



National Institute for Health Research

CLINICAL RESEARCH NETWORK

Introduction

The vision of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research.

This document sets out how the NIHR Clinical Research Network is contributing to this vision. Information about other elements of the NIHR clinical research infrastructure can be found in companion documents.

Overview

The NIHR Clinical Research Network (NIHR CRN) provides world-class health service infrastructure (e.g. research support staff such as clinical research nurses; and research support services such as pharmacy, pathology and radiology) to support clinical research in the NHS in England.

The NIHR CRN comprises 15 Local Clinical Research Networks (LCRNs) and a national co-ordinating centre working together with shared principles values and behaviours.

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

The NIHR CRN allocates and manages funding to meet NHS Service Support (e.g. additional nursing time; pathology sessions; lab costs; imaging; additional out-patients costs) for eligible studies. These comprise randomised controlled clinical trials of interventions (including prevention, diagnosis, treatment and care) and other high quality well designed studies. The criteria governing eligibility of studies for Network support can be found on the NIHR [CRN website](#). Industry-sponsored contract research is conducted on a cost recovery basis as stipulated in the NHS Finance Manual.

The NIHR CRN is embedded within the NHS and comprises local NHS staff and other support funded via DH Agreements with NHS Trusts acting as LCRN Hosts.

The NIHR CRN is the English component of the UK Clinical Research Network (UKCRN), developed under the auspices of the [UK Clinical Research Collaboration](#)

Aim

The NIHR CRN aims to:

- Promote equality of access, ensuring that wherever possible, patients have parity of opportunity to participate in research
- Improve the quality, speed and co-ordination of clinical research by removing the barriers to research in the NHS
- Streamline and performance manage NHS Support for eligible studies to ensure that the NHS Service Support Costs of these studies are met in a timely and efficient manner
- Work in partnership to unify and streamline administrative procedures associated with regulation, governance, reporting, and approvals
- Meet the research delivery needs of the life sciences industry including; pharmaceutical; biotechnology; diagnostic; medical technology; and contract research organisations (CROs)
- Further integrate health research and patient care
- Engage the NHS in research in line with the NHS Constitution to promote research participation and a research culture

Structure

Prior to April 2014 the NIHR CRN comprised a managed set of eight clinical research networks (six topic specific clinical research networks: Cancer; Mental Health; Medicines for Children; Diabetes; Stroke; and Dementia and Neurodegenerative disease, plus a primary care research network and a comprehensive research network). Each Network had a co-ordinating centre, and there was a central overall co-ordinating centre. Each of the eight research networks comprised between six to 32 Local Research Networks (LRNs) across the NHS. There was a total of 102 LRNs across the eight research networks. Each LRN was funded by DH via a funding agreement with an NHS organisation (the Host). Many NHS organisations acted as a Host for more than one LRN. Each LRN Host distributed its allocated NIHR CRN funding to providers of NHS services within its local area via local agreements.

This complex structure was the result of incremental growth as funding became available. The DH decided that, on expiry of contracts (contracts for the LRN Hosts expired on 31st March 2014, and contracts for the Co-ordinating Centres expired on 31st March 2015) the NIHR CRN would transition to an integrated structure and delivery model comprising 15 Local Clinical Research Networks (LCRNs) and a single national NIHR CRN Co-ordinating Centre.

The 15 Local Clinical Research Networks (LCRNs) are integrated across all clinical themes, and have catchment areas based on the geographical footprints of the Academic Health Science Networks (see Figure 1 below)

4.01 Clinical Research Network
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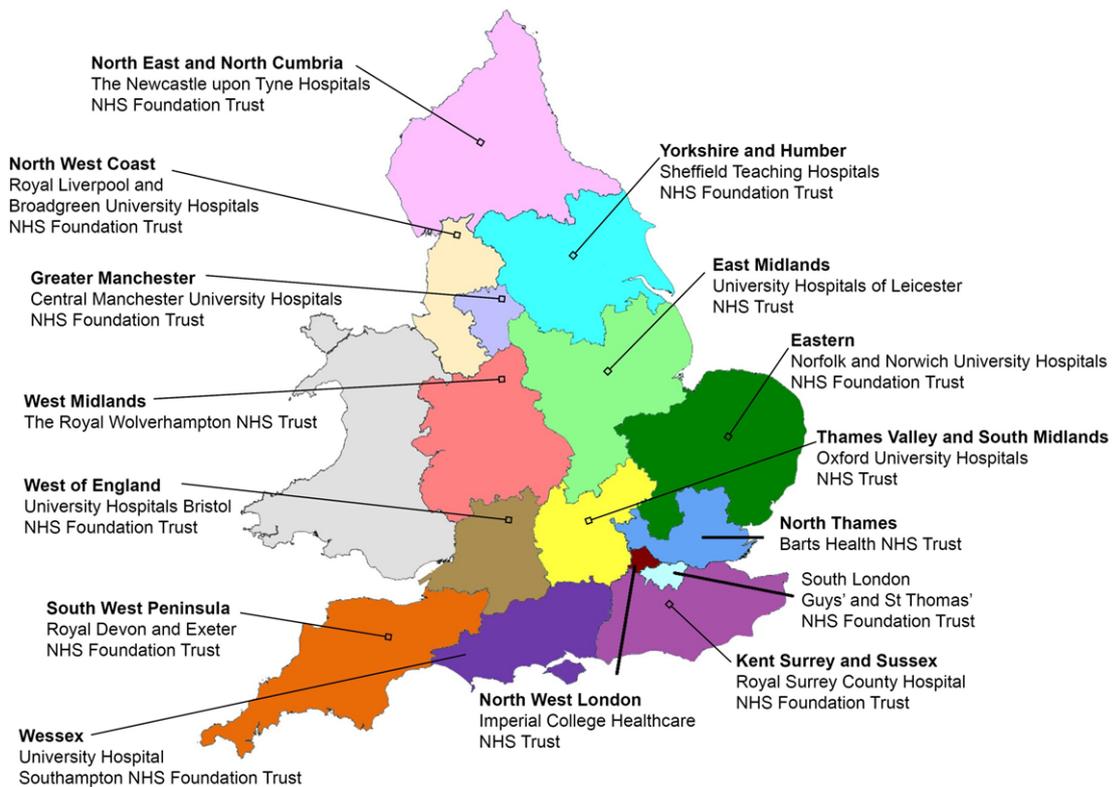


Figure 1 Local Clinical Research Networks (LCRN)

Each LCRN supports research studies across all clinical specialties and disciplines.

Each LCRN has a single Host, a provider of NHS services, that has a contract with DH to deliver the LCRN. Each LCRN Host distributes LCRN funding to providers of NHS services across its geographical catchment via standard template LCRN Partner Agreements provided by DH. Figure 1 shows the LCRN Host organisations which were announced in September 2013.

The DH Agreements for the LCRN Hosts commenced in April 2014. The total value of all these 15 Agreements is about £280m per annum.

All therapy areas are represented by thirty Clinical Research Specialties. Clinical Research Specialties across the LCRNs are communities of clinicians who champion, and encourage engagement in, the NIHR CRN Portfolio of studies in their field of clinical practice. There is also a National Clinical Research Specialty Lead for each of the specialties, each of which acts for the individual specialty on behalf of the NIHR CRN as a whole. These Leads are drawn from, and work with, the LCRNs. Their responsibilities are: to maintain an overview of the national NIHR CRN portfolio in their specialty; to provide the NIHR CRN link for the specialty with external specialty-specific NIHR CRN Stakeholder (e.g. charity funders); and to support collaboration of the NIHR CRN in relation to the specialty with other parts of the NIHR.

The thirty specialities are:

Ageing	Dementia and Neuro Degeneration (DeNDRoN)	Haematology	Metabolic and Endocrine Disorders	Public Health
Anaesthesia, Peri-operative Medicine and Pain Management	Dermatology	Health Services and Delivery Research	Musculoskeletal Disorders	Renal Disorders
Cancer	Diabetes	Hepatology	Neurological Disorders	Reproductive Health and Childbirth
Cardiovascular Disease	Ear, Nose and Throat	Infectious Diseases and Microbiology	Ophthalmology	Respiratory Disorders
Children	Gastroenterology	Injuries and Emergencies	Oral and Dental Health	Stroke
Critical Care	Genetics	Mental Health	Primary Care	Surgery

Dividing the workforce of each LCRN into thirty separate segments to match the clinical research specialties would be impractical and inflexible. Therefore six “divisions” have been created. A division is a section of the LCRN delivery workforce, which carries out clinical research study activity across a defined number of specialty areas. Each division is responsible for ensuring that all the specialty areas they cover receive appropriate resources, and for managing delivery and performance in that division. Divisions are not public facing. In addition to the six divisions, LCRNs also have a “Cross-Divisional Team” that undertakes or co-ordinates cross-cutting research delivery activities across all divisions (e.g. industry operations activities).

In December 2014 the Department of Health awarded a five-year contract for a new national Coordinating Centre for the NIHR Clinical Research Network to a Consortium comprising the University of Leeds and Guy’s & St Thomas’ NHS Foundation Trust. The Consortium is leading an Alliance of organisations including King’s College London, Imperial College London, the Universities of Liverpool and Newcastle and PA Consulting. The purpose of the NIHR CRN Coordinating Centre is to provide the headquarters of the NIHR CRN including executive and operational leadership, management, and governance of the whole of the NHS research infrastructure that comprises the NIHR CRN working with, and on behalf, of the Department of Health.

It is important that each Clinical Research Specialty is appropriately represented at the top level of the overall NIHR CRN governance structure. Therefore, the NIHR CRN Coordinating Centre has six Theme Leads under which the specialties are grouped, are:

- Cardiovascular Disease; Diabetes; Metabolic and Endocrine Disorders; Renal Disorders; and Stroke;
- Respiratory Disorders; Ear Nose and Throat; Gastroenterology; Hepatology; and Infectious Diseases and Microbiology;
- Anaesthesia, Perioperative Medicine and Pain Management; Critical Care; Dermatology; Health Services and Delivery Research; Injuries and Emergencies; Mental Health; Primary Care; and Public Health;
- Children; Haematology; Musculoskeletal Disorders; Ophthalmology; and Reproductive Health and Childbirth;
- Ageing; Dementias and Neurodegeneration (DeNDRoN); Genetics; and Neurological Disorders; and
- Cancer; Oral and Dental

These Theme Leads are clinical research leaders who represent a group of Clinical Research Specialties on the CRN Management Board and form part of the CEO's leadership team. In addition to providing internal direction, they have an outward-facing role to promote the NIHR as a whole, the NIHR CRN and their group of Clinical Research Specialties nationally. A "theme" is not an operational unit and the NIHR CRN is not managed (e.g. reporting finances or performance) by theme.

Functions and activities

The core activities of each of the **Local Clinical Research Networks** are:

- Site identification and feasibility;
- Recruiting patients to participate in eligible studies;
- Managing the progress of patients through the research process;
- Carrying out investigations, assessments and tests attributed as NHS Support activities;
- Helping researchers to cost research proposals properly by identifying Research Costs, NHS Support Costs, and NHS Treatment Costs (including Excess Treatment Costs) as defined in and in accordance with AcoRD;
- Liaising with commissioners and providers of NHS services in planning the treatment costs of research;
- Implementation of the NIHR Research Support Services framework;
- Providing a local advice service, linked to the national advice service offered by the NIHR CRN Coordinating Centre, to give consistent high quality first-line

advice on working with regulations, such as the EU Clinical Trials Directive and other legislation affecting clinical research;

- Advising researchers on the processes for application for ethical review and other authorisations;
- Providing the local element of the NIHR Coordinated System for gaining NHS Permission (NIHR CSP), and advising researchers on the processes associated with NIHR CSP.;
- Working with research employers and where applicable NHS England to implement and manage research passports that simplify honorary contracts and related checks, in accordance with published guidance on research passports;
- Working with the research ethics committee system and arranging site-specific assessments to support ethical review;
- Working with researchers and NHS data guardians to facilitate research studies, including epidemiological and survey-based research;
- Liaising with research sponsors on sponsorship issues;
- Signposting investigators towards support in carrying out research that has been approved and funded;
- Signposting investigators towards support in developing high quality research proposals, e.g. the NIHR Research Design Service;
- Making decisions about whether to deliver a research project on the basis of capacity and capability, determined by efficient and proportionate processes that make use of existing assurances from others;
- Provision of all necessary Information Technology (IT) equipment and services, and access to information systems as specified by the NIHR CRN Coordinating Centre for the LCRN funded staff;
- Provision of good quality, modern office space, facilities and equipment required for research administration for the LCRN funded staff;
- Collecting, collating and submitting local performance management data for individual studies, for study portfolios, and for the LCRN and other LCRNs as a whole, using Information Systems as required by the NIHR CRN Coordinating Centre, including the CRN Portfolio Database (currently) / the Central Portfolio Management System (in future) and local portfolio management database;
- Facilitating the active involvement of patients and public in NIHR CRN activities;
- Working collaboratively with the rest of the NIHR clinical research infrastructure, the NIHR Office for Clinical Research Infrastructure (NOCRI) and with Academic Health Science Networks and Academic Health Science Centres;
- Promoting the NIHR brand and values and supporting national NIHR CRN initiatives and campaigns, at a local level and in relation to promoting the clinical research agenda; and

- Developing the capacity and capability of LCRN funded staff.

The core activities of the NIHR CRN Coordinating Centre are:

- Providing the headquarters of the NIHR CRN;
- Liaising with the Department of Health;
- Performance management of, and planning for the NIHR CRN;
- Ensuring that NIHR CRN customers' needs are met or exceeded;
- Supporting patient and public involvement and engagement in research delivery;
- Engaging with NIHR CRN stakeholders;
- Financial management and assurance of the NIHR CRN;
- Governance of the NIHR CRN;
- Workforce planning and learning and development of all NIHR CRN staff; and
- Provision, use, management, and development, of Information and Communications Technology systems

NHS Service Support

NHS Service Support Funding meets the NHS Service Support¹ resource requirements of eligible funded non-commercial research via a number of dedicated funding streams each concentrating on a particular area of need. A substantial proportion of NHS Service Support is allocated and managed via the NIHR CRN.

Different clinical research studies are expected to require different NHS support to achieve their objectives. For example, a mental health study may require additional clinical psychology support, while a stroke study may require additional radiology support. Although the specific nature of a requirement may be different (psychology *c.f.* radiology), the general nature of the requirement (NHS service support) is similar.

The type of support that will be provided through the NIHR Clinical Research Network includes some or all of the following:

- Clinical Leadership
- Local Clinical Research Network Manager
- Research Nurses (or similar staff)
- Data Managers
- Secretarial support
- Medical staff sessions
- Other clinical staff sessions relevant to the topic area (e.g. clinical psychology, community psychiatric nursing, physiotherapy, occupational therapy).

¹ See [Attributing the costs of health and social care Research & Development \(AcoRD\)](http://www.dh.gov.uk/health/2012/05/attributing-the-costs-of-health-social-care-research-development-acord)
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- Appropriate diagnostic test or clinical services costs, such as:
 - Pharmacy support
 - Pathology support
 - Radiology support
 - Information technology support.
 - Essential running costs.

Further Information

Full details on progress and key events are available from [NIHR CRN website](#)

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