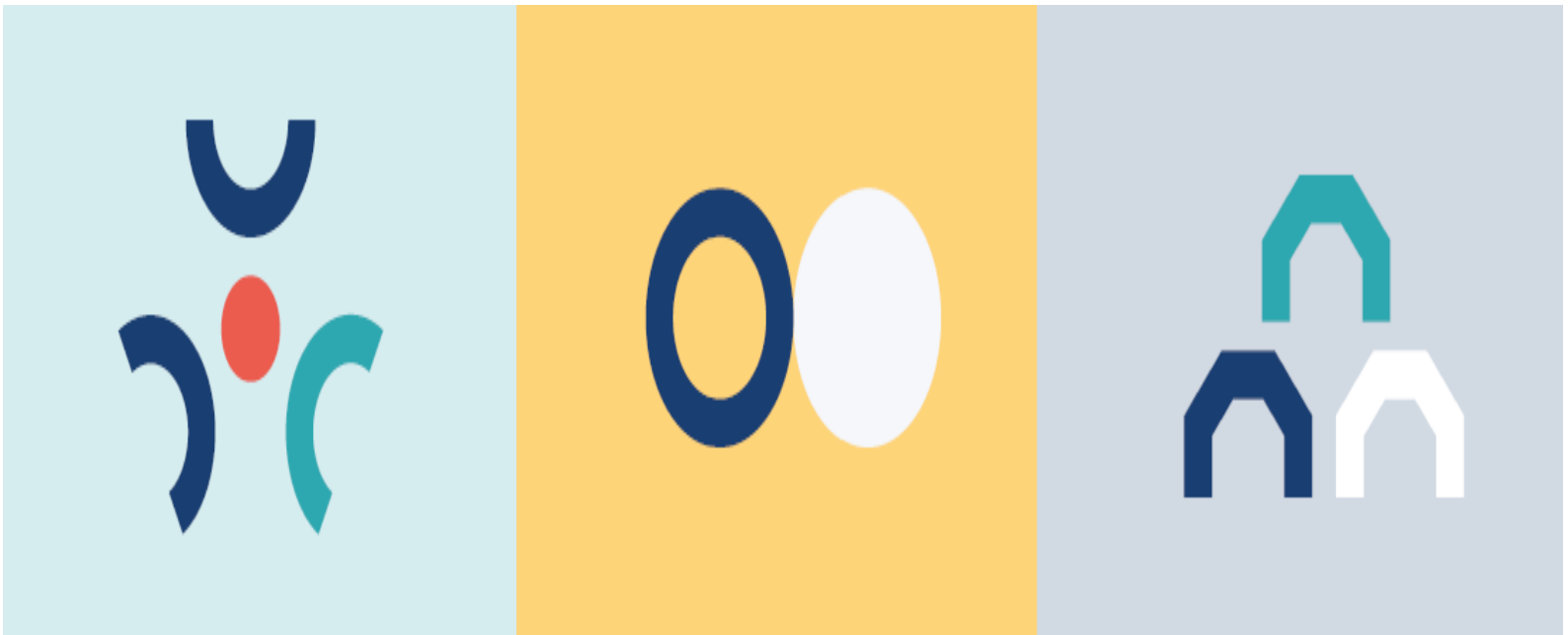
NIHR | National Institute for Health Research

Performance and Operating Framework 2019/20



APPENDIX A

PERFORMANCE AND OPERATING FRAMEWORK

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Part A: Context

A.1. Structure and Purpose of the NIHR CRN

A.1.1. 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.

A.1.2. The NIHR CRN provides NHS, public health and social care providers with an excellent research infrastructure to support delivery of the NIHR CRN Portfolio of high quality clinical, public health and social care research studies and to facilitate participation of NHS patients, users of social care services, carers, the public and others in these studies throughout England.

A.1.3. 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 prominently within the government's Life Sciences Industrial Strategy.

A.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. For studies delivered in wider health and social care settings the equivalent of NHS support is provided (e.g. research carried out in social care, care homes, hospices or public health settings).

A.2. Aims of the NIHR CRN

A.2.1. The aims of the NIHR CRN are defined by the Department of Health and Social Care (DHSC) 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

A.2.2. The aims of the NIHR CRN are to:

(a) Promote equality of access, ensuring that wherever possible, patients, the public, and users of social care services 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 and wider health care settings

(c) Streamline and performance manage NHS Support for eligible studies, to ensure the NHS Service Support Costs of these studies (or equivalent support in wider health and social care settings) 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

(h) Engage the providers of Public Health and social care services to promote research participation and a research culture.

A.3. Working Principles

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

(a) Participant-centred: We never lose sight of the fact that the research we help to carry out is for patient and public benefit

(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 and wider health and social care settings, including all providers of healthcare services, who are committed to the delivery of high-quality health and social care 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 health and social care 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 people 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 Sponsor type (commercial/non-commercial)
- Rare diseases

(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 disease Specialties across all NHS sectors and wider health and social care services

(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 and wider health and care settings

(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.

A.4. NIHR CRN Priorities 2019/20

A.4.1. Context

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

A.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.

A.4.2. NIHR CRN Strategies

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

(a) Business Development

(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.

A.4.2.2. These strategies were a DHSC contract requirement, and were approved by the DHSC through the DHSC/ 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.

A.4.2.3. During 2018 a detailed review of each strategy was carried out with internal and external stakeholders. Based on this work an assessment was made by the Executive Director sponsor for individual strategies, as to which goals were completed, now part of business as usual or remained a priority. This has led to the development of a proposed National CRN Coordinating Centre Annual Business Plan which is structured around key organisational wide priorities and incorporating those strategic priorities from the original strategies still viewed as important for the organisation.

A.4.3. 'One NIHR' Programmes

A.4.3.1. The five NIHR National Coordinating Centres have from April 2018 collaborated to deliver a number of work programmes in areas that 'cut across' the five centres and that will benefit the NIHR as a whole.

A.4.3.2. These programmes are managed through the NIHR Centres Executive Board.

A.4.3.3. The NIHR Centres Executive Board has yet to agree the programmes for the contract year 2019/20 but we expect to contribute to the following:

(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) Global Health Research Programme

(d) Research Charity Engagement Programme

(e) Workforce Development and Learning Programme

A.4.4. CRN Optimisation Programme

A.4.4.1. The DHSC has requested that the CRN seeks to identify potential improvements to CRN structures, processes and working arrangements in order to ensure that the CRN is optimised to support NHS, public health and social care research in the longer term.

A.4.4.2. This programme of work will be included as an individual section in the National CRN Coordinating Centre Annual Business Plan 2019/20.

A.4.5. NIHR CRN High Level Objectives

A.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 and other health and care settings. 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 'ambitions' set on an annual basis by the DHSC.

A.4.5.2. For 2019/20 a primary focus will remain on all NIHR Local Clinical Research Networks meeting the ambition that 80% of CRN Portfolio studies are delivered to recruitment target and time (HLO 2 relating to commercial studies and non-commercial studies).

A.4.6. Integrated Research Intelligence System (IRIS)

A.4.6.1. The Integrated Research Intelligence System (IRIS) Programme ensures that there is oversight and governance of all activity impacting on systems that are components of the CRN. Specifically the NIHR CRN Central Portfolio Management System (CPMS) and the Local Portfolio Management Systems (LPMS) of the 15 NIHR Local Clinical Research Networks, Open Data Platform and other future systems identified or created that are deemed 'relevant information systems'.

A.4.6.2. To achieve the goal of having a single research intelligence system, the NIHR CRN is adopting the principle that all research activity will be collected within LPMS and provided electronically to CPMS.

A.4.6.3. For 2019/20 the CRN will focus on delivering an integrated system which enables data flow from the local source of the research activity and the provision of core study information to all organisations to improve data quality while reducing cross-checking of information. This will directly enable swifter action in support of study delivery based on this more accessible intelligence. Nationwide, near real time data for research conducted by NHS Providers as a collective is a huge advantage in a global market, with increased research activity improving the health and wealth of the nation.

A.4.6.4. This will:

- Enable 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;
- Drive the efficient provision and best use of intelligence for NIHR research studies;
- Support the government view that providing better information about public organisations will deliver better value for money in public spending, drive growth and inform choice;
- Support the UK Information Strategy which applies to all aspects of the NHS, including research.

A.4.6.5. Data integration designed into CPMS/LPMS is formed of three principles:

(a) “Get Study” - the functionality to exchange core details of CRN studies between CPMS and LPMS’;

(b) “Capacity and Capability” -the functionality to exchange information on the readiness of research sites to conduct a CRN study;

(c) “Research Activity” -the functionality to exchange information on participation and participants in a CRN study.

A.4.7. Development of National CRN Coordinating Centre during contract extension period

A.4.7.1. The rapidly changing clinical research landscape is both an asset and a challenge.

A.4.7.2. The NIHR CRN is expected to extend its reach into health and social care settings and to work in new, innovative and novel ways. Equally there is an expectation of efficiency and effectiveness in the use of resources. Mindful of this the National CRN Coordinating Centre has worked with its senior managers to agree a focus of unified priorities for 2019/22. This will ensure corporate focus on those areas that are viewed as adding most value to the work of the CRN. They are as follows:

- In conjunction with our partners, actively connect and develop our digital assets to ensure equity of access to opportunities.
- Ensure that the research engaged workforce can rapidly access high quality learning opportunities at point of need.
- Lead the management and development of high quality and innovative research services in all health and care settings.
- Deliver a diverse range of digital engagement activities to support the empowerment and personalisation of research for patients, carers and the public.
- Evidence the impact and value of the activity of the CRN on the health and care sector.

  Work with the life sciences sector to support the development of the global research system.

A.4.8. Implement Optional Services as required

A.4.8.1. Under clause 7.5 (“Optional Services”) of the DHSC 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

B.1. Introduction

B.1.1. This Part B of Appendix A sets out the NIHR CRN Performance Framework effective from 1 April 2019.

B.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.

B.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.

B.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.

B.2. LCRN Performance Indicators - Background

B.2.1. The following sets of indicators will be used by the National CRN Coordinating Centre and DHSC 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 Compliance Indicators	The performance of the LCRN in operating in compliance with mandated operational structures and processes
4	Initiating and Delivering Clinical Research Performance Indicators	The performance of individual providers of NHS services in initiating and delivering clinical research as set out in Clause 3A (Performance in Initiating and Delivering Clinical Research) of Section 2 (Terms and Conditions) of the Contract between the LCRN Host Organisation and the DHSC
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

B.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)

B.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.

B.2.4. The National CRN Coordinating Centre carried out an extensive consultation with the 15 LCRNs and their Partner organisations during 2018. The final revised set of objectives approved by DHSC is set out at Table 1.

B.2.5. The LCRN Host Organisation will plan and report on the LCRN's contribution to these national HLOs.

B.2.6. The most significant change to the previous set of High Level Objective is that single and specific targets for set-up (HLOs 4 and 5) have been removed as key performance indicators of CRN activity. This is in recognition of the wider

NIHR and DHSC requirement for providers to report and publish clinical trial initiation and delivery data for all clinical trials as noted in the NHS England consultation for simplifying research arrangements (Supporting Research in the NHS: A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract). This follows the removal of the 70 day benchmark single target for set-up and initiation of clinical trials in 2018 as previously required in the Plan for Growth. A new measure of data completeness for trial initiation and delivery data, defined in the NIHR Minimum Data Set, will underpin the ability of NIHR and DHSC to report and publish these data.

Set 2 – Clinical Research Specialty Objectives

B.2.7. The Clinical Research Specialty Objectives are the development and performance objectives for the 30 NIHR CRN Clinical Research Specialties. The NIHR CRN National Specialty Groups propose the objectives on an annual basis, for approval by the National CRN Coordinating Centre and the DHSC.

B.2.8. The LCRN Host Organisation will plan and report on the LCRN's local contribution to these national Clinical Research Specialty Objectives and targets.

B.2.9. 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.

B.2.10. 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).

B.2.11. The Clinical Research Specialty objectives are presented in Table 2 below.

Set 3 – LCRN Operating Framework Compliance Indicators

B.2.12. 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.

B.2.13. 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.

B.2.14. The LCRN Operating Framework Indicators are presented in Table 3 below.

Set 4 – Initiating and Delivering Clinical Research Performance Indicators

B.2.15. 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.

B.2.16. With effect from 1 April 2018, improvement in clinical trial performance and reducing site set up and participant recruitment time is no longer assessed against a '70 day benchmark'. A renewed focus is being placed on transparency, accuracy and meeting Sponsor expectations by a number of agencies including the Health Research Authority (HRA), Clinical Commissioning Facility (CCF) and the National CRN Coordinating Centre.

B.2.17. The minimum data set and definitions in relation to the Performance in Initiating and Delivering Clinical Research have been updated to reflect this change. 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

B.2.18. The LCRN Host Organisation Agreement and the "flow down" agreement between the LCRN Host Organisation and each relevant Category A LCRN Partner ("relevant" meaning that the organisation is a provider of NHS services) 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. This has reaffirmed the existing requirement for providers to report and publish clinical trial initiation and delivery data for all clinical trials, as part of the ongoing NHS England led activities for simplifying research arrangements, outlined at: https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm.

B.2.19. The Authority will hold the LCRN Host Organisation and each relevant 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.

B.2.20. The LCRN Host Organisation and relevant 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.

B.2.21. Other providers of NHS services, including Category B and Category C LCRN Partners, have an important part to play in increasing performance in the initiation and delivery of research through supporting complete and accurate minimum data set reporting.

Set 5 – LCRN Partner Satisfaction Indicators

B.2.22. 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.

B.2.23. 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.

B.2.24. 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

B.2.25. 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.

B.2.26. 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

B.2.27. The research that the NIHR CRN helps to carry out is for patient and public benefit. Patients and the public remain central to what we do.

B.2.28. The LCRN Host Organisation will coordinate an annual survey of research participants, referred to as the 'Patient Research Experience Survey'. The survey will elicit patients' views of their experience of taking part in research and will also demonstrate to participants, and all those in delivery of care or

services to them, that we value their contribution and their experience of taking part in research. In addition, LCRNs should promote other mechanisms for participants to give feedback on their experience of taking part in research.

B.2.29. Each LCRN will design and deploy a survey to include a small number of standard questions specified by the National CRN Coordinating Centre. LCRNs are expected to achieve year-on-year improvements in response rates to the survey, with a target to elicit responses from a minimum of 1% of participants recruited into NIHR CRN Portfolio studies in the previous financial year. Each LCRN will report the local results of their survey to the National CRN Coordinating Centre, develop an action plan to improve survey response rates in the future to help inform improvements in research delivery and address the issues identified for improvement in patient experience.

B.3. Performance Management Processes

B.3.1. Annual Plan and Annual Report

B.3.1.1. 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.

B.3.1.2. 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.

B.3.1.3. 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.

B.3.1.4. 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.

B.3.1.5. The LCRN Annual Report will include a year-end financial report.

B.3.1.6. 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.

B.3.1.7. 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

B.3.1.8. 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.

B.3.1.9. 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).

B.3.1.10. The Mid-Year review meetings will be attended by members of the National CRN Coordinating Centre Executive team, Senior Management Team Links and the LCRN Clinical Director(s) and LCRN Chief Operating Officer. The LCRN Host Organisation Nominated Executive Director and LCRN Partnership Group Chair are invited to attend but attendance is not mandatory. Up to two additional observers from within the LCRN may also attend.

B.3.1.11. The annual performance review meetings will be attended by members of the National CRN Coordinating Centre Executive team, Senior Management Team Links and the LCRN Clinical Director(s) and LCRN Chief Operating Officer. The LCRN Host Organisation Nominated Executive Director and LCRN Partnership Group Chair are expected to attend.

B.3.1.12. The LCRN Annual Report will be reviewed at the Annual Review meeting in the second quarter of each contract year.

B.3.1.13. The National CRN Coordinating Centre will monitor compliance of LCRN Host Organisations in respect of the DHSC/LCRN Host Organisation Agreement, including the Performance and Operating Framework via a LCRN Contract Compliance Assurance Framework.

B.3.1.14. 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.

B.3.1.15. 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

B.3.1.16. 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.

B.3.1.17. 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.

B.3.1.18. 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.

B.3.1.19. 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.

B.3.1.20. 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.

B.3.1.21. The LCRN Host Organisation will be responsible for ensuring all LCRN Partners have access to timely LCRN performance data.

B.3.1.22. 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.

B.3.1.23. The LCRN Host Organisation will support local performance improvement projects which address underperformance against the NIHR CRN objectives.

B.3.1.24. 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.

B.3.1.25. The LCRN Host Organisation and its LCRN Partner organisations will actively contribute to national programmes for development, performance review and support.

B.3.2. 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 the LCRN Performance Indicators which are accessible on the NIHR Hub:

Ref	Title
CSD002	NIHR CRN High Level Objectives Data Point Grid

CSD031	NIHR CRN Performance Management Framework
CSD033	Requirements for LCRN Annual Planning
CSD034	Requirements for LCRN Annual Reporting
CSD035	Risks and Issues Log Requirements
CSD041	NIHR CRN Specialty Objectives Data Point Grid
CSD060	LCRN Planning, Reporting and Review Cycle: Key Dates
CSD067	LCRN Operating Framework Indicators Data Point Grid
CSD070	Patient Experience Feedback

B.4. LCRN Performance Indicators - Tables

Table 1 – NIHR CRN High Level Objectives

Objective		Measure	Ambition
1	Deliver significant levels of participation in NIHR CRN Portfolio studies	A - Number of participants recruited to NIHR CRN Portfolio studies	697,254[i]
		B - Number of participants recruited to commercial contract NIHR CRN Portfolio studies	40,010[i]
2	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	A - Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN 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 studies delivered for the commercial sector with support from the NIHR Clinical Research Network	A - Number of new commercial contract studies entering the NIHR CRN Portfolio	741[ii]
		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%

Objective		Measure	Ambition
4	Withdrawn. Replaced by new HLO 9.		
5	Withdrawn. Replaced by new HLO 9.		
6	Widen participation in research by enabling the involvement of a range of health and social care providers	A - Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	99%
		B - Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies	70%
		C - Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	45%[iii]
		D – Number of non-NHS sites recruiting into NIHR CRN Portfolio studies	TBC[iv]
7	Deliver significant levels of participation in NIHR CRN Portfolio Dementias and Neurodegeneration (DeNDRoN) studies	Number of participants recruited into Dementias and Neurodegeneration (DeNDRoN) studies on the NIHR CRN Portfolio, each year	25,000

Objective		Measure	Ambition
8	Demonstrate to people taking part in health and social care research studies that their contribution is valued	Number of NIHR CRN Portfolio study participants responding to the Patient Research Experience Survey, each year	10,000[v]
9	Reduce study site set-up times for NIHR CRN Portfolio studies by 5% [1]	A – Median study site set-up time for commercial contract studies, at confirmed Network sites (days) [2]	80[vi]
		B – Median study site set-up time for non-commercial studies (days) [2]	62[vi]

TABLE NOTES

[1] Site set up time defined as “Date Site Selected” to “Date First Participant Recruited”

[2] Average site set-up time defined as the median average of all individual site set-up times for all studies in a reporting year

[i] HLO 1A / 1B The Ambition values is the mean of the annual values for the 5-year period 2014/15 to 2018/19

[ii] HLO 3A The Ambition value is an increase in the 2018/19 annual value

[iii] HLO 6C Reverted to 2018/19 value of 45%

[iv] HLO 6D The Ambition value is the 2018/19 annual value plus 5%

[v] HLO 8 The Ambition value of 10,000 respondents represents an increase of 14% on the 2018/19 outturn of 8,779 respondents

[vi] HLO 9A / 9B The Ambition value is the 2018/19 annual value less 5%

Table 2 – Clinical Research Specialty Objectives

Specialty Objective	Specialties Included	Measure	Target
1. To develop local LCRN schemes/programmes for promoting and improving early career researcher (ECR) involvement in NIHR research	All	A. LCRNs to have at least one named individual who acts as an ECR/Training Lead **AND** B. LCRNs to demonstrate year on year increases in ECR involvement in at least 50% of specialties (e.g. new PIs or CIs, links with Royal College or other professional organisations, record of ECR staff per specialty and the trials to which they are recruiting – they may not necessarily be LCRN funded)	A. 1 ECR/Training Lead per LCRN **AND** B. 5% Increase in ECR involvement in 50% of all specialties
2. To increase opportunities for people to participate in health research in less established specialties (<70 open studies on the NIHR CRN Portfolio in April 2018)	● Ageing ● Anaesthesia, Perioperative Medicine and Pain Management ● Critical Care ● Dermatology ● Ear, Nose and Throat ● Haematology ● Injuries and Emergencies ● Oral and Dental Health ● Public Health	Each LCRN to increase recruitment in studies or the number of studies open to recruitment within all of these nominated specialties	LCRN demonstrates either 5% increase in recruitment or 5% increase in open studies in ALL nominated specialties

Specialty Objective	Specialties Included	Measure	Target
3. To broaden participation within well-established specialties, particularly in areas or groups who have historically been underrepresented on the NIHR CRN Portfolio	**Cancer** ● Cancer Surgery ● Radiotherapy ● Rare Cancers ● Teenage and Young Adults **Diabetes** ● Diabetes managed, Primary Care supporting PLUS Primary Care managed, Diabetes supporting PLUS any specialty managed, if both Diabetes AND Primary Care are supporting **Hepatology** ● Nonalcoholic fatty liver disease ● Nonalcoholic steatohepatitis **Gastroenterology** ● Endoscopy **Injuries and Emergencies** ● Pre-hospital care and Trauma **Infection** ● Antimicrobial Resistance **Mental Health** ● Children and Young People	A. Increase recruitment by 5% into at least 50% of the nominated sub-specialties	A. 5% increase in recruitment for 50% of the nominated sub-specialties

Specialty Objective	Specialties Included	Measure	Target
	Metabolic and Endocrine Disorders ● Obesity **Respiratory Disorders** ● Rare Diseases **Stroke** ● Hyperacute AND Acute Care studies (sum of both)		
	Cardiovascular Disease	B. 2nd year of a two-year objective begun in 2018/19: LCRNs to enact the cardiothoracic surgery workforce plan made as part of the 2018/19 objective	B. Cardiothoracic surgery workforce plans implemented
4. To ensure specialty or sub-specialty representation and leadership is embedded in all LCRNs	**Ear Nose and Throat** ● Audiology Champion **Infection** ● STI Champion **Health Services Research Champion** **Primary Care** ● 2 GP Champions (or equivalent) **Oral and Dental Health** ● Primary Care Dental Champion	All nominated specialties to have a local named Champion	15 LCRNs

Specialty Objective	Specialties Included	Measure	Target
	Public Health Champion **Renal Disorders** ● Urology Champion		
5. To record the age (or year of birth) of participants recruited into NIHR CRN Portfolio studies in order to assess the extent to which recruitment age profiles match the age demographics of the incidence/prevalence of diseases	● Ageing ● Cancer ● Children ● Dementias and Neurodegeneration ● Mental Health ● Neurological Disorders	For the six nominated specialties, 80% of Trusts/Research organisations within each LCRN either to: A. Record age (or year of birth) for NIHR CRN Portfolio study participants from April 2019 so that anonymised data can be extracted from LPMSs directly **OR** B. Provide the LCRN with a quarterly report of anonymised age data, relating to participants in NIHR CRN Portfolio studies **OR** C. If neither (A) or (B) above are currently possible within an LCRN, to develop a plan/solution for implementation in 2020/21 that will allow age data to be obtained for participants in NIHR CRN Portfolio	For all studies within the six nominated specialties, 80% of Trusts/Research organisations within an LCRN either: A. To record age (or year of birth) in the LPMS **OR** B. To provide anonymised age data on participants **OR** C. The LCRN to develop a plan that will allow age data to be collected for NIHR CRN Portfolio studies from 80% of

Specialty Objective	Specialties Included	Measure	Target
		studies from 80% of Trusts/Research organisations	Trusts/Research organisations by 2020/21

Table 3 – LCRN Operating Framework Indicators

ID	Domain	Indicator	Assessment Approach
1.1	Governance and Management	Each 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	Each LCRN Clinical Director and/or LCRN Chief Operating Officer attends all National CRN Coordinating Centre/LCRN Liaison meetings	Attendance registers for National CRN Coordinating Centre/LCRN Liaison meetings
1.3	Governance and Management	Each LCRN Host Organisation and LCRN Category A Partner submits an NHS Data Security and Protection Toolkit annual assessment to NHS Digital. All NHS Trusts were asked to provide an initial baseline assessment in October 2018 LCRN Host Organisations and LCRN Category A Partners should aim to achieve "Standards Met" (i.e. completed all mandatory evidence items and assertions) If "Standards Not Met" remains after completion or publication, the Host Organisation will be required to assess whether this impacts business delivered on behalf of the NIHR CRN. If this is the case, the Host Organisation is required to submit a report to the National CRN Coordinating Centre outlining the failure and mitigating actions to ensure improvement and achievement of the mandatory data security and protection standards	Review of submitted Host Organisation Report outlining failures and mitigating actions

ID	Domain	Indicator	Assessment Approach
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
1.6	Governance and Management	Category C LCRN Partner flow down contract templates used to contract with all Category C 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 requirements of the LCRN Minimum Financial Controls Contract Support Document 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%) ● 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

ID	Domain	Indicator	Assessment Approach
3.1	CRN Specialties	LCRN has an identified Lead for each NIHR CRN Specialty	Each LCRN Host Organisation shall: ● 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 ● Notify the National CRN Coordinating Centre if there are changes within the financial year ● 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
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	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

ID	Domain	Indicator	Assessment Approach
		Coordinating Centre and available as part of the LCRN Contract Support Documents	
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 elements of the LCRN Contract Compliance Assurance Framework ● Analysis of percentage of missing and inaccurate data points from each LCRN
5.1	Information and Knowledge	Each 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	Each 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 in place a senior manager to coordinate business intelligence activities within the LCRN. The identified lead will participate in nationally agreed business intelligence improvement initiatives and attend national NIHR CRN business intelligence meetings	● Attendance registers for national NIHR CRN business intelligence meetings ● Individual's name and contact details provided to the National CRN Coordinating Centre
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
5.5	Information and Knowledge	Each LCRN has a plan to ensure that the best researchers, wherever they are based, undertake clinical, and public health and social care research in the areas of England with the greatest health needs	● Review and monitoring of LCRN Annual Plan ● Review of outcomes as reported within LCRN Annual Report ● Monitoring of national metrics relating to the priority disease areas specified by the DHSC
6.1	Stakeholder Engagement and Communications	Each LCRN has an experienced and dedicated communications function to support national CRN, NIHR and local CRN objectives	● 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	Each LCRN has in place a senior leader experienced in PPIE to support national CRN, NIHR and local CRN objectives	● Individual's name and contact details provided to the National CRN Coordinating Centre ● Evidence of LCRN PPIE activity and continuous improvement based on recorded participant experience and reported in the LCRN Annual Plan and Report ● Non-pay budget line sufficient for PPIE plan delivery ● WTE role(s) identified in LCRN Annual Plan
6.4	Stakeholder Engagement and Communications	Each LCRN records metrics of research opportunities offered to patients and users of wider health and care services	● Each 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 participant evaluation system

ID	Domain	Indicator	Assessment Approach
			● Progress discussed at national PPIE meetings and reported in LCRN Annual Report
6.5	Stakeholder Engagement and Communications	Each LCRN has in place an active programme of learning activities supporting patient and public involvement in research	● 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 ● Programme of work and continuous improvement in participant involvement, engagement, learning activities and participant experience 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 Be Part of Research (formerly known as 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 as specified by the National CRN Coordinating Centre	Evidence of PRA activity, continuous improvement of project delivery and reporting of impacts in LCRN Annual Plan and Report
6.8	Stakeholder Engagement and Communications	Each LCRN delivers and reports on the Patient Research Experience Survey, as specified by the National CRN Coordinating Centre	● Monitoring of the responses to the Patient Research Experience Survey as required by the Patient Research Experience Framework ● Patient experience survey findings and impacts reported to National CRN Coordinating Centre with an accompanying plan for continuous improvement presented in LCRN Annual Plan and Report

ID	Domain	Indicator	Assessment Approach
6.9	Stakeholder Engagement and Communications	Each LCRN develops and implements a plan to increase and continuously improve the quality of local healthcare engagement, capitalising on opportunities presented by national strategic initiatives such as new CQC research markers	● Review of plans for continuously improving engagement in LCRN Annual Plan ● Review of improvement plan outcomes and impacts as reported within LCRN Annual Report ● Evidence of piloting utilisation of new data on being asked about research from CQC Inpatient Experience Survey ● Evidence of corporate positioning as a helpful partner in supporting LCRN Partners with new CQC requirements
7.1	Workforce, Learning and Organisational Development	Each LCRN has a senior leader in place to coordinate workforce planning, recruitment, development and retention. The identified lead will participate in nationally agreed workforce development initiatives, drive a culture of modern workplace learning, and support the delivery of an integrated approach to workforce development across the NIHR CRN	● Individual's name and contact details provided to the National CRN Coordinating Centre ● Implementation of the local action plan to support the LCRN Workforce ● Review and monitoring of NIHR Learn metrics
7.2	Workforce, Learning and Organisational Development	Each 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 a local action plan to support the CRN wide wellbeing framework
7.3	Workforce, Learning and Organisational Development	Each LCRN has an active programme of activities that engage the wider workforce to promote health and social care research as an integral part of healthcare for all	● Evidence of a programme of learning opportunities provided in the LCRN Annual Plan and Report ● Increased engagement of LCRN Partners in promoting the work of the NIHR

ID	Domain	Indicator	Assessment Approach
7.4	Workforce, Learning and Organisational Development	Each 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 a programme of activities provided in the LCRN Annual Plan and Report ● Effective approaches shared by Continuous Improvement Leads at national meetings
7.5	Workforce, Learning and Organisational Development	Each LCRN has in place a Good Clinical Practice (GCP) Programme Lead, a suitably qualified individual responsible for strategic oversight of GCP education across their LCRN	● Individual's name and contact details provided to the National CRN Coordinating Centre ● Annual plan of appropriate face-to-face GCP training, suitably resourced using approved GCP Facilitators ● Review and monitoring of NIHR Learn metrics
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 ● Individual's name and contact details provided for assigned LCRN Profile lead in LCRN Annual Plan
8.2	Business Development and Marketing	Each 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	Each LCRN actively contributes to the intelligence gathering process from NIHR CRN Customers by actively engaging with the Business Development and Marketing team	LCRN reports interactions with NIHR CRN Customers at the Life Sciences Industry Forum meetings

Part C: Operating Framework

C.1. Introduction

C.1.1. This Part C of Appendix A sets out the NIHR CRN Operating Framework effective from 1 April 2019.

C.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.

C.2. Governance and Management

C.2.1. General Principles

C.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.

C.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.

C.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.

C.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.

C.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.

C.2.2. Scheme of Delegation and Host Board Controls and Assurances

C.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.

C.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.

C.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.

C.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.

C.2.3. Assurance Framework and Risk Management System

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

C.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.

C.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.

C.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.

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

C.2.4. Escalation Process

C.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.

C.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.

C.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) National Chief Operating Officer, National CRN Coordinating Centre

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

C.2.5. Corporate Support Services

C.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.

C.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.

C.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.

C.2.6. Information Governance

C.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 Data Security and Protection Toolkit (DSPT), and shall complete the annual return in the timeframe specified by NHS Digital. Organisations should complete all

mandatory evidence items and mandatory assertions within their assessment and publish their results. If published, NHS Digital note that the organisation should be DSPT compliant. Any organisation who has not published will not be DSPT compliant.

C.2.6.2. LCRN Host Organisations should check to ensure that LCRN Partners have published their DSPT results. If a LCRN Host Organisation finds this not to be the case, it must investigate whether lack of publication is due to deficiencies in not meeting the required mandatory evidence items or assertions, and whether these deficiencies impact on NIHR CRN-funded activities. If so, the LCRN Host Organisation shall propose remedial actions and seek confirmation from their LCRN Partners of associated improvement plans. Remedial actions taken must be reported by the LCRN Host Organisation to the National CRN Coordinating Centre as part of the LCRN Annual Report.

C.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.

C.2.6.4. The LCRN Host Organisation must ensure a process exists to investigate and 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.

C.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 and information security best practice.

C.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 only be distributed as required only to those LCRN Partner organisations in agreement of the disclosure terms.

C.2.6.7. The LCRN Host Organisation must actively promote and enable good information governance and information security 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.

C.2.7. Accountable Officer

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

C.2.8. Leadership Team

C.2.8.1. Overview

C.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.

C.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.

C.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.

C.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.

C.2.8.2. The Nominated Executive Director

C.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”).

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

C.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.

C.2.8.2.4. The Nominated Executive Director will:

(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.

C.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.

C.2.8.3. Clinical Director

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

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

C.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.

C.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.

C.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.

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

C.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.

C.2.8.4. Chief Operating Officer

C.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.

C.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.

C.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.

C.2.8.5. Deputy Chief Operating Officer

C.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.

C.2.9. Management Team

C.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.

C.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.

C.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.

C.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.

C.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.

C.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.

C.2.10. Standard Role Outlines

C.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.

C.2.11. Management Groups

C.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.

C.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.

C.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.

C.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.

C.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.

C.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.

C.2.12. LCRN Partners

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

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

(a) Organisations that receive LCRN funding totalling £50,000 or more per annum for one or more financial years ("Category A Partners");

(b) Organisations that receive an allocation of LCRN funding of between £10,000 and £49,999 per annum for one or more financial years ("Category B Partners");

(c) Organisations that receive an allocation of LCRN funding less than £10,000 per annum for one or more financial years ("Category C Partners").

C.2.12.3. LCRN Host Organisations shall utilise the Category A, Category B, and Category C form of contracts, as provided by the DHSC and amended from time to time, for the purposes of sub-contracting with LCRN Partners.

C.2.12.4. It is expected that a single sub-contract should be put in place between the LCRN Host Organisation and each LCRN Partner organisation for a period not exceeding the term of the LCRN Host Organisation contract with the DHSC.

C.2.12.5. Where an LCRN Partner receives variable levels of funding such that its Partner category changes from year to year, then the single sub-contract used should be that for the higher amount (e.g. a Category A LCRN Partner Contract should be used to contract with a Partner that receives over £50,000 in some financial years, and between £10,000 and £49,999 in other financial years).

C.2.12.6. 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.

C.2.13. LCRN Partnership Group

C.2.13.1. The LCRN Host Organisation will constitute a formal forum for LCRN Partners. This forum may also include NHS service commissioning organisations that have NHS service contracts with LCRN Partners. 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.

C.2.13.2. The LCRN Host Organisation will agree an appropriate process that enables less research-active providers, primary care, social 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.

C.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.

C.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.

C.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, this being 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.

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

C.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.

C.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.

C.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
CSD003	NIHR CRN Governance, Leadership & Management
CSD009	Representation on LCRN Partnership Groups of primary care and independent contractors to the NHS
CSD036	Notification of Absence of LCRN Host Organisation Nominated Executive Directors, LCRN Clinical Directors or LCRN Chief Operating Officers
CSD037	Process for Notification of Changes to LCRN Host Organisation Nominated Executive Directors, LCRN Clinical Directors or LCRN Chief Operating Officers

C.3. Financial Management

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

C.3.1.2. The LCRN Host Organisation will use the funding solely to support the Work Programme 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 this purpose.

C.3.1.3. The LCRN Host Organisation will ensure that national 'top-sliced' funding is spent specifically on the purpose intended and underspends arising from this funding 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.

C.3.1.4. The LCRN Host Organisation, through the LCRN Executive Group, 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 Financial Controls Contract Support Document.

C.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 DHSC/Host contract). Further detail regarding the required controls can be found in the Payments section of the LCRN Minimum Financial Controls Contract Support Document.

C.3.1.6. The LCRN Host Organisation, through the LCRN Executive Group, 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.

C.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 Financial Controls Contract Support Document.

C.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 Financial Controls Contract Support Document.

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

(a) 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 Financial Controls Contract Support Document.

(b) 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.

(c) 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 as specified by the National CRN Coordinating Centre.

C.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 Financial Controls Contract Support Document.

C.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. An example disclosure statement can be found as an appendix of the LCRN Minimum Financial Controls Contract Support Document.

C.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.

C.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 Financial Controls Contract Support Document.

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

C.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.

C.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.

C.3.2. NIHR CRN Finance Tool Data Protection

C.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 CRN, including job title, employer and salary details.

C.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.

C.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.

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

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

C.3.2.6. Only relevant data are collected and there is no further processing other than for those reasons noted in section C3.2.2. above.

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

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

C.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.

C.3.3. Audit

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

C.3.3.2. The internal audit must cover the LCRN Minimum Financial Control standards specified by the National CRN Coordinating Centre in a Contract Support Document.

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

C.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 as requested by the National CRN Coordinating Centre.

C.3.3.5. The costs incurred by the LCRN Host Organisation in undertaking an internal audit can be charged against LCRN funding

C.3.3.6. 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 LCRN Minimum Financial Controls Contract Support Document. It is our expectation that any such 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. The costs incurred by the Partner organisations in undertaking an internal audit arising in this way can be charged against LCRN funding.

C.3.3.7. Where a review of NIHR funding is routinely incorporated into a Partner organisation's own cyclical internal audit plan, and where this review highlights a control weakness, this weakness should be reported to the LCRN Host Organisation.

C.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
CSD004	CRN Funding Reporting

CSD007	LCRN Minimum Financial Controls

C.4. CRN Specialties

C.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.

C.4.1.2. Each 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 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 develop new studies and 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 and healthcare professionals and relevant participant groups.

C.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.

C.4.1.4. Each 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.

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

C.4.1.6. The 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.

C.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.

C.4.1.8. The 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.

C.4.1.9. The National CRN Coordinating Centre is responsible for the selection and performance management of NIHR CRN National Clinical Research Specialty Leads. The LCRN Host Organisation will support the National CRN Coordinating Centre in these activities, through the provision of information and other support as required.

C.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
CSD014	NIHR CRN Urgent Public Health Research: Urgent Public Health Champion Role Outline
CSD039	Process for the Management and Escalation of Issues Relating to Local Specialty Performance

C.5. Research Delivery

C.5.1. Research Delivery Divisions

C.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 Clinical Research Specialties.

C.5.1.2. The 30 Clinical Research Specialties are grouped into six 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.

C.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 C5.1.2 to support national oversight and clinical engagement.

C.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.

C.5.1.5. The LCRN 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.

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

C.5.1.7. The LCRN 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.

C.5.1.8. The LCRN Research Delivery Managers may be employed by the LCRN Host Organisation or other LCRN Partner organisations. This should be documented in the sub-contract agreement between the LCRN Host Organisation and the relevant organisation.

C.5.2. Cross-divisional Research Delivery Team

C.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. These include:

(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.

C.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.

C.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.

C.5.3. Delivery of Research

C.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. Where applicable, Host and Partner organisations should apply the principles outlined in the HR Good Practice Resource Pack to document

individual access arrangements and support sharing of confirmation of pre-engagement checks for any NHS staff working on behalf of NIHR CRN as detailed in the LCRN sub-contract work programmes.

C.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.

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

C.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.

C.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.

C.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 Host Organisation 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.

C.5.3.7. In line with NHS England activities to simplify research arrangements, LCRNs are required to provide support for researchers to use the national standard templates referenced in the AcoRD guidance, which are mandatory for the presentation, negotiation and agreement of study costing and/or attribution. For example, the NIHR CRN Industry Costing Template for commercial contract studies or the Schedule of Events Cost Attribution Tool for non-commercial studies which enables the payment of Excess Treatment Costs.

C.5.3.8. 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.

C.5.3.9. 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.

C.5.3.10. 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.

C.5.3.11. As part of the objectives of the NIHR's CRN Teenage and Young Adults (TYA) Cancer Strategy (NIHR CRN Teenage and Young Adult Cancer Strategy LCRN Contract Support Document), the LCRN Host Organisation must identify an appropriately skilled Teenage and Young Adult Cancer Research Nurse (NIHR CRN Cancer: Teenage and Young Adult Cancer Research Nurse role outline LCRN Contract Support Document). The TYA Cancer Research Nurse will work across all relevant organisations within the LCRN to improve the access of Teenagers and Young Adults to NIHR CRN Portfolio cancer studies.

C.5.3.12. All LCRN research delivery staff must endeavour to locate and deliver study sites in areas of the greatest associated health need wherever possible, as described in the Targeting Research According to Health Needs LCRN Contract Support Document.

C.5.4. Life Sciences Industry

C.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 and 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 Strategy.

C.5.4.2. Promote and support delivery of commercial contract research in line with the requirements of the NHS England National Directive for Commercial Contract Research linked to the NHS Standard Contract requirements.

C.5.5. Delivering on the Government Research Priority of Dementia

C.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.

C.5.5.2. 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.

C.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.

C.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.

C.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 supporting a network of research-ready care homes and liaising with the NIHR School for Social Care Research and NIHR partners involved in the ENRICH project.

C.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.

C.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.

C.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
CSD006	Income distribution from NIHR CRN Industry Portfolio Studies
CSD010	NIHR CRN Urgent Public Health Research: Set Up
CSD011	NIHR CRN Urgent Public Health Research: Initiation
CSD012	NIHR CRN Urgent Public Health Research: Delivery
CSD013	NIHR CRN Urgent Public Health Research: Reporting
CSD014	NIHR CRN Urgent Public Health Research: Urgent Public Health Champion Role Outline
CSD021	Confidential information arrangements for the Life Sciences Industry Feasibility Services - Confidential Disclosure Agreement (CDA process)

CSD022	Provision of Infrastructure Support for Research Delivery in Primary Care Settings
CSD023	Provision of Good Practice in Assessing, Arranging and Confirming Local Capacity and Capability for Participating Organisations Delivering NIHR CRN Portfolio Studies
CSD024	Provision of Good Practice for Sponsors to Enable Assessing, Arranging and Confirming Local Capacity and Capability for Participating Organisations Delivering NIHR CRN Portfolio Studies
CSD027	Eligibility criteria for NIHR CRN support - Annex A- Frequently Asked Questions
CSD040	Eligibility criteria for NIHR CRN support - Implementation
CSD042	NIHR CRN Study Support Service Principles and Process for Setting and Amending Study Site Targets
CSD043	Principles for Local NIHR CRN Site Identification Process for Commercial Studies SOP
CSD044	Research Delivery Meeting Structure SOP
CSD045	Annex B Policy and Principles for New Non-Commercial Studies Applying Outside of IRAS
CSD046	Annex C: Policy and Principles for Open Studies
CSD048	Annex D Policy and Principles for Non-Commercial Studies Taking Place in Non-CRN NIHR Infrastructure Sites That require CRN Support
CSD049	NIHR CRN Study Support Service: For Activity Attribution Support and Review SOP
CSD050	CRN Study Support Service Early Contact and Engagement SOP
CSD051	NIHR CRN Study Support Service: Industry Costing Template Validation SOP
CSD052	NIHR CRN Study Support Service: Study Performance Monitoring SOP
CSD053	NIHR CRN Study Support Service Non-Commercial Feasibility Process: National Study Delivery Assessment SOP
CSD054	NIHR CRN Study Support Service for Effective Start-up SOP
CSD055	Commercial Study Milestone Schedule Process (Principles and Process for Setting and Amending Study and Site Targets)

CSD056	Study Support Service Helpdesk SOP
CSD057	Commercial Eligibility and Feasibility Process SOP
CSD063	NIHR CRN Teenage and Young Adult Cancer Strategy
CSD064	NIHR CRN Cancer: Teenage and Young Adult Cancer Research Nurse role outline
CSD065	Targeting Research According to Health Needs
CSD068	NIHR CRN Support for Research in Wider Health and Social Care Settings
CSD069	NIHR CRN Recruitment Policy

C.6. Information and Knowledge

C.6.1. Information Systems

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

C.6.1.2. The LCRN Host Organisation should ensure that their operation of information systems and the way that information is managed meets the National Data Guardian's data security standards.

C.6.1.3. The LCRN Host Organisation must adhere to the Acceptable Use Policy for the NIHR Hub issued by the DHSC.

C.6.1.4. 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.

C.6.1.5. 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.

C.6.1.6. 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.

C.6.1.7. 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.

C.6.1.8. 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.

C.6.1.9. 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.

C.6.1.10. 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.

C.6.2. Local Portfolio Management System (LPMS)

C.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 Integrated Research Intelligence System - to collect, share and visualise intelligence using multiple local portfolio management systems and an overarching central system. National CRN Coordinating Centre requirements for LPMS solutions are available on request, and any changes to the existing requirements will be communicated to LCRN Host Organisations.

C.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.

C.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.

C.6.3. LCRN Business Intelligence

C.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. There should be a nominated senior leader (Business Intelligence Lead) for each LCRN to oversee this work and to liaise with the National CRN Coordinating Centre.

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

C.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.

C.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.

C.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
CSD028	Business Acceptance Test Practice and LCRN Information Support
CSD059	Local Portfolio Management System Minimum Data Set

C.7. Stakeholder Engagement and Communications

C.7.1. Engagement and Communication

C.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 Be Part of Research (formerly known as the UK Clinical Trials Gateway (UKCTG) prior to 1 April 2019) should be communicated to all appropriate stakeholders.

C.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.

C.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.

C.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 Group.

C.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.

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

C.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.

C.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.

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

C.7.2. Patient and Public Involvement and Engagement (PPIE)

C.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 participant experience of research

through actively involving and engaging patients in research processes and engaging patients, carers and the public in research activities.

C.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.

C.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.

C.7.2.4. The LCRN Host Organisation will actively support, promote and facilitate LCRN Partners in developing and sustaining local Patient Research Ambassadors as specified by the National CRN Coordinating Centre. The LCRN will report on progress in the development and continuous improvement of local Patient Research Ambassador activity via the CRN Patient Research Ambassador reporting system as well as in the LCRN Annual Report.

C.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 a defined coherent local patient offer of information about, access to, and involvement in clinical research. The LCRN will report via the LCRN Annual Report.

C.7.2.6. The LCRN Host Organisation will support and coordinate the Patient Research Experience Survey (PRES) across their area. Research participants in NIHR CRN Portfolio studies will be surveyed in line with the NIHR CRN Patient Experience and Continuous Improvement Framework. Each LCRN is expected to achieve a minimum of 1% of survey responses based on the number of participants recruited into NIHR CRN Portfolio studies in the previous financial year. LCRN Priority Project objectives and findings will be shared with the National CRN Coordinating Centre. The LCRN Host Organisation will prepare an action plan following the survey to actively support implementation of any specific recommendations arising from the survey, as part of continuous improvement activities.

C.7.2.7. The LCRN Host Organisation will ensure active programmes of learning activities supporting patient and public involvement in research are in place.

C.7.2.8. The LCRN Host Organisation will ensure LCRN-funded staff can routinely access 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 research.

C.7.2.9. 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 when requested by the National CRN Coordinating Centre or another LCRN.

C.7.2.10. The LCRN Host Organisation will record and assess the impact of PPIE engagement events delivered in the wider community to assess the extent of the LCRN's public reach and to increase shared learning on the impact of PPIE, as outlined in the NIHR CRN PPIE Reach Framework. This should be reported on a quarterly basis as specified by the National CRN Coordinating Centre.

C.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.

C.7.2.12. The LCRN Host Organisation will have an experienced PPIE operational lead, with a specified PPIE budget, to deliver the PPIE plan.

C.7.3. NHS and Social Care Engagement

C.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 and empowering patients and public as catalysts for improvement. This will include promoting awareness of, and engagement with the National CRN Coordinating Centre managed services.

C.7.3.2. The LCRN Host Organisation will actively support its LCRN Partner organisations in fulfilling Care Quality Commission 'Well Led' Inspection and Monitoring expectations with regards to research. At least one 'Well Led' research support event to be hosted in 2019/20, as specified by the National CRN Coordinating Centre.

C.7.3.3. The LCRN Host Organisation will develop an Engagement Activities and Learning plan supported by an identified senior staff lead. The LCRN Host Organisation will report on progress to the National CRN Coordinating Centre as part of annual reporting, and the report should include any actions from the Care Quality Commission's NHS patient experience survey programme in respect of the research question asked of adult acute inpatients.

C.7.3.4. The LCRN Host Organisation will fully brief and engage with Local Specialty Leads to support the Care Quality Commission's 'Well Led' requirements for research.

C.7.3.5. The LCRN Host Organisation will actively promote and share the online Engagement support package and Toolkit for all frontline research staff (e.g. through special events, roadshows, and media channels). The LCRN Host Organisation will also provide feedback on the content of the support package and contribute to its continuous improvement.

C.7.3.6. 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.

C.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
CSD016	Communications
CSD058	Engagement and Involvement

C.8. Organisational Development

C.8.1. Workforce, Learning and Organisational Development

C.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 health and social care settings.

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

C.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.

C.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.

C.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.

C.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, drive a culture of modern workplace learning, and support the delivery of an integrated approach to workforce development across the NIHR CRN.

C.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.

C.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 Learning Directory. The LCRN Host Organisation will ensure the LCRN adopts resources from the National Learning Directory where appropriate. Formal training offered by the LCRN to CRN funded staff should be managed via the NIHR Learn platform.

C.8.1.9. NIHR CRN (Good Clinical Practice) GCP courses must be made available to all research delivery staff conducting NIHR CRN Portfolio studies with freedom to act. The balance of online and face to face training used to meet this need in each LCRN may be different, and LCRN programmes should be planned with local priorities and resources in mind.

C.8.1.10. 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.

C.8.1.11. The LCRN Host Organisation must ensure all LCRN-funded staff have opportunities to engage with the strategic initiatives of the NIHR CRN.

C.8.2. Continuous Improvement

C.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.

C.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.

C.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.

C.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.

C.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
CSD025	NIHR CRN Good Clinical Practice Programme
CSD026	National Learning and Development Programmes
CSD073	Embedding Continuous Improvement across the NIHR CRN

C.9. Business Development and Marketing

C.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.

C.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.

C.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. NIHR Medtech and Patient engagement in clinical development offers

(c) provide intelligence on local 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 and the UK Plc clinical research offer.

C.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**
CSD032	Business Development & Marketing

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