



NIHR Office for Clinical Research Infrastructure

FUNDING LINKED TO IVD AND MEDICAL DEVICE CLINICAL RESEARCH & DEVELOPMENT



Funding Sources/Organisations

- Basic Research
 - Medical Research Council (MRC)
 - Engineering Physical Sciences Research Council (EPSRC)
 - Innovate UK (Formerly Technology Strategy Board TSB)
 - Horizon 2020 (FP7)
- Clinical Research
 - National Institute for Health Research (NIHR)
 - Innovate UK
 - NHS England (SBRI)
 - Charities
 - Horizon 2020
 - ...

NIHR Research Programmes

- The NIHR funds a range of programmes addressing a broad range of health priorities
- Funding is based on the quality and relevance of the research to personal social services, public health and the NHS
- Calls are issued for:
 - commissioned research to address specific topic areas
 - researcher-led research to fund questions proposed directly by researchers
 - themed calls to meet an identified health challenge or government priority



NIHR Funding Streams

Commissioned Research

- Innovation for Innovation (i4i) – Challenge Awards
- Efficacy Mechanism Evaluation (EME)
- Health Technology Assessment (HTA)
- Health Service and Delivery Research (HS&DR)
- Public Health Research

Research-Led Research

- Invention for Innovation (i4i)
- Efficacy Mechanism Evaluation (EME)
- Health Technology Assessment (HTA)
- Health Service and Delivery Research (HS&DR)
- Public Health Research
- Research for Patients Benefit (RfPB)
- Programme Grants for Applied Research
- Programme Development Grants

NIHR Funding Streams

NIHR Clinical Commissioning Facility (NIHR-CCF)

- Invention for Innovation (i4i)
- Programme Grants for Applied Research (PGfAR)
- Programme Development Grants (PDG)
- Research for Patient Benefit (RfPB)
- Health Innovation Challenge Fund (HICF) – Co-funded between DH & Wellcome Trust

NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)

- Efficacy and Mechanism Evaluation (EME) Programme
- Health Services and Delivery Research (HS&DR) Programme
- Health Technology Assessment (HTA) Programme
- Public Health Research (PHR) Programme
- Systematic Reviews (SR) Programme
- NIHR Clinical Trials Unit (CTU) Support Funding

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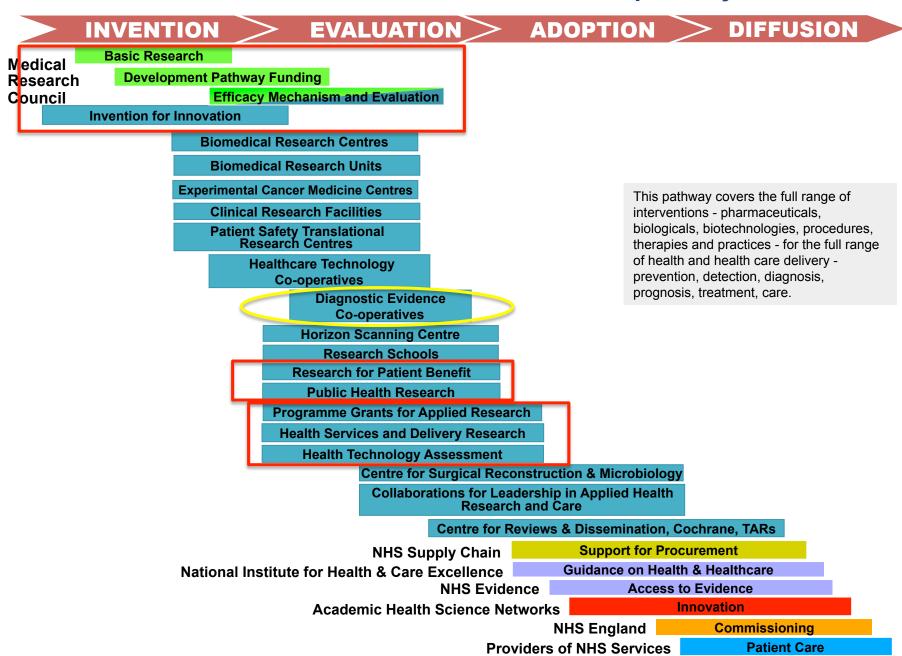
Research programme

Broad research area	EME	HS&DR	нта	i4i	PGfAR	PDG	PHR	RfPB	SR
Public health	✓	✓	✓	✓	✓	✓	✓	✓	✓
Health services and organisation	×	✓	✓	×	✓	✓	×	✓	✓
Clinical evaluation and translation	✓	×	✓	✓	√	✓	×	✓	✓
Technology development	×	×	×	√	×	×	×	×	×
Types of evidence									
Evidence synthesis	×	✓	✓	×	✓	✓	✓	✓	✓
Evidence generation	✓	✓	✓	√	√	✓	√	√	×
'Programmes' of research	×	✓	×	×	✓	✓	✓	×	✓

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	Research programme								
	EME	HS&DR	нта	i4i	PGfAR	PDG	PHR	RfPB	SR
Calls and competitions (number of opportunities to apply per year)									
Researcher-led	3	3	3	2	2	2	3*	3	1*
Commissioned	3	3	3	2	N/A	N/A	3*	N/A	N/A
Themed	Frequency and participating programmes as advertised								
Funding amounts and periods									
Funding limit**	No limit	No limit	No limit	No limit	No limit***	£100k	No limit	£350k [†]	£400k
Period of funding	No fixed period	No fixed period	No fixed period	Up to 3 years	No fixed period***	0-18 months	No fixed period	Up to 3 years	Up to 3 years

Role of NIHR research in the innovation pathway





Overview

In simple terms:

– MRC: Basic science (can it work?)

– i4i: Technical development (how does it work?)

– EME: Evaluation (does it work?)

– HTA: Cost-effectiveness (is it worth it?)

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NIHR Invention for Innovation (i4i)



i4i Programme

- Support for R&D and clinical adoption of innovative healthcare technologies
- Funding for collaborative projects involving academics, clinicians or companies
- Two funding streams
 - i4 Product Development Awards
 - i4i Challenge Awards

Project Eligibility

- Minimum of two organisations involved HEI, NHS Trust, Industry
- Lead applicants and collaborators must be based in England or Wales
- Sub-contractors may be from abroad
- Up to three years in duration
- No upper funding limits
- No work packages including animal studies
- Project must have progressed beyond basic research

Not supported:

 Drug development, incremental R&D, clinical trials of fully developed products or interventions, impact of service delivery, infrastructure, etc



Assessment Criteria

- Clinical need, health economic case & NHS adoption
- Project plan
- Strength of the research/management teams
- IP
- Commercial strategy
- PPI
- Quality of outline and full applications



Record and Upcoming Calls

- To date, i4i has funded over 70 projects in the fields of medical devices and in vitro/in vivo diagnostics with a spend of £44 million
- 9th call for Product Development Awards
- 4th call for Challenge Awards
- Opening November, closing January, dates to be confirmed



Contact Details

Website: http://www.ccf.nihr.ac.uk/i4i/

Email: i4i.programme@nihr-ccf.org.uk

Tel: 020 8843 8015

NIHR Central Commissioning Facility
Grange House
15 Church Street
Twickenham TW1 3NL

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NIHR EFFICACY MECHANISM EVALUATION (EME)



Efficacy and Mechanism Evaluation

Aim:

 Support excellent clinical science with an ultimate view to improving health or patient care

Dual Approach:

- "Science driven" examine the efficacy of a technology intervention (i.e. pharmaceutical, diagnostic test, surgical or psychological therapies, or public health measures) and/or explore its mechanisms of action
- Clear patient focussed outcomes in areas of need for health care research

EME – Programme Remit

Support studies in patients which seek to:

- Evaluate the clinical efficacy of interventions (where proof of concept in humans has already been achieved)
- Add significantly to our understanding of biological or behavioural mechanisms and processes
- Explore new scientific or clinical principles

Within the main clinical intervention study, if relevant to the EME remit, will support:

- Development or testing of new methodologies
- Studies that use validated surrogate markers as indicators of health outcome
- Laboratory based, or similar embedded studies
- Pilot and feasibility studies



EME – Programme Remit

The EME Programme will not support:

- Confirmatory studies or trials of incremental modifications to existing medical interventions
- Proof-of-concept, proof-of-mechanism in humans, nor 'confidence in effect' studies
- Research involving animals
- Commercial collaborations are welcome in applications, however, the lead applicant must be from academia or the NHS
- The funding projects range from £120,000 to £3.1 million and the durations range from 18 to 66 months

EME – Open Commissioned Calls

Topic	Deadline	Commissioning brief	Guidance notes	Apply
14/142 Mechanisms of action of health interventions*	7 October 2014, by 1pm	Access commissioning brief (pdf, 131.04 KB)	Access guidance notes (pdf, 360.59 KB) □	Apply
14/144 Bowel control and faecal incontinence in adults	7 October 2014, by 1pm	Access commissioning brief (pdf, 133.11 KB)	Access guidance notes (pdf, 304.14 KB) □	Apply
14/145 Pituitary and/or adrenal disorders and related diseases	7 October 2014, by 1pm	Access commissioning brief (pdf, 132.66 KB)	Access guidance notes (pdf, 304.14 KB)	Apply
14/146 Renal failure resulting from intrinsic renal diseases	7 October 2014, by 1pm	Access commissioning brief (pdf, 132.97 KB)	Access guidance notes (pdf, 304.14 KB)	Apply
14/147 Wound healing	7 October 2014, by 1pm	Access commissioning brief (pdf, 132.28 KB)	Access guidance notes (pdf, 304.14 KB)	Apply

EME - Examples

Developing a novel, biopsy-based diagnostic for patient stratification: A Randomised, open labelled study in anti-TNFalpha inadequate responders to investigate the mechanisms for Response, Resistance to Rituximab versus Tocilizumab in Rheumatoid Arthritis patients

Professor Costantino Pitzalis (University of London) 33 months from 1st December 2012 (£1,002,635)

Aims to establish whether a sample of the joint lining can predict which patients will respond to treatment.

Enhanced Neoplasia Detection and Cancer Prevention in Chronic Colitis (ENDCaP-C)

Dr Glenn Matthews (University of Birmingham) 24 months from 1st February 2013 (£1,552,675).

Aims to develop a diagnostic test to be used alongside colonoscopy, and so improve the detection of tumours at an early stage.



EME – Key Points and Resources

- Have good preliminary data to justify your proposal
- Gather a team with relevant scientific and project management skills
- Have an appropriate study design and strong statistical support
- Be realistic and accurate when costing the study
- Talk your proposed study through with EME before submitting an application
- EME website: http://www.eme.ac.uk/index.asp
- EME video/podcast: <u>http://www.youtube.com/watch?v=ICtXbGgc5nU</u>
- EME secretariat: contact us at <u>info@eme.ac.uk</u> or 02380 594304

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NIHR Health Technology Assessment (HTA)

What is a "Health Technology"?

The term 'health technology' covers a range of methods used to promote Health, prevent and treat disease and improve rehabilitation and long term care including:

- Drugs: such as antidepressants, contraceptives, antibiotics
- Devices: such as pacemakers, dialysis machines, hearing aids
- Procedures: such as surgical techniques, physiotherapy, counselling
- Screening: for cancer, sexually transmitted diseases, stroke
- Evaluation of diagnostic tests

Remit

- The HTA Programme supports research that is immediately useful to clinical practice and NHS decision makers
- HTA research is undertaken when there is evidence to show the technology has demonstrated efficacy but there is uncertainty around its clinical and cost effectiveness in a real life NHS setting in comparison to the current best alternative
- There may also be uncertainty around its place in the existing care pathway



HTA Contact

 National Institute for Health Research -Evaluation, Trials and Studies Coordinating Centre

University of Southampton

Alpha House, Enterprise Road

Southampton SO16 7NS

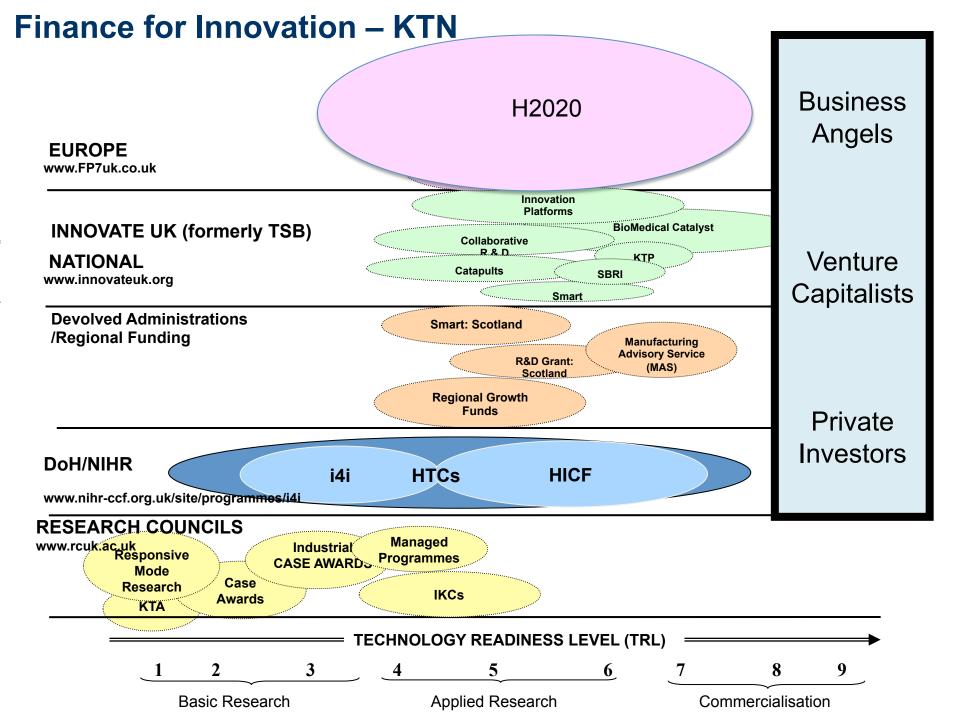
Tel: 023 8059 5586

Email: hta@hta.ac.uk

Web: www.nets.nihr.ac.uk/hta

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Other Funding Streams



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Innovate UK

Technology Strategy Board

Driving Innovation







Innovate UK - Biomedical Catalyst

- Joint Technology Strategy Board (TSB) and Medical Research Council (MRC) programme
 - £90m Innovate UK: New programme for business
 - £90m MRC: Rebranding of DPFS/DCS for academics
- Small and medium-sized commercial enterprises (SMEs),and researchers looking to work either individually or in collaboration to develop solutions to healthcare challenges.
- An integrated translational funding programme that can support innovative ideas
 - Any sector or discipline that demonstrate the potential to provide significant positive healthcare and economic impact.

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Innovate UK – Biomedical Catalyst

Feasibility award



This grant enables the exploration and evaluation of the commercial potential of an early-stage scientific idea, through:

- review of research evidence and identification of application
- assessment of business opportunity
- investigation of intellectual property position
- experimental studies to validate initial concepts or existing pre-clinical work
- scoping for further development.

Key features

Business-led applications:

Duration - up to 12 months

Maximum grant - £150k

Funding proportion – up to 75% of total eligible project costs

Academic-led applications:

Confidence in Concept Awards will be made available to researchers in major universities

Early-stage award



This grant is to evaluate the technical feasibility of an idea and establish proof of concept in a model system, through:

- experimental evaluation (lab-scale)
- initial demonstration using in vitro and in vivo models (not human trials)
- exploration of potential production mechanisms
- early-stage prototyping
- product development planning
- intellectual property protection*.

Key features

Business-led applications:

Duration - up to three years

Maximum grant - £2.4m

Funding proportion – SME's up to 60% of total eligible project costs

Academic-led applications:

Duration - up to three years

Maximum grant - £3m

Funding proportion – awarded at RCUK fEC rules

Late-stage award



This grant takes a well-developed concept and demonstrates its effectiveness in a relevant environment through:

- initial human proof-of-concept studies
- demonstration of clinical utility and effectiveness
- demonstration of safety and efficacy (including phase I and II clinical trials)
- development of production mechanisms
- prototyping
- market testing
- intellectual property protection*.

Key features

Business-led applications:

Duration - up to three years

Maximum grant - £2.4m

Funding proportion – SME's up to 60% of total eligible project costs

Academic-led applications:

Duration - no formal limit

Maximum grant - no formal limit

Funding proportion – awarded at RCUK fEC rules



Smart

- Co-funding for UK-based pre-start-ups, start-ups, micro businesses and SMEs - science, engineering and technology R&D projects leading to successful new products, processes and services
- The Smart programme is 'always open' and is not restricted to projects in certain themes or sectors.
- Three types of grant are available:
 - Proof of market
 - Proof of concept
 - Development of prototype

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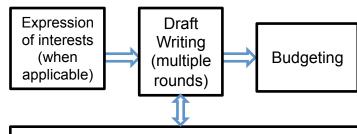
3 months (12 weeks) in advance Funding call received

Assess eligibility and suitability

PI decides on who applies to what and when

10 weeks in advance

Confirm internal and external collaborators



Internal peer review

Co-applicants (internal and external) approval

Final approved from the College

1 weeks in advance

Application Deadline

Submission

Decision

Submission



Common Issues with Applications

- Sample size/power calculation
- Recruitment
- Lack of preliminary data
- Study design
 - Choice of patients/population: inclusion/exclusion
 - Endpoints
 - Randomisation
 - Standardisation of intervention across centres
 - Dosage
- Study team
- Justification of costs
- Lack of embedded PPI involvement
- Unclear relationship with industry
- Sticking to the call brief



What should you do?

- Sign up for NIHR Funding Bulletins
 - http://www.nets.nihr.ac.uk/news/?a=2936
- Download the NIHR Funding Booklet
 - http://www.nihr.ac.uk/documents/about-NIHR/NIHR-Publications/NIHR-funding-opportunities-booklet.pdf
- View Open NIHR Funding Calls
 - http://www.nihr.ac.uk/funding-opportunities/

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NIHR INFRASTRUCTURE TO SUPPORT EVIDENCE GENERATION

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Invention

Evaluation

Adoption

Early-phase clinical research

Late-phase clinical research

NIHR Biomedical Research Centres

NIHR Biomedical Research Units

NIHR Clinical Research Facilities

Experimental Cancer Medicine Centres

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

Healthcare Technology Cooperatives

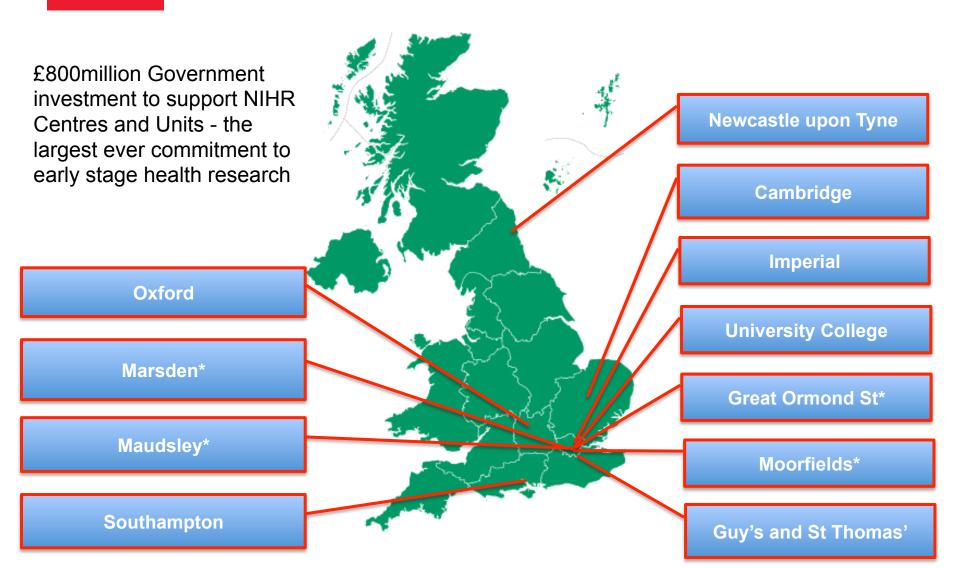
Diagnostic Evidence Cooperatives

NIHR Clinical Research Network

NIHR Collaborations for Leadership in Applied Health Research & Care

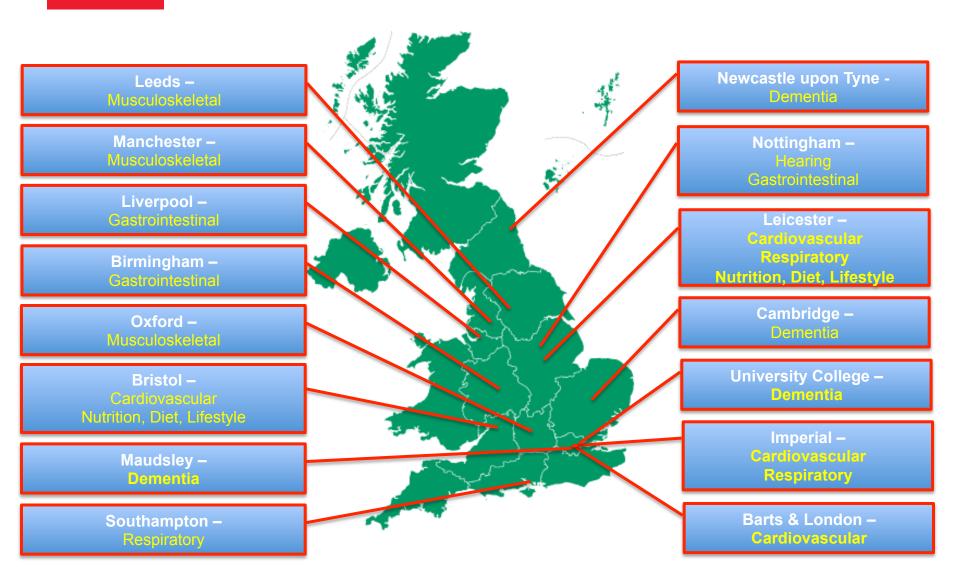
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Biomedical Research Centres (BRCs)



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Biomedical Research Units (BRUs)



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NEW MODELS FOR EFFECTIVE PARTNERSHIP



NIHR Healthcare Technology Co-operatives (HTCs)

- Aims of the NIHR HTCs:
 - Act as a catalyst for NHS "pull" for the development of new medical devices, healthcare technologies and technology-dependent interventions
 - Focus on clinical areas and/or themes of high morbidity, which have high potential for improving quality of life of NHS patients and improving the effectiveness of healthcare services that support them
 - Work collaboratively with patients and patients groups, charities, industry and academics



NIHR Healthcare Technology Co-operatives (HTCs)

- NIHR HTCs play a key role in:
 - The integration of clinical and patient need into the definition of technology and product concepts
 - Bringing partners together in close collaboration to develop, test and improve product concepts leading to clinical evaluation and demonstration of care pathway benefits
 - Reaching across primary and secondary care and care services, professional bodies and national networks of clinical champions

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NIHR Healthcare Technology Co-operatives (HTCs)

Leeds Teaching Hospitals
NHS Trust

Colorectal therapies.

Bradford Teaching Hospitals
NHS Foundation Trust
Wound prevention and treatment.

Sheffield Teaching Hospitals
NHS Foundation Trust
Devices for dignity.

University Hospitals of Birmingham NHS Foundation Trust

Trauma management.



Nottinghamshire
Healthcare NHS Trust,
Institute of Mental Health

Mental health and neurodevelopmental disorders.

Cambridge University
Hospitals NHS
Foundation Trust
Brain injury.

Barts
Health NHS Trust

Chronic gastrointestinal (GI) disease.

Guy's and St Thomas' NHS Foundation Trust Cardiovascular disease.



NIHR Diagnostics Evidence Co-operatives (DECs)

- Aims of the DECs
 - Act as a catalyst for the generation of high-quality evidence of <u>clinical validity</u>, <u>clinical utility</u>, <u>cost</u> <u>effectiveness and care pathway benefits</u> of commercially-supplied IVDs that is sought by a range of users, for example:
 - NHS clinicians and NHS commissioners
 - Accredited providers of NHS pathology services
 - Companies involved in the CE marking and marketing of IVDs
 - NICE Diagnostic Assessment Programme



NIHR Diagnostics Evidence Co-operatives (DECs)

- Aims of the DECs
 - Enable collaboration between clinicians and other healthcare professionals, patients and the <u>IVD</u> <u>industry</u>, staff of at least one accredited provider of NHS pathology services, NHS commissioners, academic researchers including health economists, and patient groups.
 - Create new, world-class methodologies for IVD assessment, where required.

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NIHR Diagnostics Evidence Co-operatives (DECs)

Leeds Teaching Hospitals NHS Trust

Liver diseases, Musculoskeletal diseases, Renal diseases.

Oxford Health NHS Foundation Trust

Primary care IVDs: Horizon scanning and rapid reviews to identify new and emerging IVDs, Identifying unmet needs for IVDs, Integrating primary care with laboratory services, Patient, carer and clinician factors in implementing IVDs, improving evidence for primary care IVDs.

Newcastle upon Tyne NHS Foundation Trust

Cancer, Cardiovascular disease and stroke, Genetics, Infection, Liver disease, Musculoskeletal disease, Respiratory, Transplantation.

Imperial College Healthcare NHS Trust

Cancer, Cardiovascular
diseases,
Gut health, Infectious diseases,
Metabolic medicine, Primary
Care,
Respiratory diseases.

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Clinical Research Network support along the study lifecycle





Feasibility

Choose the services you need from one or more of our three support packages:

- 1. Early feedback This service provides expert guidance during the stages of protocol development and set-up and will provide insight into the NHS research landscape including current UK practice.
- 2. Site intelligence Designed to compliment your own feasibility by using our site and study intelligence expertise whilst also utilizing study data from 300 closed and 200 open studies.
- 3. Full service Helps you identify sites or add to those you have already selected. Features rapid delivery of study information to interested investigators nationwide, with access to up-to-date knowledge from dedicated research staff embedded in the NHS.



Commercial costing templates

Generate a single, study-wide cost that provides a clear starting point for commercial study cost negotiations in the NHS.

They bring transparency and consistency to costing, encouraging swift agreement and reducing protracted negotiations. The template format also supports the efforts of Trusts and companies to justify changes to recommended costs.

Completed costing templates are uploaded into CSP, helping your study to achieve the CRN's 40 day permission target.

Free online and personal training and support is available.



NIHR Coordinated System for gaining NHS Permission (CSP)

Standardises and streamlines the process of gaining NHS Permission for clinical research studies in England to enable your study to meet our 40 day NHS Permission target. CSP also:

- Provides a single point of access, via the Integrated Research Application System (IRAS) for investigators applying for NHS permission
- Defines and carries out checks that only need to be done once, and those that are required for each NHS location/organisation
- Has dedicated staff to assist with applications and help progress your study towards NHS Permission.



Model agreements

Model Clinical Trial or Investigation Agreements speed up contracting between commercial companies, Contract Research Organisations and NHS Organisations.

They are designed to be used "off-theshelf", without modification to the terms and are available for a range of research scenarios for NHS studies throughout the UK.

Model agreements are uploaded into CSP and if unmodified, help your study to achieve the CRN's 40 day permission target.

The Network manages a central "modifications check" and can mediate negotiations with NHS organizations if minor alterations to the standard wording are required.



Study management

Access to NHS site recruitment data and the support of our dedicated, GCP-trained research staff results in a targeted, intelligence driven recruitment strategy. The earlier you engage with this support, the more effective it can be.

Network support increases your options when addressing recruitment challenges. We plug you into NHS patient pathways, in primary and secondary care, and provide access to referrals from across sites and sectors.

Strong relationships with local clinicians and a deep understanding of local systems means you benefit from open communication channels and targeted, face-to-face trouble-shooting.

Standardized reporting procedures underpin a consistent culture for performance management throughout the Network. Our shared reporting methods, including RAG reports, allow a simple study and site level overview of performance and a Lead Network provides a single contact to manage multiple sites.

CRN supported requirement

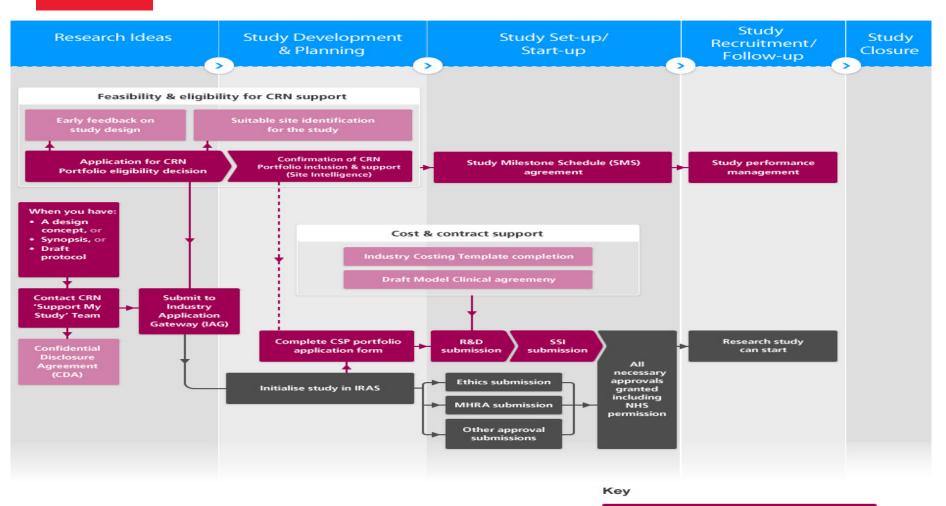
Outside network support

CRN optional service or requirement

NOCRI

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NIHR CRN Study start-up route map



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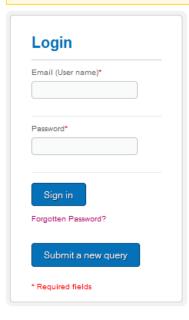
How do I submit my study for support?





Information

Please note that the system may be unavailable during scheduled maintenance periods. These are Mondays and Wednesdays, 16.00-16.30 (GMT), and Fridays 15.30-16.00 (GMT). If you are logged in when the maintenance starts, the system will log you out and any unsaved data will be lost. Please be sure to save your submissions regularly.



Name*	
Email (User name)*	Email confirmation*
Company* 🕡	Telephone*
Prefered method of contact*	•
Tagree to the Terms and Co	onditions
Register	

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Case Studies





FUTURE PLAYERS

- MRC
 - Molecular Pathology 'Nodes'
 - Regional centres
 - Discovery, Evaluation & Adoption!
 - Competition Open

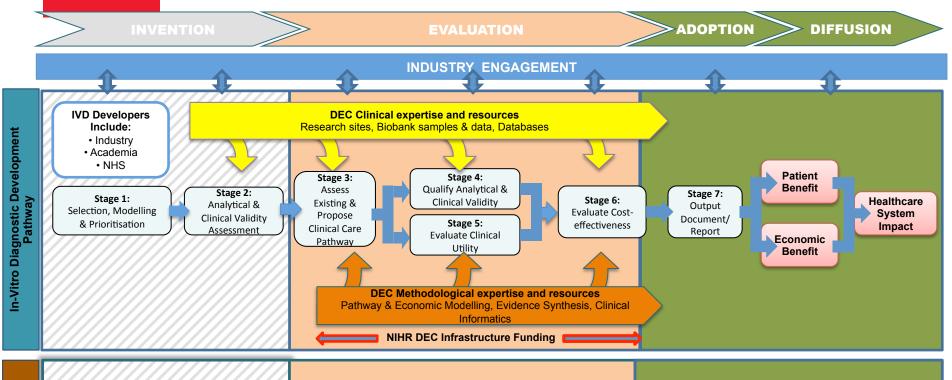
- Innovate UK (TSB)
 - Precision Medicine Catapult
 - Still to be announced formally

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DEC *IN-VITRO* DIAGNOSTIC (IVD) DEVELOPMENT PATHWAY

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IVD Development Pathway - Stakeholders



- Patient Groups & PublicNIHR Infrastructure
- •DH Academic Health Science Centres (AHSCs)
 - Trade AssociationsIVD Developers
 - NIHR Horizon Scanning Centre
 - NICE Scientific Advice

Patient Groups & Public
 NIHR Infrastructure

Medicines & Healthears products Regulations

•Medicines & Healthcare products Regulatory Agency (MHRA)

Notified Bodies

•NHS Providers of Pathology Services

•Clinical Pathology Accreditation (UK) (CPA)

•NHS commissioners

NIHR Horizon Scanning Centre

NICE Diagnostic Assessment Programme

Contributors to Discussion(s)

Patient Groups & Public
NICE Diagnostics Assessment
Programme
NHS Providers of Pathology
Services
NHS Trusts
NHS commissioners

Academic Health Science
 Networks (AHSNs)
 NIHR CLARHCs

NIHR Horizon Scanning Centre

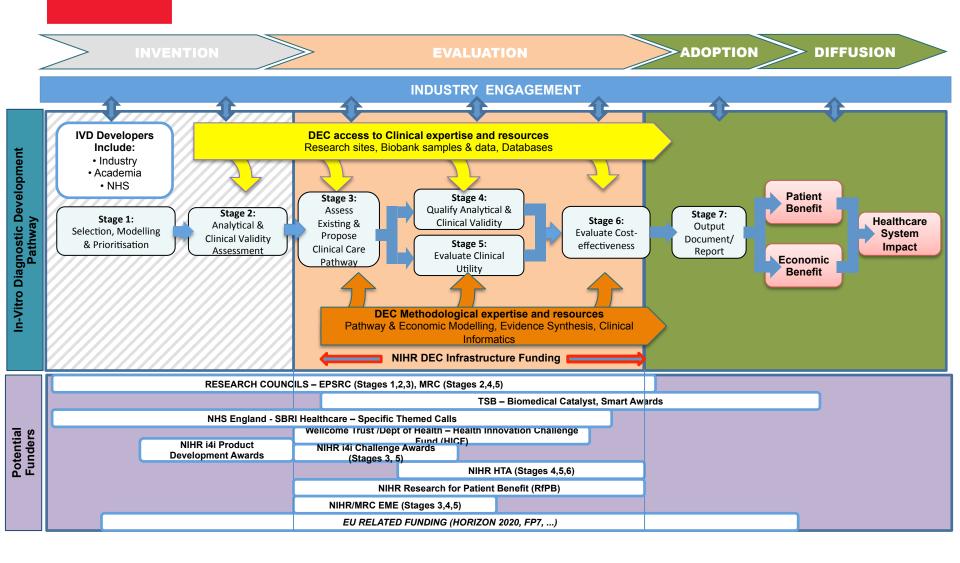
Recipients of Output

•NHS Trusts
•NHS England
•NHS commissioners

•NHS Supply Chain
•Academic Health Science
Networks (AHSNs)

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IVD Development Pathway - Funding



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To work with the Partnerships or any of the NIHR infrastructure contact the team at:

nocri@nihr.ac.uk

www.nocri.nihr.ac.uk