

A large, abstract graphic consisting of two overlapping, curved lines. One is a light green line and the other is a light orange line, both curving around the central text.

How can the NIHR Clinical Research Network support medical technology clinical studies?

Dr Clare Morgan
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UK: Family of Clinical Research Networks

England:
NIHR CRN

Topic specific
Primary care
Comprehensive

Scotland:
CSO Networks

Topic specific
Primary care

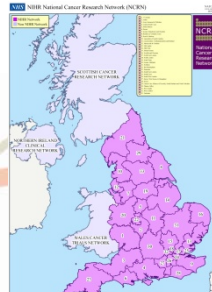
Wales:
CRC Cymru

Thematic
Research Professionals Network
Primary Care

Northern Ireland:
NICRN

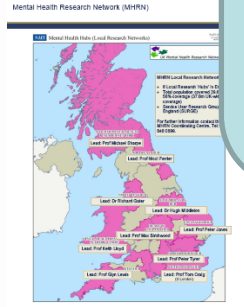
Primary Care
Comprehensive

Primary Care Research Network



6 Topic Specific Clinical Research Networks

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- Cancer
-
- Dementias and neurodegenerative diseases
-
- Diabetes
-
- Medicines for Children
-
- Mental Health
-
- Stroke
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Comprehensive Clinical Research Network



25 Comprehensive Local Research Networks

NIHR CRN Key Stages in Evolution

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- 2001 Cancer
 - 2003 Mental Health
 - 2005 UK Clinical Research Network
Diabetes, Stroke, Medicines for Children and Dementia and
Neurodegenerative Diseases
Primary Care
 - 2007 NIHR Comprehensive Clinical Research Network (CCRN)

What topics are covered by the NIHR CRN?

- Non malignant haematology
- Clinical genetics
- Dermatology
- Infectious diseases & microbiology
- Injuries and accidents
- Musculoskeletal
- Gastrointestinal
- Renal
- Reproductive health & childbirth
- Public health research
- Age & ageing
- Surgery
- Paediatrics (non medicines)
- Cardiovascular
- Ear, nose & throat
- Ophthalmology
- Immunology & inflammation

- Metabolic & endocrine (not diabetes)
- Oral & dental
- Hepatology
- Urogenital
- Respiratory
- Health services research
- Critical care
- Anaesthetics
- Nervous system disorders

PLUS existing topic specific research networks:

- *Cancer*
- *Dementias and Neurodegenerative Diseases*
- *Diabetes*
- *Medicines for Children*
- *Mental Health*
- *Primary Care*
- *Stroke*

Key functions of the CLRN

- **Research Management:**
 - NIHR CSP (Coordinated System for gaining NHS Permission)
 - Research Passports
 - Network-wide research management (for studies in the NIHR CRN portfolio)
- **Supporting the NIHR CRN portfolio:**
 - CLRNs provide infrastructure to support study involvement for researchers
 - Provide a coordinated and efficient infrastructure of research personnel and facilities to support recruitment, including industry studies, with a dedicated Industry Manager in each CLRN
 - Encourage participation in the range of high quality studies contained within the NIHR portfolio

Aims of NIHR CRN

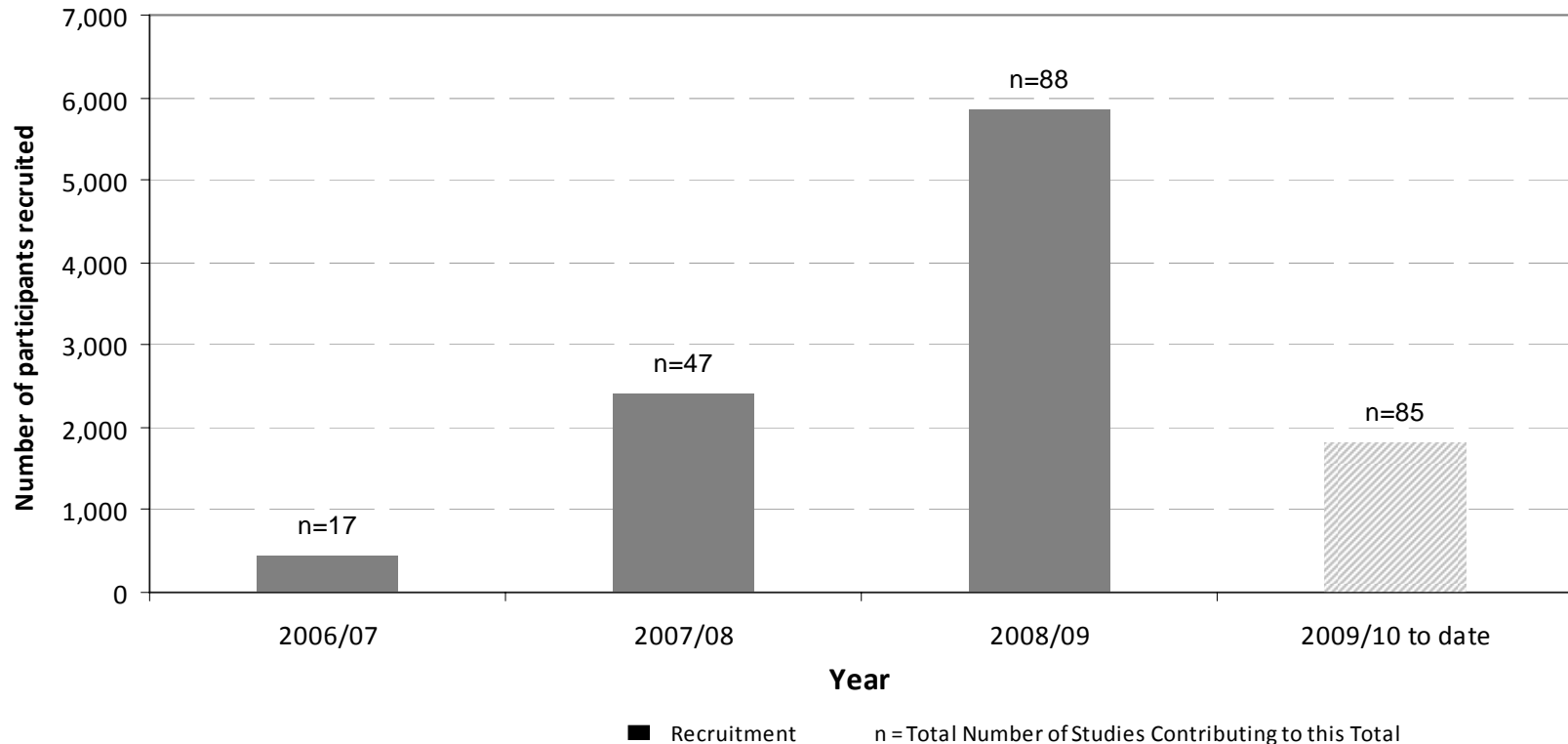
- To develop England-wide infrastructure embedded within the NHS to support high quality research across all areas of health and clinical need funded by both commercial and non-commercial funders
- Ensure that patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research
- Integrate health research and patient care
- Improve the quality, speed and coordination of clinical research by removing the barriers to research in the NHS
- Strengthen research collaboration with industry and ensure that the NHS can meet the health research needs of industry

What is the NIHR CRN to Industry?

- A single point of national access to NHS infrastructure
- A partnership to support high quality and reliable trial delivery
- Facilitation of long term partnering between researchers and Industry
- A clinical research intelligence service that provides comprehensive insight into the current research environment
- Process simplification
- Added value to direct Trust, Industry and Investigator interactions, which builds upon existing good relationships

Increasing Recruitment into adopted Industry studies

Total NIHR CRN Industry Recruitment



Levels of NIHR CRN Activity

CLINICAL RESEARCH NETWORK	Number of Adopted Industry Studies By Lead Network	Number of Industry Studies By Network, Including Co-adopted Studies	Number of Medical Device Studies Included in Total	No. of Studies Which Have NOT Been Adopted
Comprehensive	40	67	3	1
Primary Care	5	12	0	1
Cancer	86	86	0	7
Dementias & Neurodegenerative Diseases	35	36	1	0
Diabetes	34	36	2	3
Medicines for Children	55	57	2	0
Mental Health	11	12	0	3
Stroke	12	13	0	2
TOTAL	278	319 (278*)	8	17

*number of unique studies

What services does the NIHR CRN offer?

- A single point of contact and entry for all services
- Study and protocol feasibility from KOLs and active commercial researchers
- Access to the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) for R&D approvals
- Support with study start up processes and costing and contract negotiations, using standard templates
- Dedicated and trained Research Network resources to support study delivery at site level (staff and support services)
- Performance management of the adopted study in partnership with the company
- Research Network 'badging' of adopted trials

What is the NIHR CRN doing to improve reliability?

Providing robust study feasibility

- **LEVEL 1: “Top level feasibility”, “Country feasibility”, “Study feasibility”**

Rapid assessment to determine if the UK has the required subject population for the study and if the treatment plan proposed in the protocol differs fundamentally from the standard UK treatment pathway.

- **LEVEL 2: “Detailed feasibility”, “Site feasibility”, “Site capability”**

Identify potential sites that could conduct the study, addressing site specific issues such as research resources - skills, facilities, and equipment.

Benefits of obtaining feasibility with NIHR CRN

- Local Research Network sense check of proposed targets
- Ongoing support by dedicated CRN Industry Managers throughout the site selection process at both national and site level
- Access to a wider pool of Investigators with new patient populations
- Allocation of Network resources to investigators to deliver recruitment to time and target, especially study nurses and clinical support officers.
- Support to place the right study at the right site, to maximise the chance of successful delivery within the right time.

How do Industry Sponsored Med Tech studies get into the portfolio?

- Companies submit an NIHR Industry Adoption Form for Level 2 feasibility which culminates in an adoption panel review
- Studies are assessed against the following criteria:
 1. Is there a genuine and testable hypothesis or a valid research question with a possible future benefit for patients as its objective?
 2. Is there a statistically valid trial design which is reasonable for the stated main objective and main hypothesis of the trial?
 3. Have the trial and its design been subjected to an adequate protocol review process?
 4. Does the NIHR CRN CC network infrastructure have the current capacity to deliver the trial data reliably and on time?
 - a. Are there conflicting studies within the current Portfolio?
 - b. Are there sufficient patient numbers?
 - c. Is there sufficient investigator interest?
- Further information on how to apply and contacts are available at www.crncc.nihr.ac.uk/index/industry

NIHR Coordinated System for gaining NHS Permission (NIHR CSP)

- CSP provides a single and standardised application point for NHS permissions and will ensure that clinical research studies are approved quickly in a performance managed system
- CSP assures that all national checks are consistent and conducted once and in parallel for multi-site studies by the NIHR CRN Coordinating Centre and local checks are completed by dedicated staff in the Comprehensive LRNs
- All NHS Trusts in England are now able to participate in this process and are part of a Comprehensive LRN
- CSP is accessed via IRAS and is currently available to all studies adopted into the NIHR CRN Portfolio of studies

How is the NIHR CRN supporting studies to deliver on time?

Standard agreements and processes

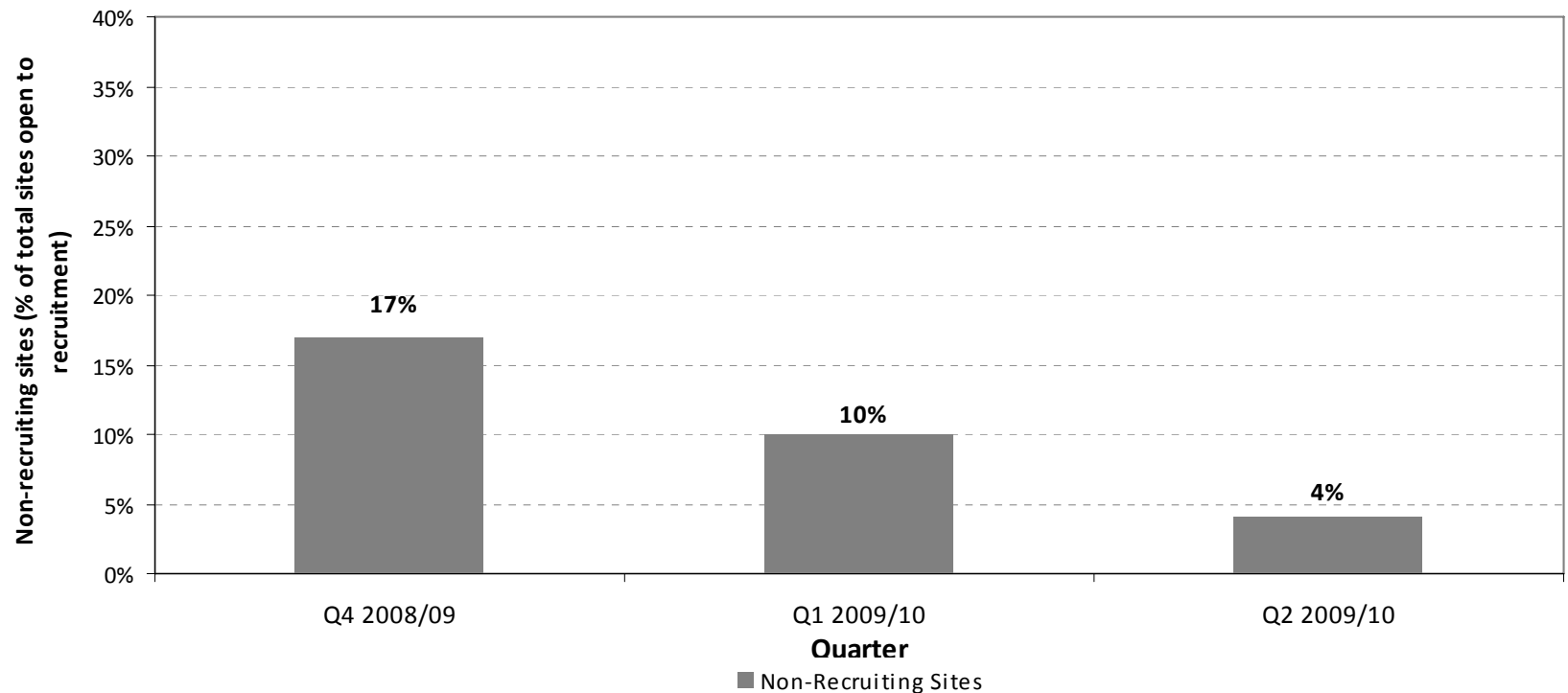
- The NIHR CRN endorses use of the unmodified suite of model Clinical Trial Agreements, which have been designed to speed up contracting between companies and NHS Trusts
- The NIHR CRN has developed model Confidential Disclosure Agreements (CDAs), which are endorsed by the ABPI and speed up discussions around feasibility
- The Company/Research Network Memorandum of Understanding (MoU) ensures all parties are working to the same agreed targets, timelines and processes

How is the NIHR CRN supporting cost effective delivery of clinical studies?

- The NIHR CRN is working to ensure that adopted commercial studies are delivered in the most cost effective manner
- A commitment to reduce the number of non-performing sites
- Delivery of adopted studies to jointly agreed times and targets
- The introduction of models to increase access to potential recruits across sites

Reducing the number of non-recruiting sites

Closed Study Performance - Number of Non-Recruiting Sites (per Quarter)



The Industry Costing Template

Providing a transparent and consistent framework on cost

- Aim to develop a clear methodology to calculate consistent and transparent prices for Industry sponsored studies, to support both the NHS and Industry to allow consistency and predictability on costing
- Intended to facilitate and speed up the start up of trials by reducing the time required for individual site negotiations
- The Industry Costing Template provides a transparent platform to support rapid costing negotiations
- Facilitated by Local Research Network staff

The Industry Costing Template

A standard Costing Template which demonstrates:

- Staff hourly rates- DIRECT COSTS
- Overheads- 70% on DIRECT COSTS
- Capacity building- 20% on DIRECT COSTS
- Geographical Variation- PbR MFF multiplier (DoH)

Recommended prices for:

- Investigations; Pharmacy; NHS R&D; other set up costs

Validation for Medical devices is ongoing

What about the quality of the clinical research?

Providing access to a national research infrastructure

- The NIHR CRN infrastructure provides training and facilities to ensure that NHS research staff have the necessary skills and environment to conduct high quality clinical research
- Flexibility gives LRNs the ability to place trained staff where trial support is needed; allocating staff to a newly adopted or struggling study as required and therefore removing delays associated with recruitment
- It also allows experienced staff to work in partnership with new investigators, to maintain high quality study delivery whilst increasing research capacity
- Industry can access this infrastructure on a full cost recovery basis to the NHS

How is NIHR developing Investigator commitment & involvement in trials?

- Development of Specialty Groups to promote excellence in research from senior Investigators to trainees
- Provision of clinical time and research staff time through NIHR Network funding
- Career development and training program for researchers through NIHR
- Networks fostering a delivery culture to achievable targets, based upon robust feasibility
- Network strategies to involve and develop research inactive organisations

How is NIHR CRN performance managing adopted Industry studies?

- Emphasis on feasibility assessment to accurately predict patient numbers and timelines
- Focus on performance management of adopted studies at a local and national level by dedicated industry managers
 - Collection of accrual data for adopted studies
 - Regular 1-1s between CRN and network industry contact
 - Implementation of contingency plans when things go off plan
- Clear communication between industry and NHS staff to define roles, responsibilities and expectations
- Delivery is the key objective

Summary of Network Services

Quality	Timeliness	Reliability	Cost
Trained Workforce in place (e.g. nurses, data managers)	NIHR Coordinated System for gaining NHS Permission (CSP)	Protocol/Feasibility support	Industry Costing Template
Research management and governance advice	Research Passport to work across Trust boundaries	Support with management and administration of study set up	Performance management of underperforming sites/studies
Clinical Specialty Groups to advise and support	Standard agreements for the conduct of research (mCTA/CIA)	Provision of dedicated, trained resource to support study delivery	Increased numbers of recruitable patients at sites
		Risk assessment and performance management with sponsor partners	Fewer 'non-performing' sites

What are the opportunities for engagement?

- Pre-adoption
- Post adoption

Opportunities Pre-adoption

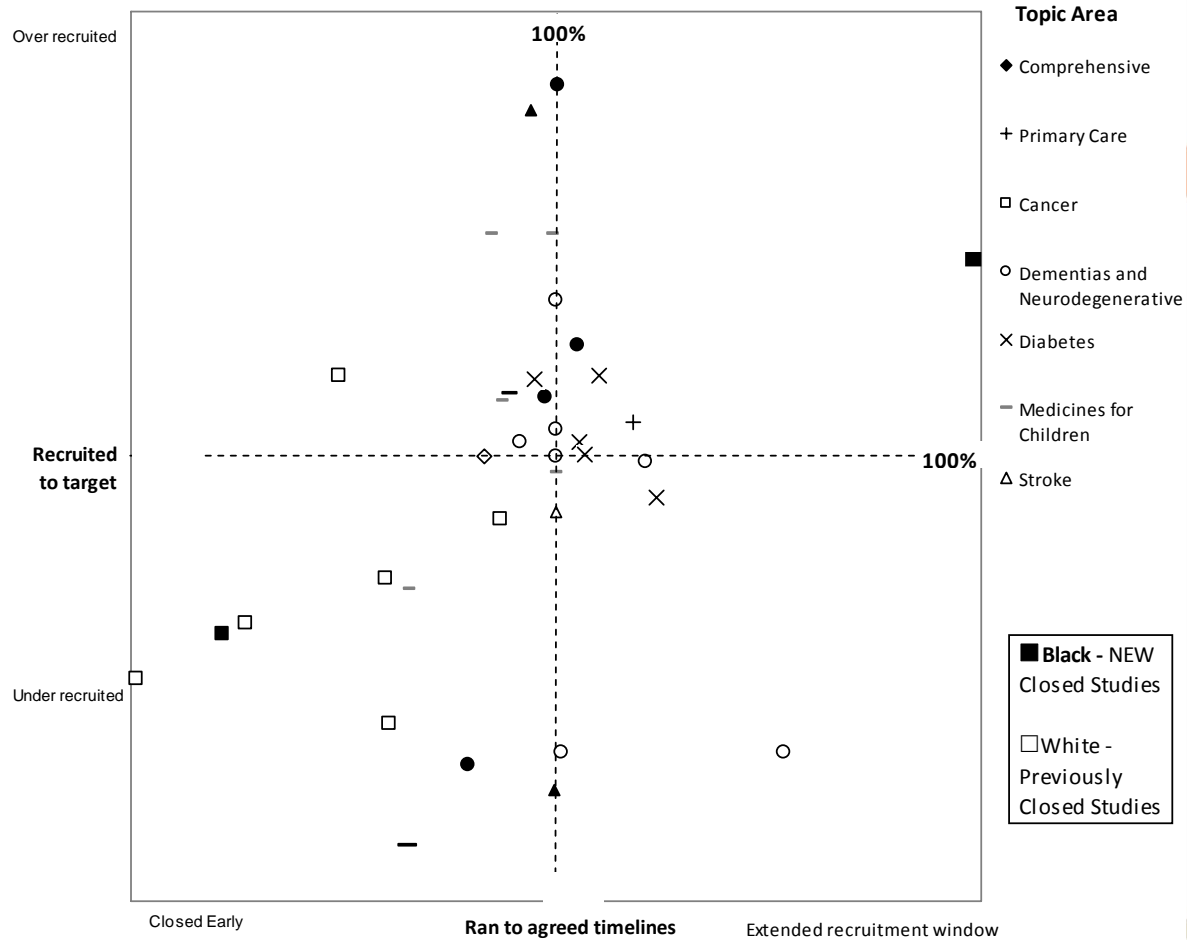
- Access to key opinion leaders for rapid feasibility on study proposals
- Additional study insight from the network coordinating centre, based on previous experience
- Knowledge of competing UK studies
- Network staff will support investigators to provide sound feasibility

Opportunities Post Adoption

- Access to new medical technology investigators and therefore patient populations
- Single point of contact for the company
- Support to place the right study at the right site, to maximise the chance of successful delivery within the right time
- Delivery support from the network coordinating centres for the company
- Trained local research staff available to support the investigator for screening or to perform study procedures
- Adopted Industry studies can access NIHR CSP

Performance – closed studies

Closed Study Performance - Recruitment to time and target by topic area



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