Réseau-1 Québec

Plenary Session: Learning from International Primary Care Research Networks

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Journée annuelle – 14 juin 2019

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#R1QJA2019

Patient-Oriented Research - U.S. Perspective

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Duke Clinical & Translational Science Institute

Conflict of interest disclosure

Duke Clinical & Translational Science Institute

Outline

- Cover recent developments in Patient-Oriented Research in the U.S.
  1. Patient-centered research
  2. Stakeholder-engaged research
  3. Pragmatic Clinical Trials
  4. Implementation Research
  5. Practice-based Research Networks
  6. Leverage technology within research
  7. Dissemination and Return of Results
- Highlight example research project

1. Increase in Patient-Centered Research

- Patient-Centered Outcomes Research helps people and their caregivers communicate and make informed healthcare decisions about their healthcare options.
  - Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
  - Is inclusive of an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
  - Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
  - May investigate optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

https://www.pcori.org/research-results/patient-centered-outcomes-research

1. PCOR (continued)

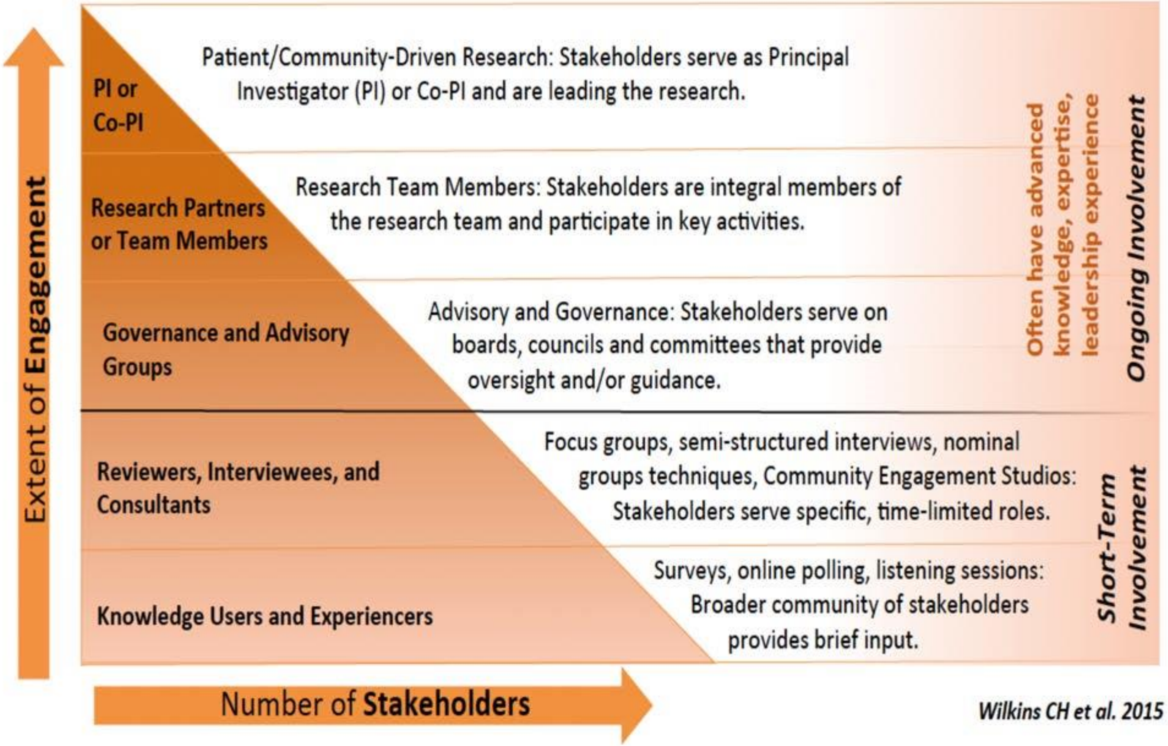
- *Rationale*:
  - inclusion of end users of research (patients, physicians, other stakeholders) will enhance the relevance of research to actual health decisions
  - increased relevance can improve uptake of evidence and improve ability to achieve desirable health outcomes

Frank L, Basch E, Shelby JV. JAMA 2014; 312(15):1513-1514.

2. Increase in Stakeholder-Engaged Research

- *Definition*: Involvement of stakeholders in entire research process
- *Rationale*: researchers are unlikely to provide the patient perspective. Engagement of relevant stakeholders is required to increase relevance of research to end users
- *Types of Stakeholders*: patient, caregiver, clinicians, health system leadership, health policy makers, and health insurers.
- *Resources*:
  - Stakeholder Engagement Plan (PCORI)
  - Community Engagement Studios (Meharry-Vanderbilt)

The Continuum of Community (Stakeholder) Engagement in Research



Extent of **Engagement**

PI or Co-PI

Patient/Community-Driven Research: Stakeholders serve as Principal Investigator (PI) or Co-PI and are leading the research.

Research Partners or Team Members

Research Team Members: Stakeholders are integral members of the research team and participate in key activities.

Governance and Advisory Groups

Advisory and Governance: Stakeholders serve on boards, councils and committees that provide oversight and/or guidance.

Often have advanced knowledge, expertise, leadership experience

Ongoing Involvement

Reviewers, Interviewees, and Consultants

Focus groups, semi-structured interviews, nominal groups techniques, Community Engagement Studios: Stakeholders serve specific, time-limited roles.

Knowledge Users and Experiencers

Surveys, online polling, listening sessions: Broader community of stakeholders provides brief input.

Short-Term Involvement

Number of **Stakeholders**

Wilkins CH et al. 2015

3. Increase in pragmatic clinical trials

- *Three key attributes of PCTs*:
  1. an intent to inform decision-makers (patients, clinicians, administrators, and policy-makers), as opposed to elucidating a biological or social mechanism;
  2. an intent to enroll a population relevant to the decision in practice and representative of the patients or populations and clinical settings for whom the decision is relevant; and
  3. either an intent to (a) streamline procedures and data collection so that the trial can focus on adequate power for informing the clinical and policy decisions targeted by the trial or (b) measure a broad range of outcomes.
- *Rationale*: trials designed and performed in real-world settings will increase external validity of findings and be implemented long-term.
- Pragmatic trial design examples – stepped wedge, adaptive RCT
- Use of single or central IRB (REB)
- Resource: Rethinking Clinical Trials online textbook (NIH Collaboratory)

4. Increase in Implementation Research

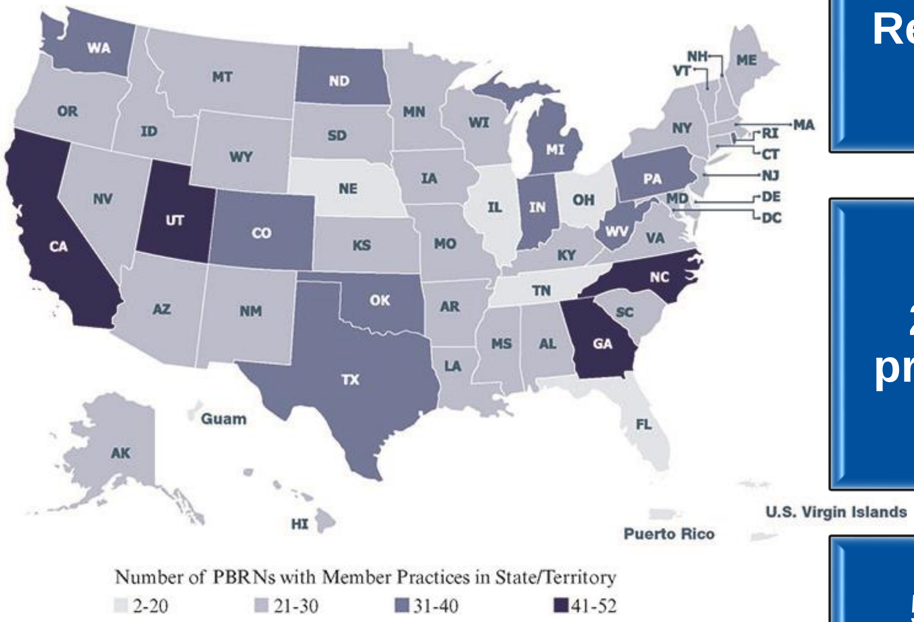
- *Definition*: Implementation research is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.
- *Rationale*: improves knowledge for how interventions are integrated within real-world practice settings and patient populations
- *Synonym*: Knowledge Transfer & Exchange research
- Resource: Dissemination & Implementation Toolkit (PCORI)

Eight Toolkits for D&I (NIH CTSA; Washington University)

5. Increase use of Practice-based Research Networks

- Definition of PBRNs
  - Groups of affiliated ambulatory-care practices devoted principally to the clinical care of patients, investigating questions related to community-based practice
  - Link practicing clinicians with investigators experienced in clinical and health services research
  - Provide a sense of ongoing commitment to the research endeavor and an organizational structure that transcends a single study
- Rationale: real-world setting; existing relationships; proven track record of collaboration
- Types: Primary Care, Emergency Department, Pharmacists, Dentists, Dieticians, Integrative Medicine, and more
- Collaborative PBRN networks (“meta-networks”)

PBRNs in 2018



183 AHRQ Registered PBRNs

140 US-based primary care PBRNs

43 other PBRNs (Affiliate and International PBRNs)

29,455 member practices & clinics

Practices per PBRN:

Average: 172

Median: 44

5,429 practices designated Patient-Centered Medical Homes (PCMH)

183 PBRNS across
29,455 Practices
153,736 Clinicians
Serving >86 million patients

6. Increase use of Technology within Research

- Rationale: computers and mobile devices can increase participation, reduce burden, and increase efficiency of research process
- Recruitment, direct to patient: EHR patient portal, Email, social media (Facebook, Twitter), Mobile phone apps
- Follow-up at home: Email, Text messaging, Online surveys, mobile phone apps
- Clinical Outcomes for existing medical records : EHR-based Distributed Data Networks, Common Data Models
- Resources: ResearchKit (Apple); PCORnet (PCORI); Virtual Data Network (HCSRN)

7. Increase diverse methods for Disseminating Results

- Rationale: end users and stakeholders receive information in a format they are familiar with
- Return of Results to participants – not just study results, but individual participant study results (labs, procedures, etc.)
- Methods – local newsletters, community presentations, mailings, online videos
- Resource – Dissemination of Rural Health Research

Strategies for Disseminating Research Findings

Example of Patient-Oriented Research

Duke Clinical & Translational Science Institute

Meta-LARC

The Meta-LARC
Advance Care Planning (ACP) Trial

Patient-Centered Outcomes Research Institute® (PCORI®) Award (PLC-1609-36277).

11/2017-4/2023

Principal Investigator: Annette Totten, PhD

Project Manager: LeAnn Michaels

Engagement Manager: Angela Combe, MS

ORPRN Oregon Rural Practice-Based Research Network

PCRC Primary Care Research Consortium

Université Laval Faculté de médecine Réseau de recherche axé sur les pratiques de première ligne (RRAPPL)

UTOPIAN

SNOCAP

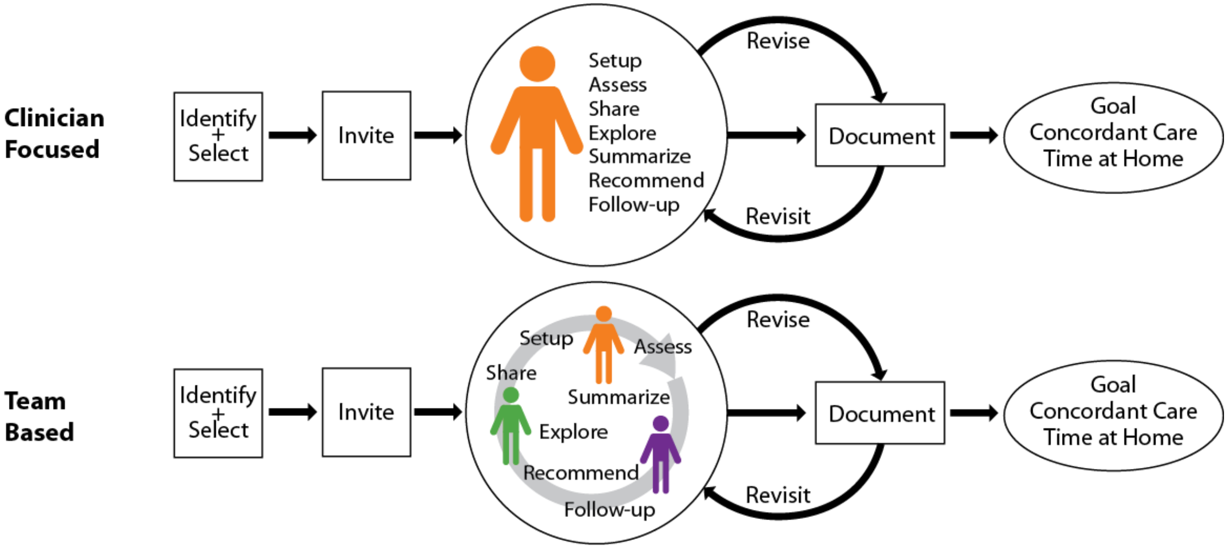
Wisconsin Research & Education Network

IRENE Iowa Research Network

Meta-LARC

Is a team approach to ACP in primary care effective?

Serious Illness Care Program



Clinician Focused

Identify + Select → Invite → Setup, Assess, Share, Explore, Summarize, Recommend, Follow-up → Document → Goal Concordant Care, Time at Home

Revise

Revisit

Team Based

Identify + Select → Invite → Setup, Assess, Share, Summarize, Explore, Recommend, Follow-up → Document → Goal Concordant Care, Time at Home

Revise

Revisit

Study compares team-based to clinician-focused advance care planning for patients with serious, life-limiting illnesses

ORPRN Oregon Rural Practice-Based Research Network

PCRC Primary Care Research Consortium

Université Laval

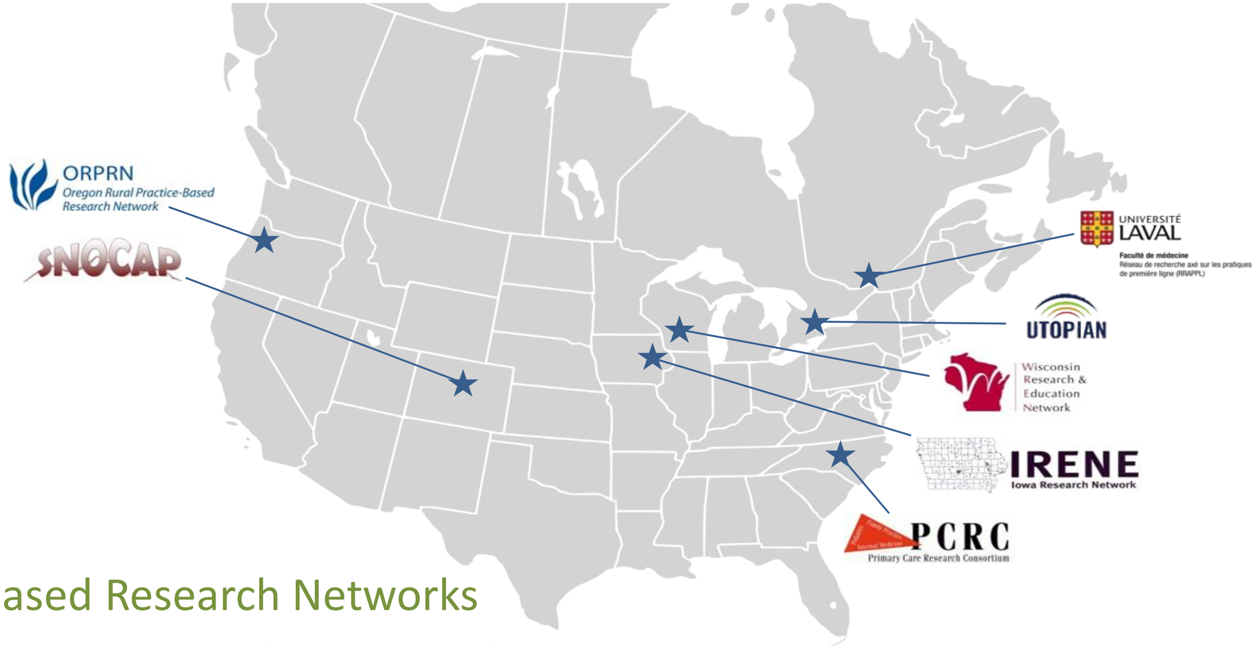
UTOPIAN

SNOCAP

Wisconsin Research & Education Network

IRENE Iowa Research Network

Meta-LARC ACP PBRNs/Partners



7 Practice-based Research Networks

42 Primary Care Practices (6 per PBRN)

1,120 Patients and care partners

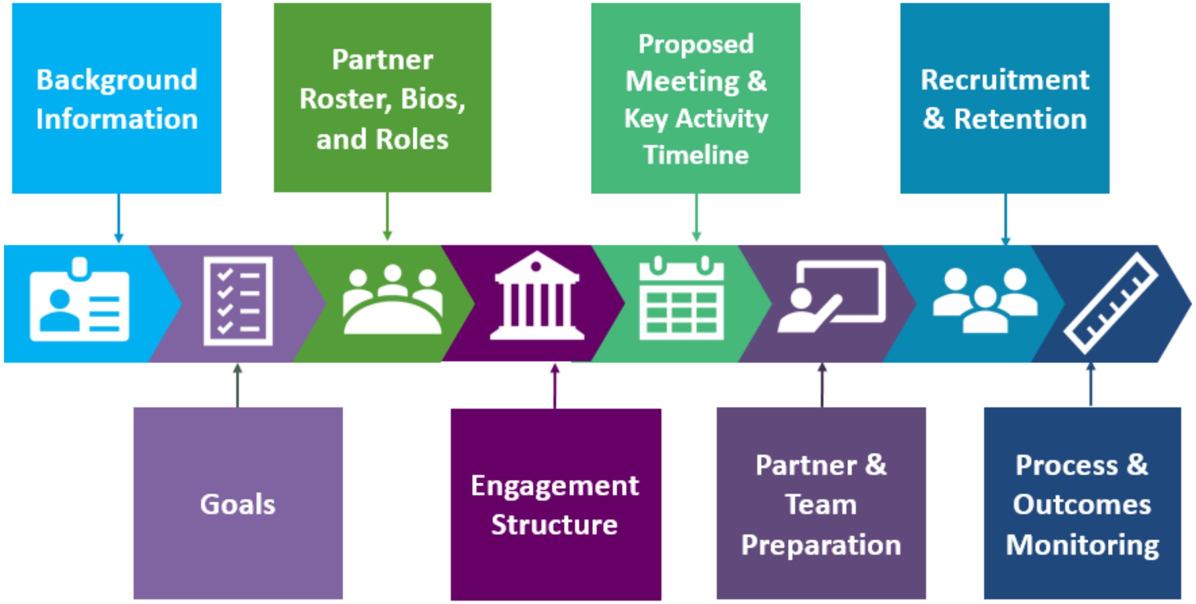
ORPRN Oregon Rural Practice-Based Research Network · PCRC Primary Care Research Consortium · UNIVERSITÉ LAVAL Faculté de médecine Réseau de recherche axé sur les pratiques de première ligne (RRAPPL) · UTOPIAN · SNOCAP · Wisconsin Research & Education Network · IRENE Iowa Research Network

Study Design

- Cluster randomized trial
  - Practices are assigned by chance to team-based or clinician-focused model for ACP
- Population
  - Patients with any serious illness or condition (would not be expected if they died in the next 2 years)
  - Living in the community (not a nursing home)
- Key outcomes
  - Goal Concordant Care that matches what matters most to patient
  - Days at home: not in the hospital or emergency room
- Other outcomes
  - Primary care clinician and team experience
  - Family caregiver experience

Patient and Family Engagement in Research

Project has an Engagement Plan as well as a Research Protocol



Background Information

Goals

Partner Roster, Bios, and Roles

Engagement Structure

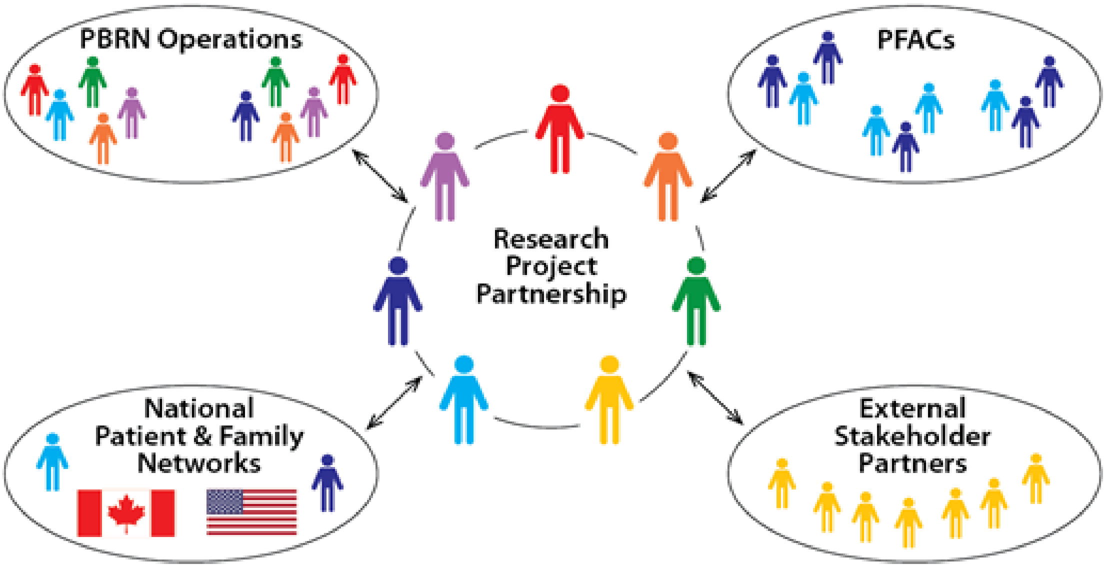
Proposed Meeting & Key Activity Timeline

Partner & Team Preparation

Recruitment & Retention

Process & Outcomes Monitoring

Engagement Structure



**Figures represent types of participants, not the number of members.*

Color Key: dark blue=patients; light blue=families; orange=primary care clinicians; green and purple=primary care staff and administrators; yellow=external stakeholders; red=researchers (Investigators and staff)

Status

Completed

- Online and in-person training developed for both arms
- Train the trainer
- Engagement plan
- IRB/REB applications
- Initial measure development
- Primary care practice recruitment
- Implementation tool kit

In Progress

- Patient and care partner enrollment until mid-2020; Complete follow-up end of 2021
- Implementation support
- Formative implementation evaluation and fidelity assessment

Attributes

Patient-Centered Outcome Research

- Goal Concordant Care, Days at Home

Stakeholder-Engaged Research

- Patient Family Advisory Council, Engagement Plan

Pragmatic Clinical Trial

- Cluster-randomization of practices, real-world setting

Implementation Research

- Compare two implementation strategies (clinician-focused vs. team-based)

Practice-Based Research Networks

- U.S.- and Canadian-based primary care clinics (42 total, 6 per PBRN)

Technology

- Some sites using EHR-algorithm to identify patients for ACP and EHR alert to notify study team when conversation occurs

Dissemination Plan

- Pending, Under development

Closing thoughts

- In the U.S., we see an increased focus on
  - patient-centered, stakeholder-engaged, pragmatic trials and/or implementation research
  - that leverages technology and diversifies methods of dissemination
  - to improve relevance and uptake of research findings in real-world settings to improve clinical care and patient outcomes.
- As a result, research requires
  - a team-based and collaborative approach, and
  - development of new methodology, resources and toolkits
  - to enhance the ability of investigators to design and implement research studies that are important to various stakeholders.

The NIHR CRN in England & Primary Care Research

14th June 2019
Montreal, Quebec

Professor Philip Evans

GP Exeter, National Speciality Lead for Primary Care & Cluster C Specialty Lead (Kings)

Conflict of interest disclosure

This talk

- The UK context for primary care research
- What is the National Institute for Health Research (NIHR) ?
- What is the Clinical Research Network (CRN) ?
- How are studies adopted ?
- Network metrics
- Practice incentives
- Digital initiatives
- Patient participation
- Challenges?

What is the big picture for general practice?

- England had **7012** open and active practices (Dec 2018)
- **308** million estimated appointments last year in these practices (NHS Digital)
- i.e. **> 1 million** appointments every working day
- Average consultation length is **12.2** minutes (Kings Fund, 2016) Average practice list size approximately **8,500** patients
- **2.71** partners per practice
- **44,396** GPs and **34,510** full-time equivalent GPs in England
- Average consultation rate = **5.16** per patient per year (2013/14) (Hobbs et al, 2016)
- **14%** increase in GP workload between 2007 and 2013 (Hobbs et al, 2016)
- Average **2.5** problems per GP consultation (Salisbury et al, 2013)

St Leonard’s Practice, Exeter, England

How primary care is changing to GP at scale

©Keep our NHS Public

What is a primary care network ?

- ~1000 across the country
- 30,000 – 50,000 patients
- 6-8 practices
- Serving "natural communities"
- More efficient with GP/nurse/pharmacist/ mental health professional
- Better access (e.g. OOH)
- New contract -> Research opportunities (see GP contract)

Questions:

- Contractual issues
- Leadership
- Research Culture

https://www.england.nhs.uk/gp/gpfv/redesign/primary-care-networks/

They should be small enough to provide the personal care valued by both patients and GPs, but large enough to have impact and economies of scale through better collaboration between practices and others in the local health and social care system.

NHS England, 2019

The new GP Contract January 2019

8. Supporting research and testing future contract changes

- **Research** 8.2 Research participation within general practice has many additional benefits: quality improvement, professional development, and generating income, amongst others.
- Working with the Royal College of General Practitioners, the National Institute of Health Research and the Clinical Practice Research Datalink, **we will use the opportunity created by Primary Care Networks to increase general practice research participation levels.**
- During 2019, we will develop a way of helping networks to do this, embedding approaches such as the RCGP *Research Ready* quality assurance model [59].
- We welcome also the National Institute of Health Research's intention to prioritise an expansion in academic research capacity into primary care.

BMA

NHS England

Investment and evolution:

A five-year framework for GP contract reform to implement *The NHS Long Term Plan*

31 January 2019

#NHSLongTermPlan

www.longtermplan.nhs.uk

The GP Workforce

- “In crisis”
- Changing rapidly
  - More embedded staff e.g. pharmacy, paramedics, physios
- Community nurses reducing in number
- Need 6000 more GPs (RCGP)
- GP Retention issues

BMA quarterly tracker survey

Current views from across the medical profession
Quarter 4: November 2015

BMA

CFWI CENTRE FOR WORKFORCE INTELLIGENCE

In-depth review of the general practitioner workforce

Final report

July 2014

evidence for better health care

nuffieldtrust

IS GENERAL PRACTICE IN CRISIS?

Mark Dayan,
Rebecca

“Boiling Frogs”

The changing role of general practice and its impact

‘If you take a frog and you stick it in some very hot water it will jump out, it won’t like it. If you take the same frog and you stick it in a pan

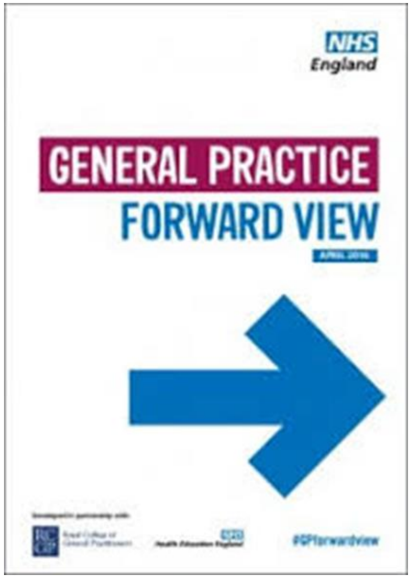
6. IMPACT ON WELLBEING
- Ill health including stress, anxiety, and burnout
- Poor work-life balance

LOW JOB SATISFACTION
- Feeling undervalued and under-appreciated
- Loss of intellectual challenge
- Fearing litigation or practising defensively
- Less time for reflection
- Feel no longer giving a good service (impact on quality and continuity of patient care)
- Burdened by conflicting priorities
- Having to cut corners
- More stress, time pressures, and

LEAVING UK GENERAL PRACTICE

Trends in general practice

- Ageing population (especially over 85s)
- Multimorbidity increasing
- Increasing need for better access
- Reducing continuity of care
- Increasing patient access to records
- Digital Health and apps e.g. *GP at hand*
- Big data applications



NHS England

GENERAL PRACTICE
FORWARD VIEW

#GPforwardview

NIHR | National Institute for Health Research

NIHR | National Institute for Health Research

The UK Research Landscape

The UK Research Landscape

- Political commitment to supporting life-sciences industry
- Health & Social Care Act 2012/NHS Constitution 2013
- We aim to embed clinical research in all aspects of care


BIS

Strategy for UK Life Sciences


NHS

INNOVATION HEALTH AND WEALTH

ACCELERATING ADOPTION AND DIFFUSION IN THE NHS


Health and Social Care Act 2012


THE NHS CONSTITUTION

the NHS belongs to us all

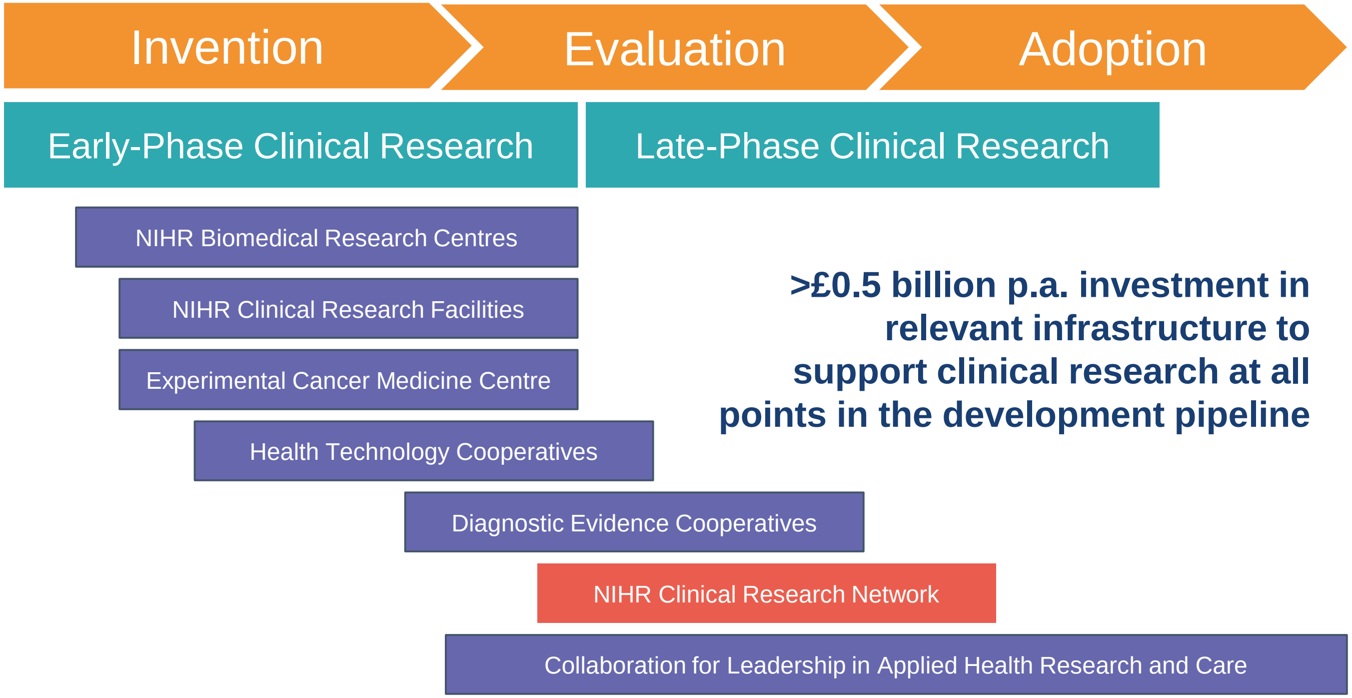

Department of Health

Eligibility Criteria for NIHR Clinical Research Network Support

The National Institute for Health Research (NIHR)

- Established by the Government to improve the nation’s health and wealth through research
- Plays a key role in the Government’s strategy for economic growth, attracting investment by the life-sciences industries
- Represents the most **integrated health research** system in the world
- Training and funding research
- Executing studies - the **Clinical Research Network**

Where we fit in



Invention

Evaluation

Adoption

Early-Phase Clinical Research

Late-Phase Clinical Research

NIHR Biomedical Research Centres

NIHR Clinical Research Facilities

Experimental Cancer Medicine Centre

Health Technology Cooperatives

Diagnostic Evidence Cooperatives

NIHR Clinical Research Network

Collaboration for Leadership in Applied Health Research and Care

>£0.5 billion p.a. investment in relevant infrastructure to support clinical research at all points in the development pipeline

How the CRN works

DELIVERY… DELIVERY…DELIVERY

The CRN supports studies by:

- Funding research support posts in the NHS and providing training - ensuring researchers have access to experienced frontline staff
- Funding to meet the costs of using facilities, such as scanners and x-ray
- Helping identify and recruit patients, enabling researchers to complete their study on time and on target

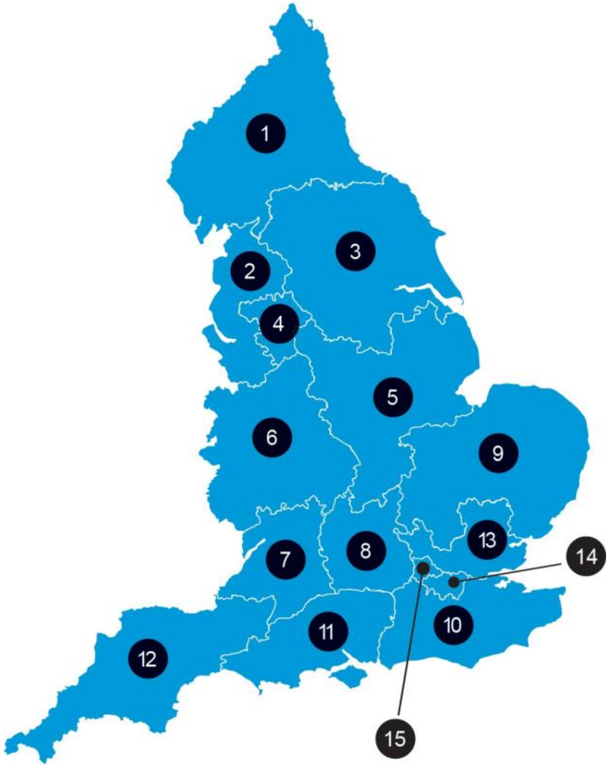
Clinical specialties

Each Local Clinical Research Network delivers research across 30 clinical specialties:

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

Local Clinical Research Networks (LCRNs)

1. North East and North Cumbria
2. North West Coast
3. Yorkshire and Humber
4. Greater Manchester
5. East Midlands
6. West Midlands
7. West of England
8. Thames Valley and South Midlands
9. Eastern
10. Kent, Surrey and Sussex
11. Wessex
12. South West Peninsula
13. North Thames
14. South London
15. North West London



The NIHR CRN High Level Objectives

Our High Level Objectives

1. Increase the **number of participants** recruited into NIHR CRN Portfolio studies

2. Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment **time and target**

3. Increase the **number of commercial** contract studies delivered through the NIHR CRN

Our High Level Objectives

4. Reduce the time taken for eligible studies to **achieve set up** in the NHS

5. Reduce the time taken to **recruit first participant** into NIHR CRN Portfolio studies

6. Increase **NHS participation** in NIHR CRN Portfolio studies

7. Increase the number of participants recruited into **Dementias and neurodegeneration** (DeNDRoN) studies on the NIHR CRN Portfolio

NIHR Clinical Research Network

Annual statistics 2018/19

NIHR | National Institute for Health Research

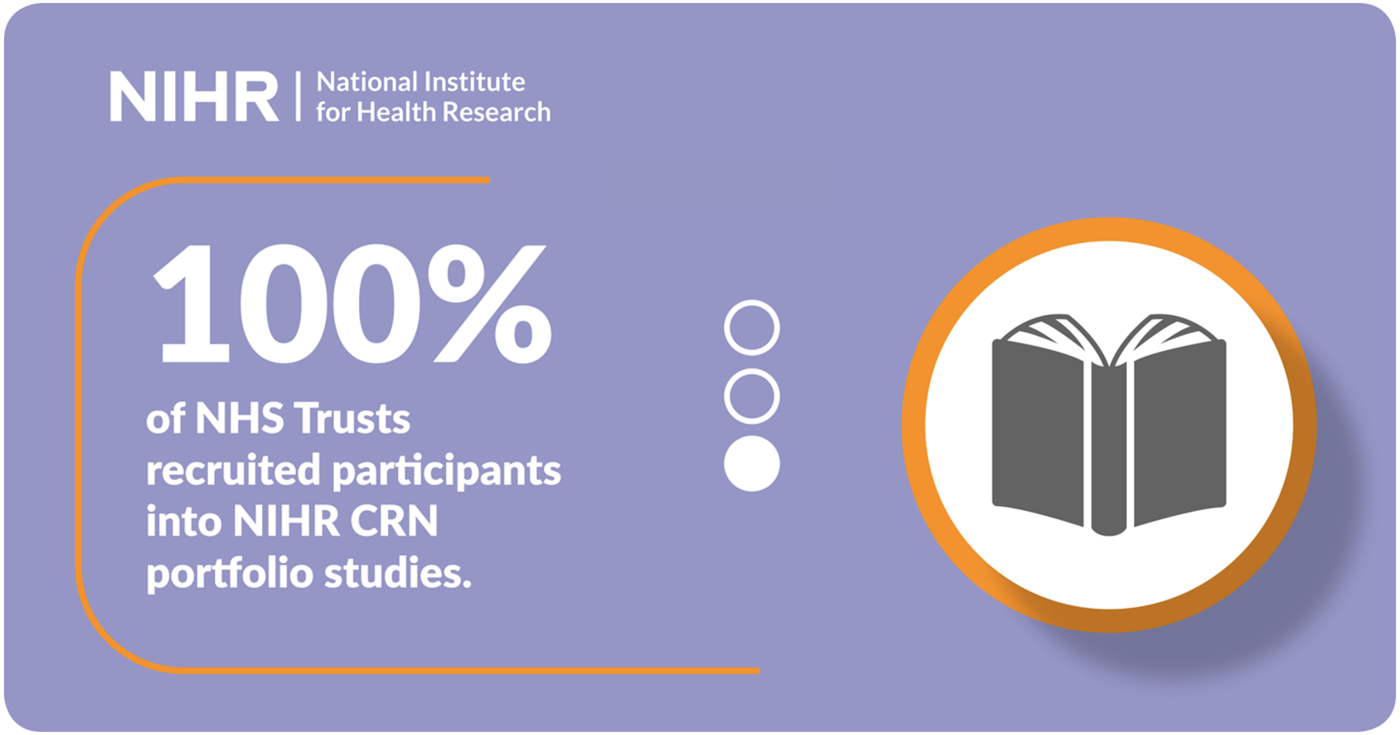
Number of participants

NIHR | National Institute for Health Research

870,250

participants took part in clinical research across England. This is the equivalent of 2,383 per day!

NHS recruitment

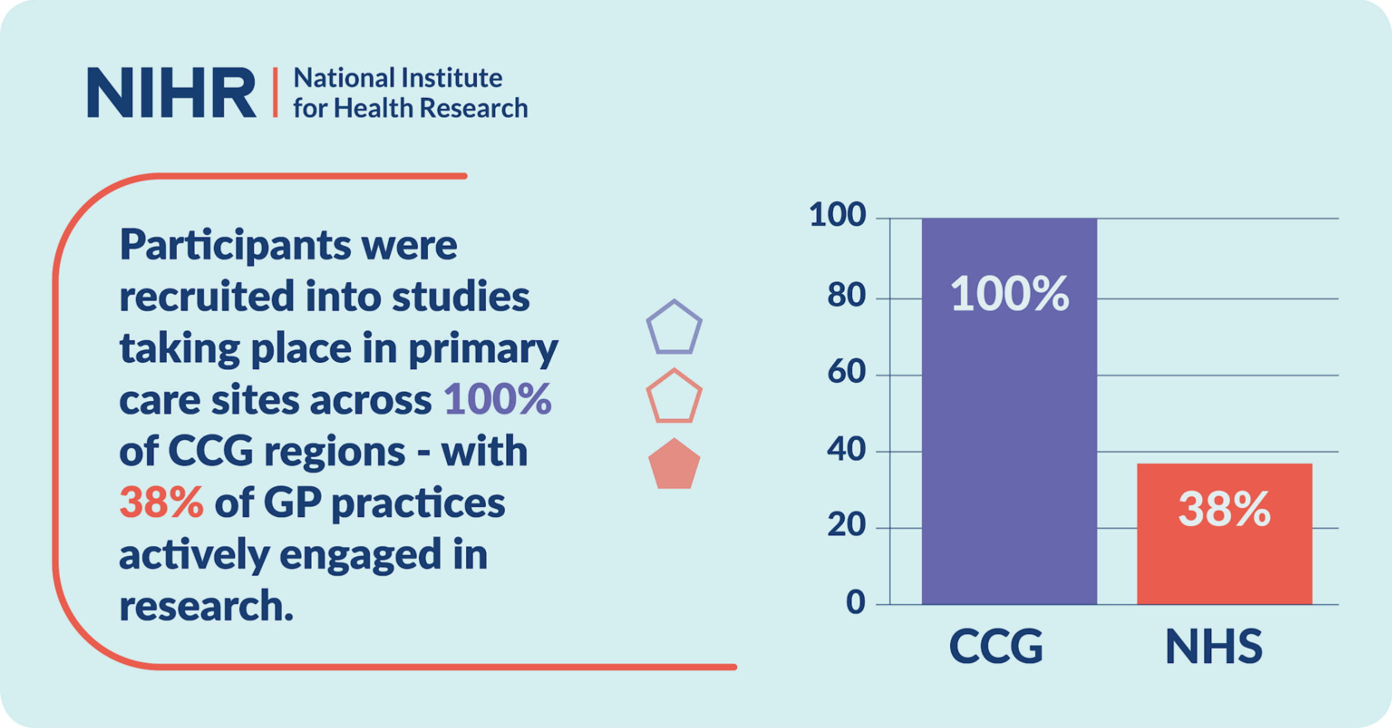


NIHR | National Institute for Health Research

100%

of NHS Trusts recruited participants into NIHR CRN portfolio studies.

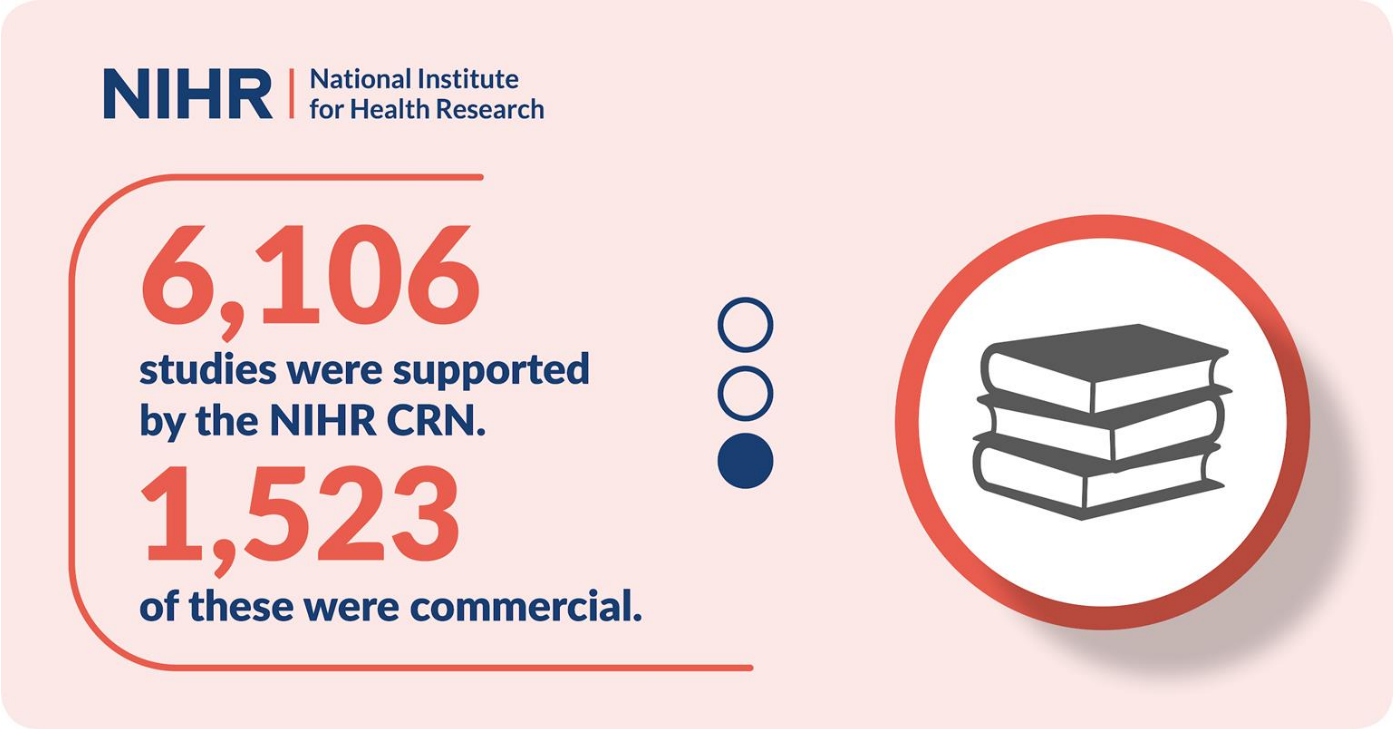
Primary care recruitment



NIHR | National Institute for Health Research

Participants were recruited into studies taking place in primary care sites across 100% of CCG regions - with 38% of GP practices actively engaged in research.

Ongoing studies 2018/19



NIHR | National Institute for Health Research

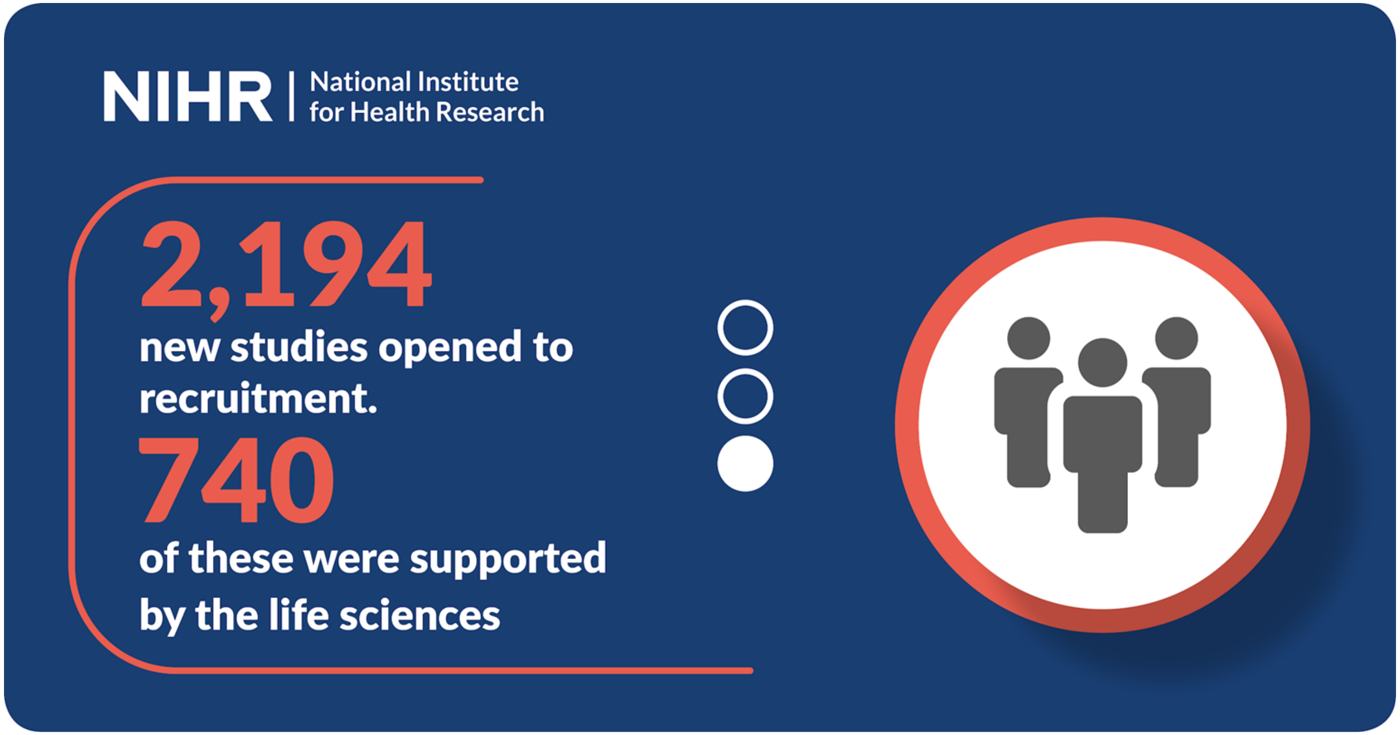
6,106

studies were supported by the NIHR CRN.

1,523

of these were commercial.

New portfolio studies 2018/19



NIHR | National Institute for Health Research

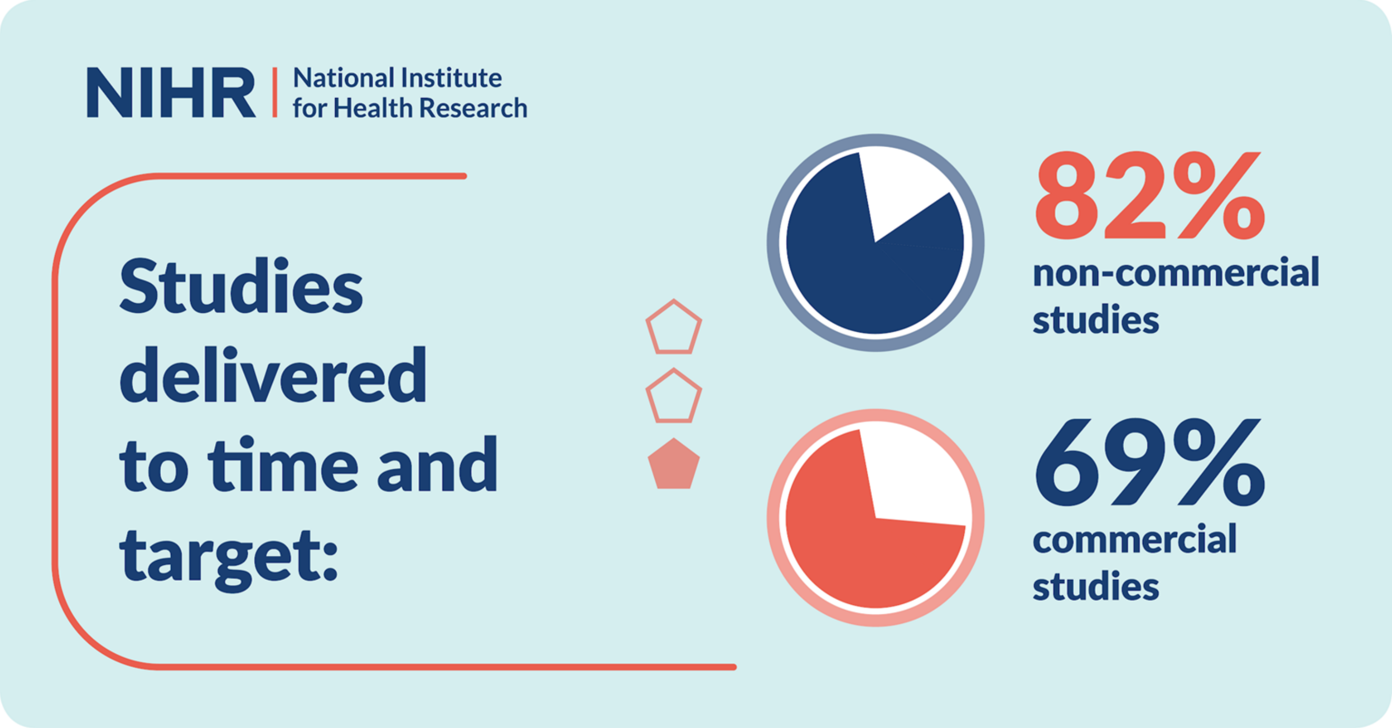
2,194

new studies opened to recruitment.

740

of these were supported by the life sciences

Time and target delivery



NIHR | National Institute for Health Research

Studies delivered to time and target:

82% non-commercial studies

69% commercial studies

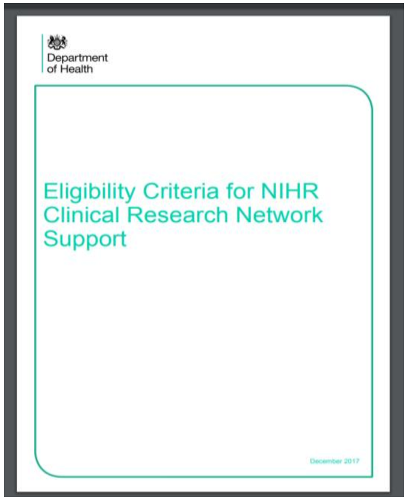
Expansion of CRN Support

Expansion of CRN Support

The NIHR Clinical Research Network (CRN) has extended support into health and social care research taking place outside of NHS settings.

The Department of Health and Social Care agreed an important change to the criteria that describes which clinical research studies can benefit from CRN support.

The **Eligibility Criteria for NIHR Clinical Research Network Support Policy** is online here:



Department
of Health

Eligibility Criteria for NIHR Clinical Research Network Support

December 2017

www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support

Better patient outcomes at research-active hospitals

- Study tested whether hospitals with a high level of participation in bowel cancer trials have improved care outcomes
- Patients treated at hospitals with a high level of research had a mortality rate of 5%, compared to 6.5% in less research-active hospitals
- And 44.8% of patients were still alive five years after initial diagnosis, compared to only 41%
- Even patients who are not involved in trials benefit from care in research-active hospitals

Downing A, Morris EJ, Corrigan N, *et al* High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. *Gut* 2017;**66:**89-96.

How are studies adopted onto the CRN portfolio ?

- Research (as defined), fully funded, ethically approved and from eligible funders.
- 2 criteria :
  - Clear value to the NHS, social care or public health
  - Ensuring the study takes account of the priorities, needs and realities of the NHS, social care or public health
- “TOP-DOWN” network
- NIHR commissions some “bottom-up” research from on the ground ideas

The CRN offer : Study Support Service

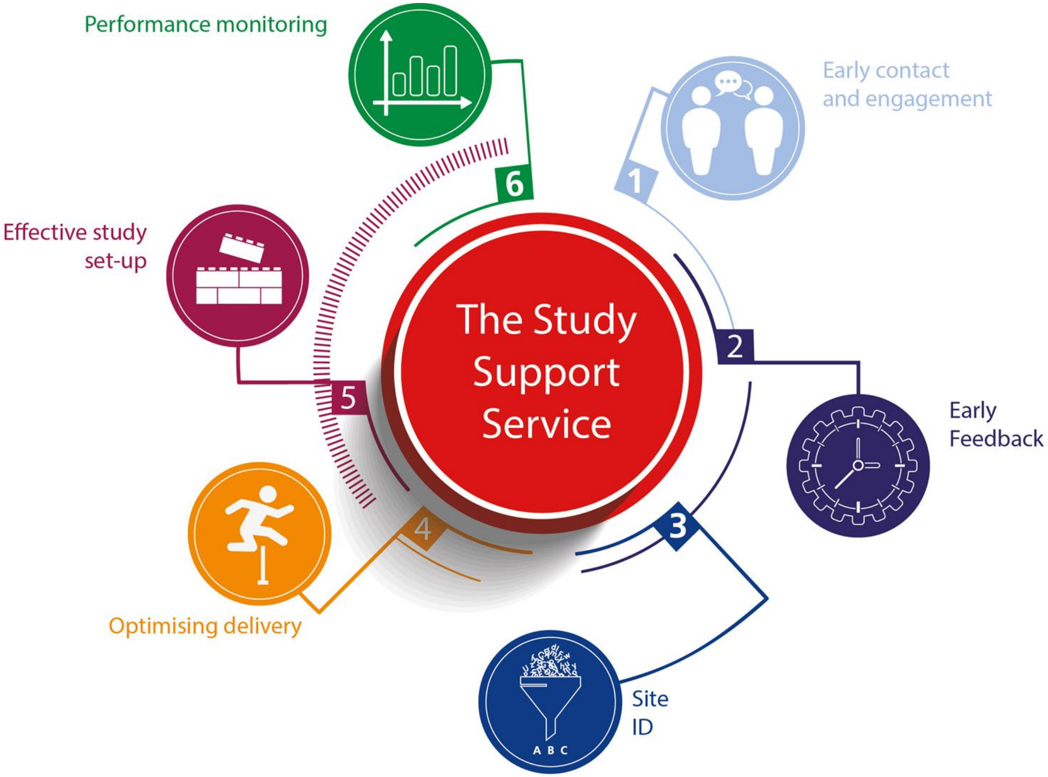
- Supports researchers and life-sciences industry to develop, set up and deliver research to time and target

- CRN provides a range of services across the research pathway for eligible studies, commercial or non-commercial

- Consistent, high quality support provided for all CRN portfolio studies, regardless of study type, size or therapy area

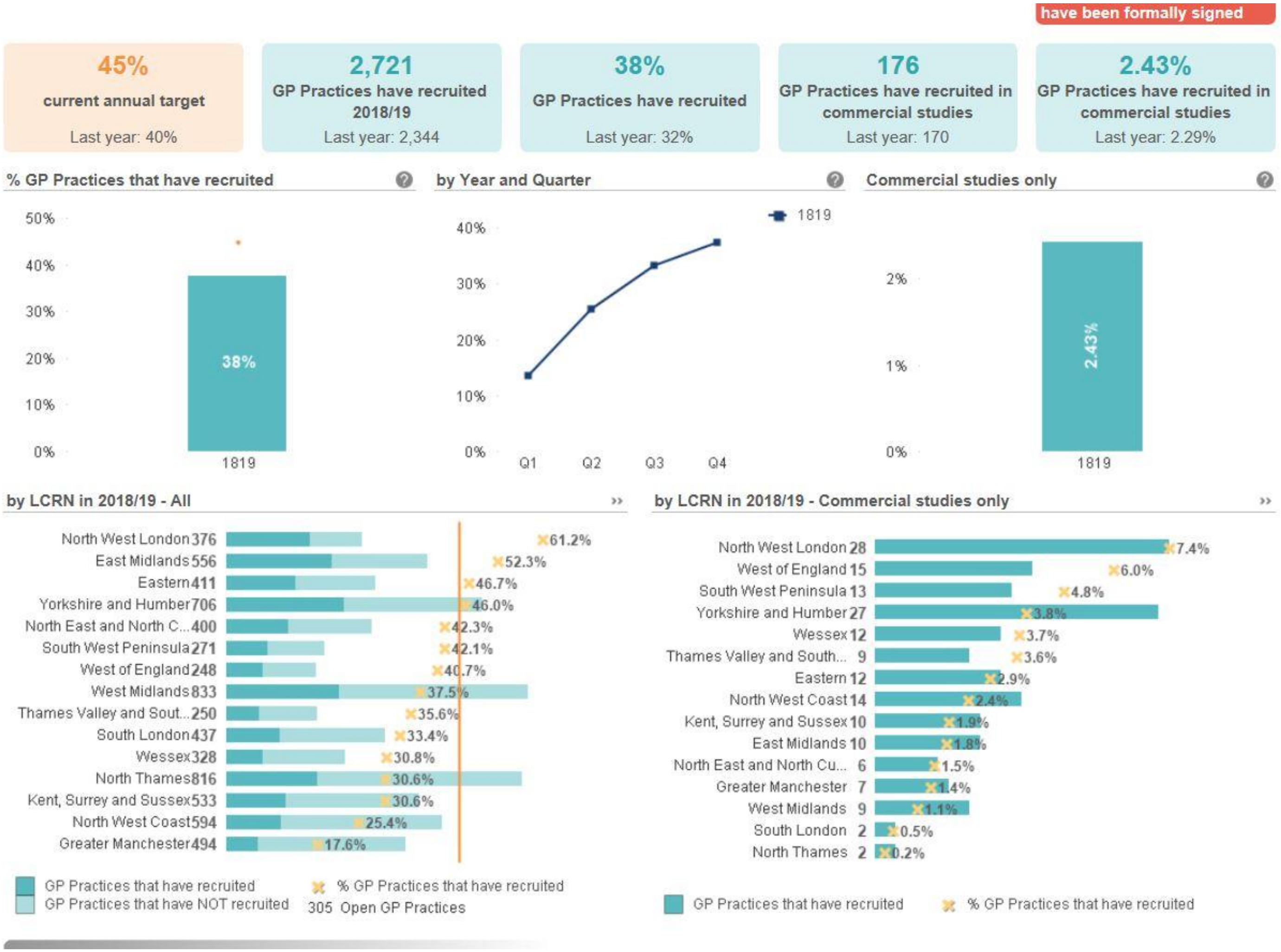
- Our advisors help with regulatory approvals, assistance with site identification, or guidance with the study costings - providing access to the NHS research environment.

Study Support Service



CRN primary care performance metrics

HLO6c



have been formally signed

45% current annual target. Last year: 40%

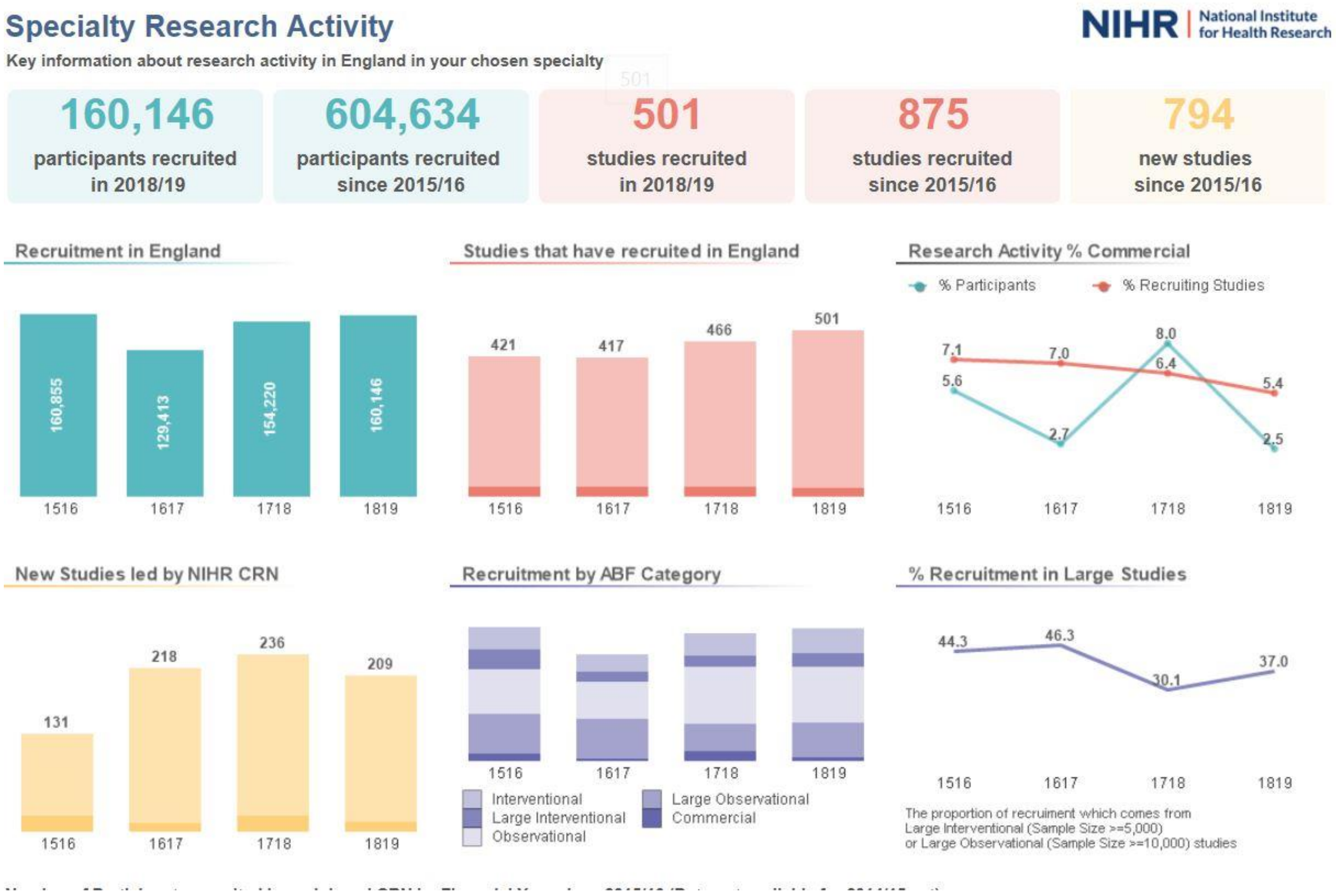
2,721 GP Practices have recruited 2018/19. Last year: 2,344

38% GP Practices have recruited. Last year: 32%

176 GP Practices have recruited in commercial studies. Last year: 170

2.43% GP Practices have recruited in commercial studies. Last year: 2.29%

NIHR | National Institute for Health Research



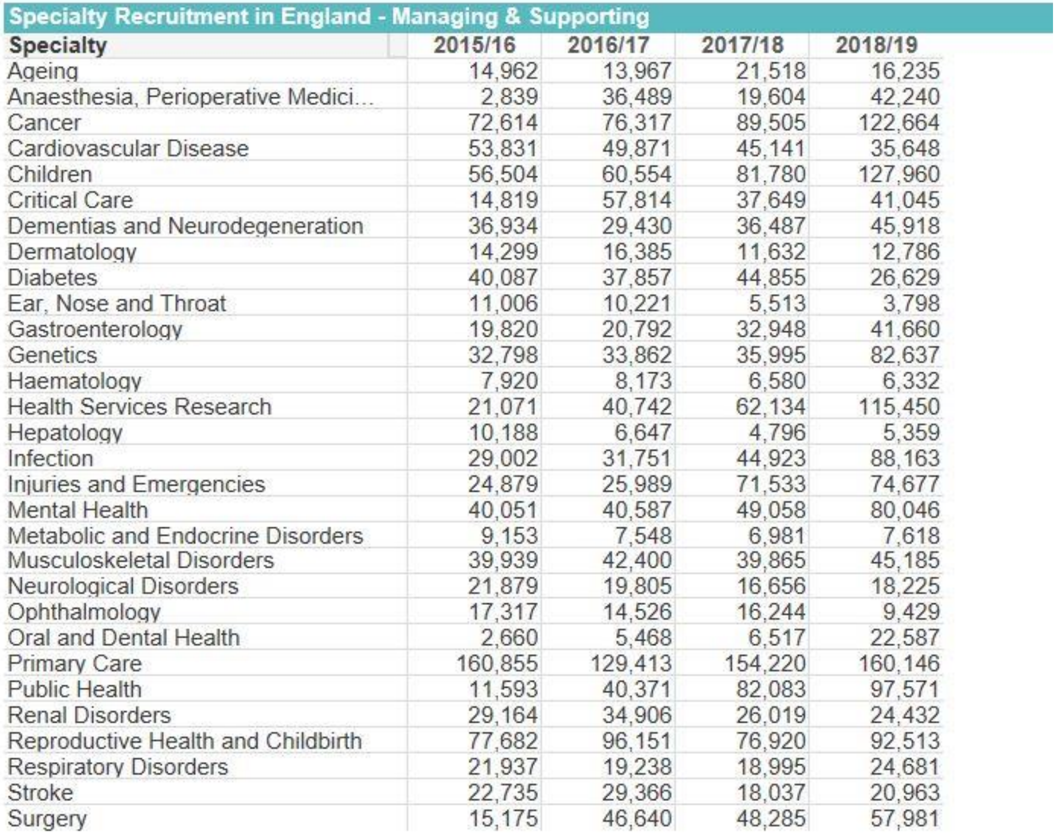
Specialty Research Activity

Key information about research activity in England in your chosen specialty

NIHR | National Institute for Health Research

160,146	**604,634**	**501**	**875**	**794**
participants recruited in 2018/19	participants recruited since 2015/16	studies recruited in 2018/19	studies recruited since 2015/16	new studies since 2015/16

The proportion of recruiment which comes from Large Interventional (Sample Size >=5,000) or Large Observational (Sample Size >=10,000) studies

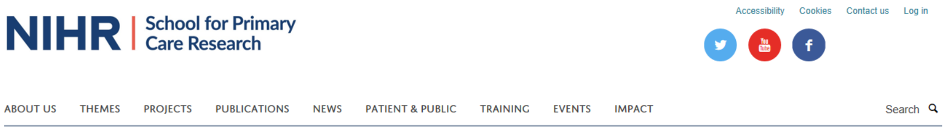


Specialty Recruitment in England - Managing & Supporting

Specialty	2015/16	2016/17	2017/18	2018/19
Ageing	14,962	13,967	21,518	16,235
Anaesthesia, Perioperative Medici…	2,839	36,489	19,604	42,240
Cancer	72,614	76,317	89,505	122,664
Cardiovascular Disease	53,831	49,871	45,141	35,648
Children	56,504	60,554	81,780	127,960
Critical Care	14,819	57,814	37,649	41,045
Dementias and Neurodegeneration	36,934	29,430	36,487	45,918
Dermatology	14,299	16,385	11,632	12,786
Diabetes	40,087	37,857	44,855	26,629
Ear, Nose and Throat	11,006	10,221	5,513	3,798
Gastroenterology	19,820	20,792	32,948	41,660
Genetics	32,798	33,862	35,995	82,637
Haematology	7,920	8,173	6,580	6,332
Health Services Research	21,071	40,742	62,134	115,450
Hepatology	10,188	6,647	4,796	5,359
Infection	29,002	31,751	44,923	88,163
Injuries and Emergencies	24,879	25,989	71,533	74,677
Mental Health	40,051	40,587	49,058	80,046
Metabolic and Endocrine Disorders	9,153	7,548	6,981	7,618
Musculoskeletal Disorders	39,939	42,400	39,865	45,185
Neurological Disorders	21,879	19,805	16,656	18,225
Ophthalmology	17,317	14,526	16,244	9,429
Oral and Dental Health	2,660	5,468	6,517	22,587
Primary Care	160,855	129,413	154,220	160,146
Public Health	11,593	40,371	82,083	97,571
Renal Disorders	29,164	34,906	26,019	24,432
Reproductive Health and Childbirth	77,682	96,151	76,920	92,513
Respiratory Disorders	21,937	19,238	18,995	24,681
Stroke	22,735	29,366	18,037	20,963
Surgery	15,175	46,640	48,285	57,981

Primary care research funding

- NIHR School for Primary Care Research (SPCR)
- NIHR funding streams (NETS-CC)
- Research Council funding
- Other funding bodies e.g. Diabetes UK
- CRN funds NHS Service Support Costs
- NHS Excess Treatment Costs paid by NHS (CCGs)



Impact of research

Documenting Impact of research

- Research helps to improve NHS quality and productivity
- We supported the STarT Back study - a new stratified approach to managing back pain
- Study showed improved patient outcomes and estimated cost savings of £34 per patient
- New approach is now being applied across the country

Incentivisation

Practice incentivisation

- Financial e.g. staff time (e.g. GP and Practice Nurse), admin time, meeting time “back-fill”, training costs etc.
  - Research Ready accreditation (RCGP) encouraged
  - Good Clinical Practice (GCP) mandatory
- Feedback to practices e.g. data quality (RSC), specific audits (CPRD)
- Training costs e.g. Good Clinical Practice training (mandatory) and Research Ready accreditation support

An example :
Research Sites Initiative in SW England

Funds level of infrastructure in practices

- hierarchy of funding and activity – performance managed
- In addition each study has Service Support Costs - national costing templates
- Core criteria- Research Ready and GCP training and all practice agreement and engagement
  - **Level 0 -** (affiliated) -low level activity no obligation
  - **Level 1** - low level activity – data base searches/PIC activity
  - **Level 2** - 5 or more studies/benchmarked for EOI and recruitment. Some feasibility and complex work
- **Sessional practices** –embedded research, funded nurse/GP/administrator time
- High level recruitment/complex studies. Pilot and pre feasibility/commercial encouraged
- **CI** in primary care- growing- 6 and increasing

Financial Incentives e.g. SW Peninsula

Level 1	<5 studies pa	£1800
Level 2	5+ studies pa	£3800
Sessional	7+ studies	~£10K

- Lead GP and all practice partners sign up
- Annual Primary Care meeting
- Regular CRN meetings / review with local team (visit practice)
- Performance managed

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Patient and Public Involvement and Engagement (PPIE)

Patient and Public Involvement and Engagement (PPIE) Programme Strategy

Five year goals (2015-2020)

1. Talk about research in the NHS: We will help raise awareness of research by improving the availability, variety and usefulness of accessible information.

2. Make it easy for people to participate: We will work in partnership with patients, carers and the public to reduce barriers to participation.

3. Reach out: We will ensure greater diversity by engaging communities so that a wider range of people get more opportunities to participate and to be involved.

Patient and Public Involvement and Engagement (PPIE) Programme Strategy

Five year goals (2015-2020) *continued...*

4. Connect with the public, healthcare professionals and partners: We will increase engagement to improve connectivity and will be innovative in the way we communicate e.g. by the use of digital and social media.

5. Support and value patient public involvement and engagement: We will strengthen partnerships making involvement a meaningful and effective part of improving the quality of service.

Current PPIE Projects

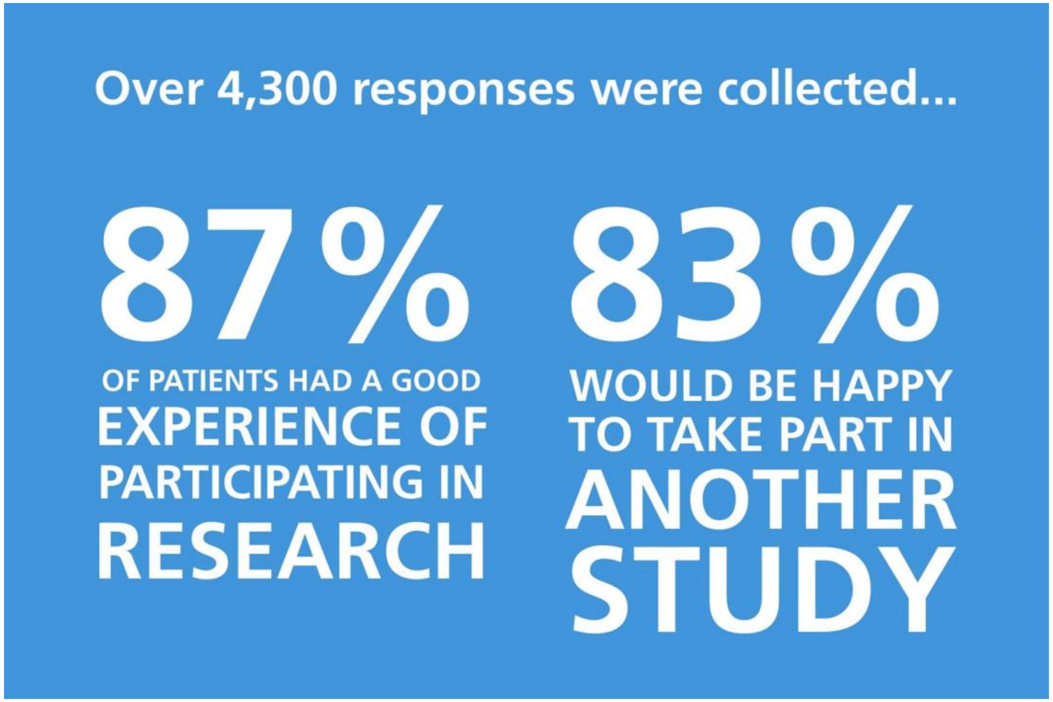
- Patient Research Ambassador Initiative
- Driving service improvement through using patient research experience feedback
- Learning support for PPIE
- Specialty guidance: a new integrated approach

Patient Research Experience

The Clinical Research Network has a commitment to collecting data on patient experience of participating in research and using it.

Each of our 15 LCRNs run an annual satisfaction survey. Embedded within each of these local surveys are a set of national questions.

Patient Experience of Research National Survey Results 2017-18



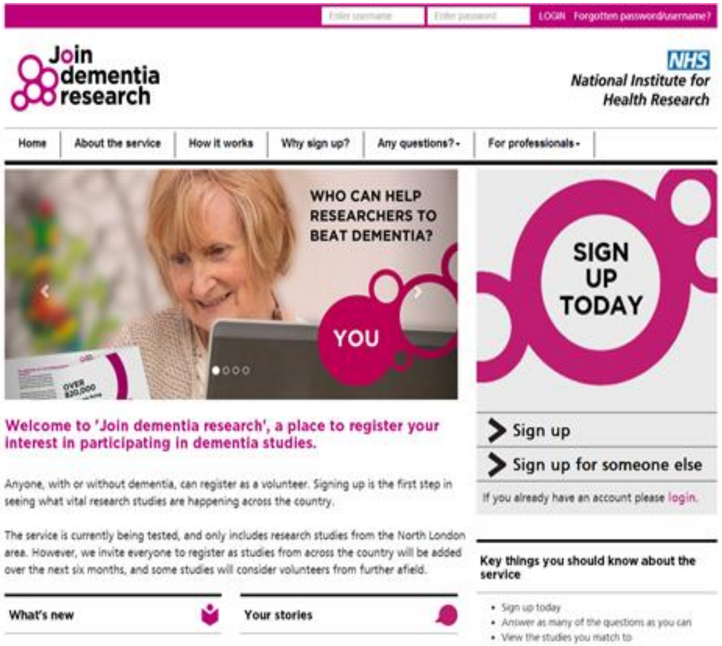
Over 4,300 responses were collected...

87% OF PATIENTS HAD A GOOD EXPERIENCE OF PARTICIPATING IN RESEARCH

83% WOULD BE HAPPY TO TAKE PART IN ANOTHER STUDY

Consent to contact approaches e.g. Join Dementia Research

Join dementia research



Welcome to 'Join dementia research', a place to register your interest in participating in dementia studies.

Anyone, with or without dementia, can register as a volunteer. Signing up is the first step in seeing what vital research studies are happening across the country.

The service is currently being tested, and only includes research studies from the North London area. However, we invite everyone to register as studies from across the country will be added over the next six months, and some studies will consider volunteers from further afield.

If you already have an account please login.

Key things you should know about the service

- Sign up today
- Answer as many of the questions as you can
- View the studies you match to

What is Join Dementia Research?

- A nationwide service that helps anyone in the UK find and take part in vital dementia research studies.
- Supporting delivery of Government's Challenge on Dementia 2020

Join Dementia Research is funded by the Department of Health and delivered in partnership with the National Institute for Health Research, Alzheimer Scotland, Alzheimer's Research UK and Alzheimer's Society.

Alzheimer Scotland
Action on Dementia

Alzheimer's Research UK
The Power to Defeat Dementia

Alzheimer's Society
United Against Dementia

Innovative trial designs

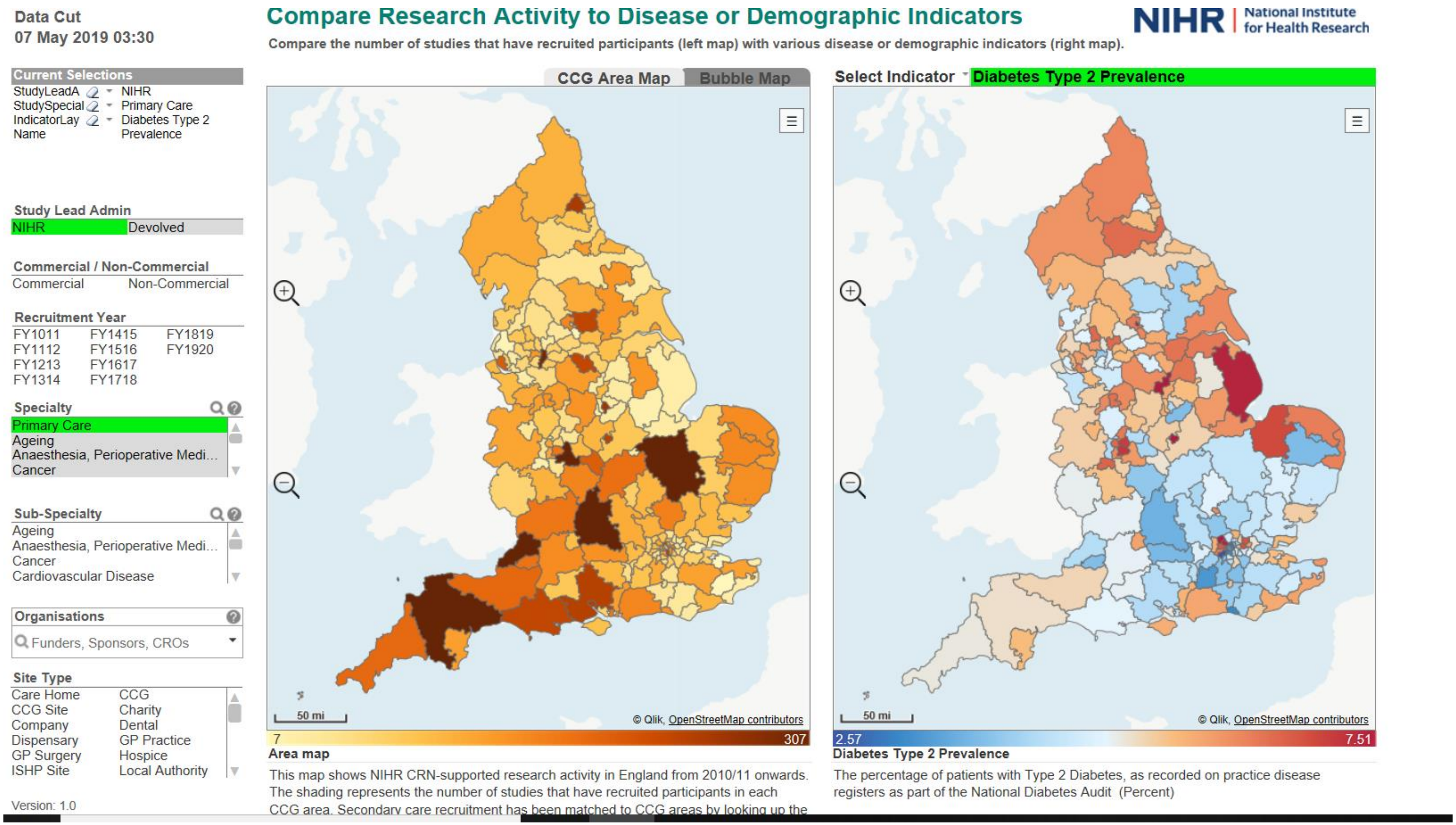
We are supporting in primary care:

- Large numbers of cluster RCTs (often pragmatic)
- Adaptive trial designs e.g. ALICE
- Stepped wedge designs for implementation
- Platform trials
- Complex studies in stratified/personalised medicine e.g. genomics studies in primary care
- Real world studies including point of care randomisation e.g. DIRECT

Information Technology

IT and primary care research

- EHR based e.g. pop-ups and templates
- On-site or off-site
- IT solutions – validated search strategy comes with each study
- Digital platforms on GP computer systems to promote recruitment
- End-to-end digital execution of studies
    - *NHS App* – direct to patient promotion
- Mapping research v. prevalence of disease



Data Cut
07 May 2019 03:30

Compare Research Activity to Disease or Demographic Indicators

Compare the number of studies that have recruited participants (left map) with various disease or demographic indicators (right map).

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Current Selections

StudyLeadA	NIHR
StudySpecial	Primary Care
IndicatorLay Name	Diabetes Type 2 Prevalence

Study Lead Admin
NIHR Devolved

Commercial / Non-Commercial
Commercial Non-Commercial

Recruitment Year
FY1011 FY1112 FY1213 FY1314 FY1415 FY1516 FY1617 FY1718 FY1819 FY1920

Specialty
Primary Care
Ageing
Anaesthesia, Perioperative Medi…
Cancer

Sub-Specialty
Ageing
Anaesthesia, Perioperative Medi…
Cancer
Cardiovascular Disease

Organisations
Funders, Sponsors, CROs

Site Type
Care Home
CCG Site
Company
Dispensary
GP Surgery
ISHP Site
CCG
Charity
Dental
GP Practice
Hospice
Local Authority

Version: 1.0

Area map

This map shows NIHR CRN-supported research activity in England from 2010/11 onwards. The shading represents the number of studies that have recruited participants in each CCG area. Secondary care recruitment has been matched to CCG areas by looking up the

Diabetes Type 2 Prevalence

The percentage of patients with Type 2 Diabetes, as recorded on practice disease registers as part of the National Diabetes Audit (Percent)

Commercial research and primary care

- >2% of all practices
- Greater regulatory governance
- Supported by CRN
- Income stream to practices
- Increasingly data-driven
- Increasingly in large practices

“Big data” initiatives

GP practices submit routine clinical data (free of charge) to :

- Clinical Practice Research Datalink (CPRD)
- NHS Digital
- QResearch
- RCGP Research Surveillance Centre

For:

Epidemiology and pharmacoepidemiology

Acute illness surveillance e.g. influenza

Feasibility and delivery of trials and real world studies

Challenges for network research in primary care

- Drop last year (2018/19) to 38% of practices
- Indemnity for research - now state-sponsored
- Data protection issues
- Financial incentives still needed
- Changing culture in practices to encourage research participation
- Keeping up with changing architecture of primary care
- Embedding research into routine care in the NHS

Merci beaucoup pour votre attention