfolio research as part of the single research intelligence system - a virtual network to collect, share and visualise intelligence using multiple local portfolio management systems and an overarching central system. The LPMS System of Choice requirements' specification and supporting documentation are available from https://sites.google.com/a/nihr.ac.uk/crncentral/knowledge-info/information-systems/lpmssoc-1.

6.2.2. The LCRN funding allocation provides for the ongoing provision of an LPMS solution, for use by LCRN-funded staff supporting research delivery in the LCRN Host Organisation and LCRN Partners. This should be made available for LCRN Partners to use for both NIHR CRN Portfolio and non-NIHR CRN Portfolio studies.

6.2.3. Where there is a requirement to migrate data from existing systems, the LCRN Host Organisation should work with its preferred supplier to support migration.

6.3. LCRN Business Intelligence

6.3.1. The LCRN Host Organisation is responsible for providing a specialist, experienced and dedicated LCRN Business Intelligence function which will provide information and data analysis relating to the performance of LCRN-funded activities.

6.3.2. The LCRN Host Organisation must ensure the LCRN Business Intelligence function has access to necessary Business Intelligence tools (i.e. QlikView) and adheres to requirements set out in the relevant LCRN Contract Support Documents provided by the National CRN Coordinating Centre.

6.3.3. The LCRN Host Organisation must ensure LCRN Business Intelligence staff contribute to the work of the national CRN Business Intelligence function, and support and collaborate with peers in other LCRNs, as required by the National CRN Coordinating Centre.

6.3.4. When sharing or citing LCRN performance data, e.g. in LCRN Annual Reports, plans and local communications, the LCRN Host Organisation must ensure that the data used are the official data as issued by the National CRN Coordinating Centre. Data should be generated from the NIHR CRN Open Data Platform as set out in the National CRN Coordinating Centre policy on data use and reporting.

6.4. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Information and Knowledge which are accessible on the NIHR Hub:

Ref	Title
SM/028	Business Acceptance Test Practice and LCRN Information Support
SM/059	Local Portfolio Management System Minimum Data Set

7. Stakeholder Engagement and Communications

7.1. Engagement and Communication

7.1.1. The LCRN Host Organisation has a duty to promote research opportunities to patients and public in line with the NHS Constitution for England, including informing patients about research that is being conducted within the LCRN area. Engagement opportunities offered by the National CRN Coordinating Centre-managed services such as Join Dementia Research (JDR) and the UK Clinical

Trials Gateway (UKCTG) should be communicated to all appropriate stakeholders.

7.1.2. The LCRN Host Organisation will take a proactive approach to supporting new and emerging NIHR strategies containing Stakeholder Engagement and Communication goals, relevant to the delivery of NIHR CRN objectives.

7.1.3. A sufficient non-pay budget line to deliver patient and public involvement, stakeholder engagement and communications activities should be provided. This includes LCRN-level resource required to deliver the JDR service.

7.1.4. The communications resource may be employed by the LCRN Host Organisation or another organisation, but the lead for communications must report directly to the LCRN Executive.

7.1.5. The LCRN Host Organisation will ensure the LCRN communications function develops and delivers a local communications plan that recognises the LCRN's position as part of a national system, and that supports:

(a) the implementation of the NIHR CRN NHS Engagement and Communications strategies and the NIHR Communications Strategy

(b) the implementation of the Communications Contract Support Document

(c) the development and maintenance of the LCRN's positive reputation

(d) transparency of local performance on research delivery

(e) strong internal and external stakeholder relationships

(f) patient, staff, carer and public awareness of local clinical research opportunities

(g) effective working with other parts of the NIHR, at a local, regional and national level.

7.1.6. The LCRN communications plan should also encompass local delivery of national NIHR campaigns.

7.1.7. The LCRN Host Organisation must contribute to national NIHR campaigns and initiatives in line with LCRN Contract Support Documents from the National CRN Coordinating Centre.

7.1.8. The LCRN Host Organisation must ensure the whole LCRN operates in line with the brand guidelines, operational requirements and national messaging as advised by the National CRN Coordinating Centre.

7.1.9. LCRN Partner organisations or researchers that are in receipt of funds or support from the NIHR should acknowledge this in publications.

7.2. Patient and Public Involvement and Engagement (PPIE)

7.2.1. The LCRN Host Organisation has a duty to promote research opportunities to patients and the public, in line with the NHS Constitution for England, including informing patients about research that is being conducted within the LCRN area,

and continuously improving patient experience of research through actively involving and engaging patients in research processes and engaging patients, carers and the public in research activities.

7.2.2. The LCRN Host Organisation will support the development and implementation of the NIHR CRN Patient and Public Involvement and Engagement Strategy and will write and deliver an adequately resourced workplan with outcomes, milestones and measurable targets for ensuring that patient choice, equality and diversity, experience, leadership and involvement are integral to all aspects of LCRN activity, in partnership across NIHR CRN. The LCRN Host Organisation must ensure adherence to the requirements set out in the Stakeholder Engagement Contract Support Document provided by the National CRN Coordinating Centre.

7.2.3. The LCRN Host Organisation will ensure it and LCRN Partners actively engage and involve patients, carers and the wider public in all aspects of local research delivery activity to improve the quality and delivery of NIHR CRN Portfolio research and patient access to it.

7.2.4. The LCRN Host Organisation will actively promote and facilitate LCRN Partners in hosting and supporting Patient Research Ambassadors and report on progress in the development of these roles via the LCRN Annual Report and to the PPIE Forum.

7.2.5. The LCRN Host Organisation will work with other local research organisations (e.g. Collaborations for Leadership in Applied Health Research and Care, Biomedical Research Centres, Biomedical Research Units, the Research Design Service and regional INVOLVE initiatives) to provide an accessible, coherent and consistent local patient offer of information about, access to, and involvement in clinical research.

7.2.6. The LCRN Host Organisation will gather feedback from study participants and potential participants in NIHR CRN Portfolio studies in line with the NIHR CRN Patient Experience and Continuous Improvement Framework as part of a local managed programme of innovation with LCRN Partner organisations to optimise patient and public experience of research.

7.2.7. The LCRN Host Organisation will roll out the patient experience survey to research participants and arrange for findings to be shared with the National CRN Coordinating Centre. The LCRN Host Organisation will actively support implementation of any specific recommendations arising from the survey, as part of continuous improvement activities.

7.2.8. The LCRN Host Organisation will actively support collaboration across LCRN Partners in developing joint work plans with measurable outcomes for provision of learning resources (e.g. Building Research Partnerships, Massive Online Open Courses (MOOCs)).

7.2.9. The LCRN Host Organisation will ensure LCRN-funded staff have easy access to the NIHR Hub, digital and social media and other developing sites as required by

the National NIHR CRN Coordinating Centre in order to reach out and engage diverse audiences in the development and delivery of engagement and involvement activities.

7.2.10. The LCRN Host Organisation will hold up-to-date information on its contact with patient, carer, public groups and stakeholder organisations and make it available in line with the NIHR CRN PPIE Information Framework.

7.2.11. The LCRN Host Organisation must identify a senior leader to take responsibility for PPIE within the LCRN. The identified lead will participate in nationally agreed PPIE initiatives and support the delivery of an integrated approach to PPIE across the NIHR CRN.

7.3. Health and care systems engagement

7.3.1. The LCRN Host Organisation has a duty to promote research opportunities to patients and the public, in line with the NHS Constitution for England, including ensuring healthcare and care professionals are informed about research that is being conducted within the LCRN area, and continuously improving processes through actively involving and engaging staff and their representative organisations in research activities. This will include promoting awareness of, and engagement with the National CRN Coordinating Centre managed services, such as Join Dementia Research and the UK Clinical Trials Gateway.

7.3.2. The LCRN Host Organisation will support the development and implementation of the NIHR CRN NHS Engagement strategy, and will work to deliver an adequately resourced workplan with outcomes, milestones and measurable targets, in partnership across NIHR CRN and the wider NIHR.

7.3.3. The LCRN Host Organisation must ensure adherence to the requirements set out in the Stakeholder Engagement Contract Support Document provided by the National CRN Coordinating Centre.

7.4. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Stakeholder Engagement and Communications which are accessible on the NIHR Hub:

Ref	Title
COM/016	Communications Contract Support Document
SEC/058	Stakeholder Engagement Contract Support Document

8. Organisational Development

8.1. Workforce, Learning and Organisational Development

8.1.1. The LCRN Host Organisation will support the development of effective networking leaders, who take an innovative and evidence-based approach to developing the capacity and capability of the workforce to deliver timely and high quality research in all clinical care settings.

8.1.2. The LCRN Host Organisation will support the continued implementation and refresh of the NIHR CRN Workforce Development strategy.

8.1.3. In order to ensure consistency in the provision of LCRN services, the LCRN Host Organisation will ensure LCRN-funded staff, patients and carers involved in the delivery of LCRN activities have learning and development commensurate with their role. LCRN Host Organisations will ensure that an awareness of clinical research is provided to staff at induction.

8.1.4. The LCRN Host Organisation shall establish a profile of NIHR CRN funded staff employed within the LCRN geography and demonstrate active workforce planning developed in partnership with relevant stakeholders.

8.1.5. The LCRN Host Organisation will develop a comprehensive workforce plan for LCRN staff that will enable a responsive and flexible workforce to deliver NIHR CRN Portfolio studies both current and anticipated. This will be developed in partnership with relevant stakeholders.

8.1.6. The LCRN Host Organisation shall identify a senior leader to coordinate workforce planning, recruitment, development and retention within the LCRN. The identified lead will participate in nationally agreed workforce development initiatives and support the delivery of an integrated approach to workforce development across the NIHR CRN.

8.1.7. The LCRN Host Organisation will contribute to the continuing development of learning and development resources in support of the NIHR CRN its services and people. Time should be released for funded CRN staff to contribute their knowledge and expertise across workforce, learning and organisational development initiatives. In addition the LCRN will champion a culture of improvement and innovation including knowledge transfer across the NIHR and the development of best practice.

8.1.8. The LCRN Host Organisation will be responsible for adhering to NIHR CRN defined quality standards and processes applicable to learning materials, resources and tools made available by the National CRN Coordinating Centre via the National Directory. The LCRN Host Organisation will ensure the LCRN adopts resources from the National Directory where appropriate.

8.1.9. The LCRN Host Organisation will attend to the wellbeing of all LCRN-funded staff by providing a positive work environment including appropriate professional line management, performance reviews, continuing professional development plans

and opportunities to undertake learning and development, in line with the NIHR CRN Workforce Development strategy.

8.1.10. The LCRN Host Organisation must ensure all LCRN-funded staff have opportunities to engage with the strategic initiatives of the NIHR CRN.

8.2. Continuous Improvement

8.2.1. The LCRN Host Organisation will promote and sustain a culture of Continuous Improvement (innovation and improvement) across all areas of LCRN activity to develop the NIHR CRN and its services including optimising performance.

8.2.2. The LCRN Host Organisation will ensure the LCRN adopts a breadth of appropriate approaches and interventions to ensure that it is responsive to the needs of its customers and the business, delivering innovative, streamlined, efficient and high quality services that demonstrate impact and benefit.

8.2.3. The LCRN Host Organisation will ensure continuous improvement awareness, knowledge and skills are a core competency of LCRN staff as appropriate to their role and that building capability (expertise and leadership) in this area is incorporated within the LCRN's workforce development strategy.

8.2.4. The LCRN Host Organisation shall identify a senior leader to take responsibility for embedding continuous improvement across the LCRN to:

(a) ensure the local delivery of the nation-wide Study Support Service is subject to continuous improvement, improving local processes and working arrangements to achieve the nation-wide service deliverables

(b) ensure LCRN leadership contributes to national/NIHR CRN-wide innovation and improvement programmes and projects

(c) work with the LCRN Chief Operating Officer and other key staff to oversee the development and execution of appropriate responses to improving local performance.

8.3 LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Workforce, Learning and Organisational Development which are accessible on the NIHR Hub:

Ref	Title
WL/025	NIHR CRN Good Clinical Practice programme
WL/026	National Learning and Development programmes
AHP/026	Embedding Continuous Improvement across the NIHR CRN

9. Business Development and Marketing

9.1.1. Business development with established national life science companies and non-commercial funders is the responsibility of the National CRN Coordinating Centre. Engagement with local small and medium sized enterprises within LCRN areas is the responsibility of the LCRNs with support from the National CRN Coordinating Centre.

9.1.2. The LCRN Host Organisation will ensure close working and open communication with the Business Development and Marketing team in the National CRN Coordinating Centre to ensure the needs of the customer are being met and the NIHR CRN is responsive to change.

9.1.3. The LCRN Host Organisation will:

(a) promote the continued importance of the industry agenda to LCRN Partner organisations and clinical teams

(b) work in partnership with the national Business Development and Marketing team to support national business development initiatives e.g. Biosimilars offer

(c) provide intelligence on interactions with NIHR CRN customers

(d) maintain an up to date LCRN "profile" to highlight the unique selling points of the LCRN for use by the National CRN Coordinating Centre for marketing purposes nationally and internationally

(e) supported by the national Business Development and Marketing team in ensuring that life sciences companies are appropriately briefed about the NIHR CRN Study Support Service offer during the NIHR CRN Industry Costing Template validation stage.

9.2. LCRN Contract Support Documents

LCRN Leadership Teams should ensure that all elements of the LCRN operate in compliance with the following LCRN Contract Support Documents in respect of Business Development and Marketing which are accessible on the NIHR Hub:

Ref	Title
BDM/032	Business Development & Marketing Contract Support Document

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