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MediWales & BIVDA: Diagnostics Industry Update
NIHR: generating clinical evidence

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NIHR Office for Clinical Research Infrastructure (NOCRI)

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Overview – What to expect

- NIHR INFRASTRUCTURE TO SUPPORT RESEARCH
- MODELS FOR EFFECTIVE PARTNERSHIP
- NOCRI – SUPPORTING COLLABORATION
- NEW DEVELOPMENTS

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NIHR INFRASTRUCTURE TO SUPPORT RESEARCH

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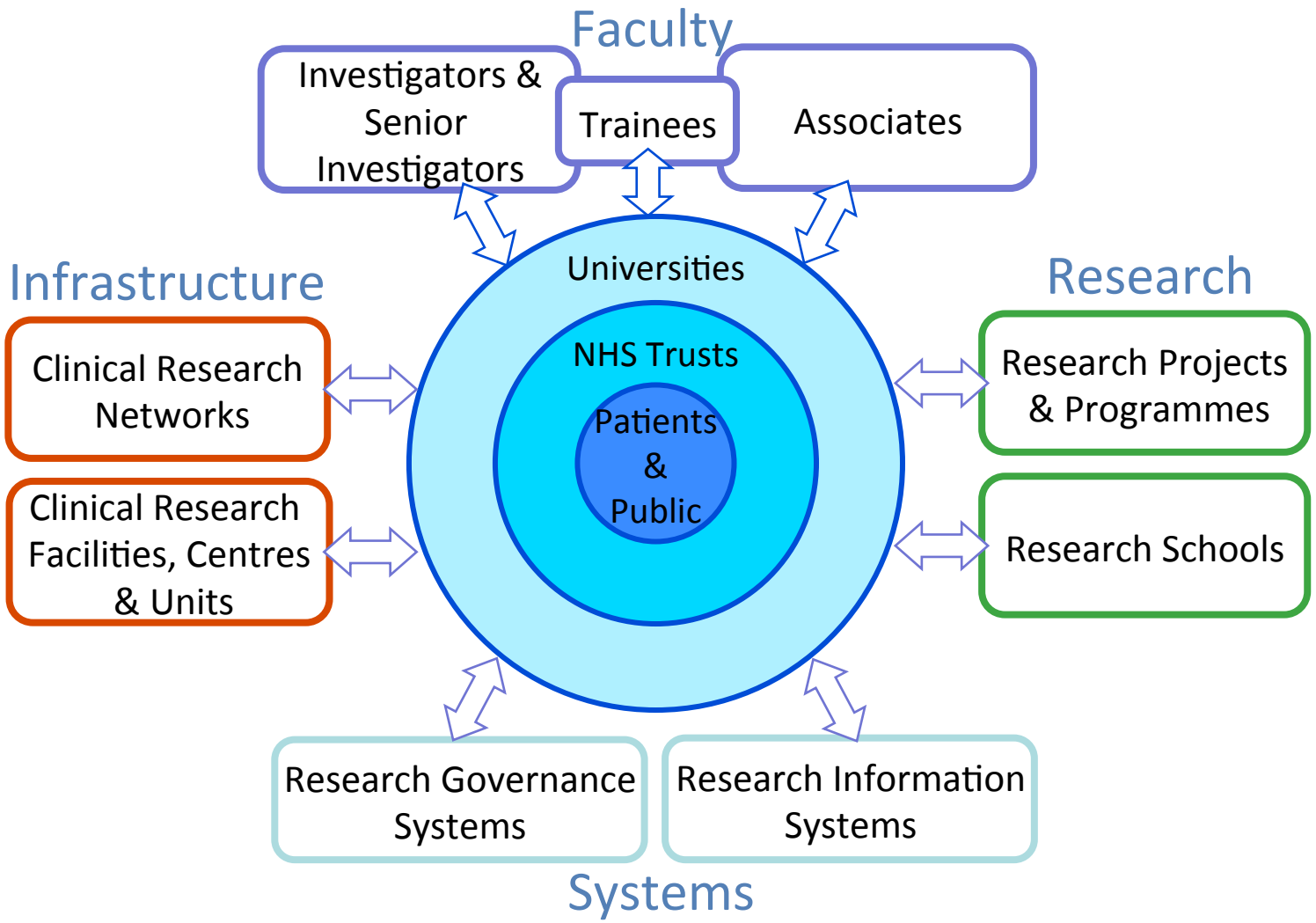
The NIHR Health Research System



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NIHR Research Infrastructure

Innovation → Evaluation → Adoption

Early-phase clinical research

- NIHR Biomedical Research Centres
- NIHR Biomedical Research Units
- NIHR Clinical Research Facilities
- Experimental Cancer Medicine Centres
- Healthcare Technology Cooperatives

Late-phase clinical research

- Diagnostic Evidence Cooperatives
- NIHR Clinical Research Network
- NIHR Collaborations for Leadership in Applied Health Research & Care

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

NIHR-Supported Facilities

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NIHR Biomedical Research Units
Newcastle – dementia
Leeds – musculoskeletal
Central Manchester – musculoskeletal
Liverpool – gastrointestinal
Nottingham – hearing/respiratory/gastrointestinal
Leicester – cardiovascular/respiratory/nutrition
Birmingham – gastrointestinal
Bristol – cardiovascular/nutrition
Oxford – musculoskeletal
Southampton – respiratory
London Imperial – cardiovascular/respiratory
Barts – cardiovascular
UCL – dementia
South London and Maudsley - dementia

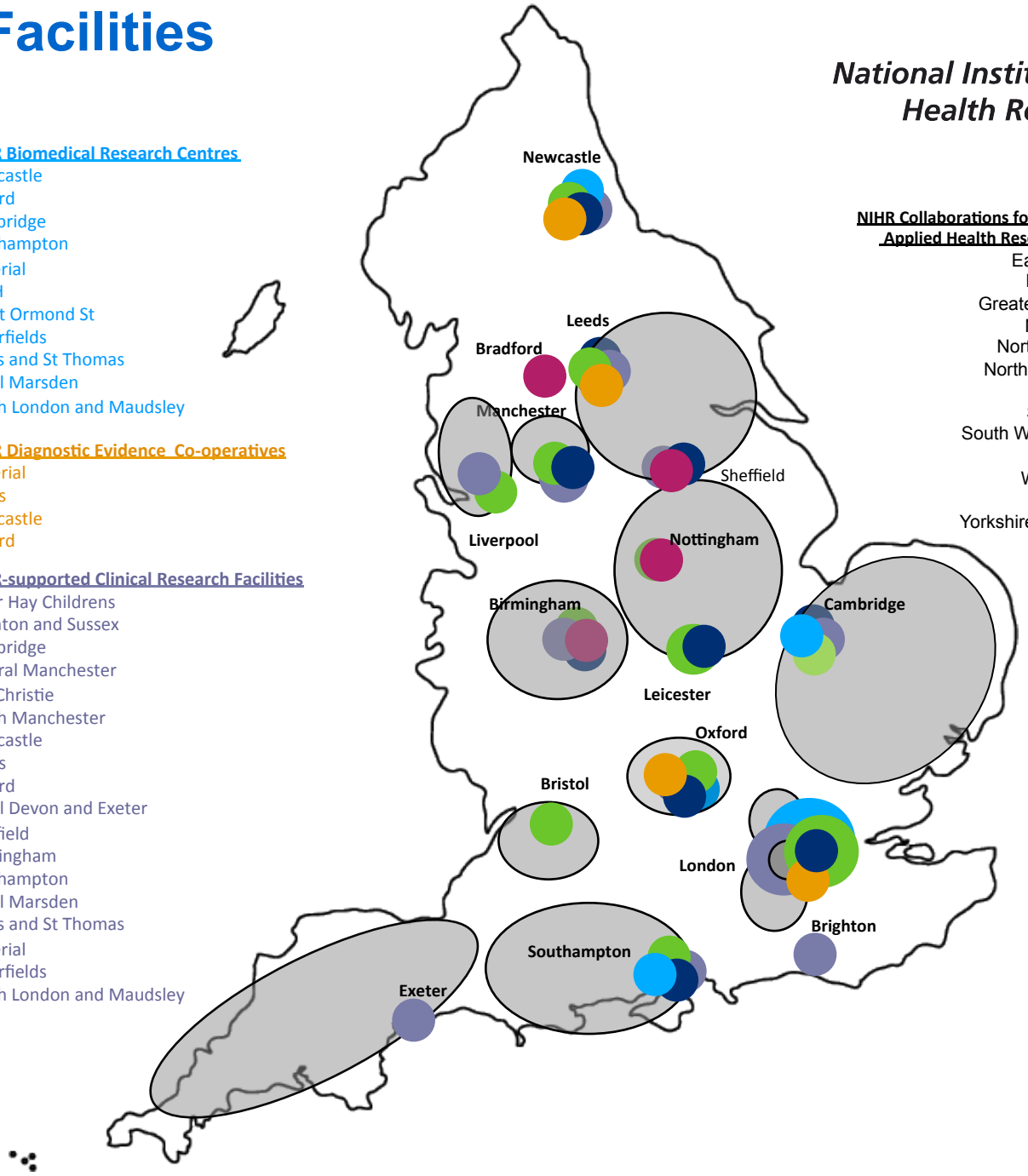
NIHR Healthcare Technology Co-operatives
Birmingham
Bradford
Leeds
Nottingham
Sheffield
Barts
Cambridge
Guy's & St Thomas'

NIHR Experimental Cancer Medicine Centres
Birmingham
Cambridge
Cardiff
Leeds
Leicester
Barts/ Brighton
ICR
Imperial
King's College London
UCL
Manchester
Newcastle
Oxford
Sheffield
Southampton

NIHR Biomedical Research Centres
Newcastle
Oxford
Cambridge
Southampton
Imperial
UCLH
Great Ormond St
Moorfields
Guy's and St Thomas
Royal Marsden
South London and Maudsley

NIHR Diagnostic Evidence Co-operatives
Imperial
Leeds
Newcastle
Oxford

NIHR-supported Clinical Research Facilities
Alder Hay Childrens
Brighton and Sussex
Cambridge
Central Manchester
The Christie
South Manchester
Newcastle
Leeds
Oxford
Royal Devon and Exeter
Sheffield
Birmingham
Southampton
Royal Marsden
Guy's and St Thomas
Imperial
Moorfields
South London and Maudsley
UCL



NIHR Collaborations for Leadership in Applied Health Research and Care
East of England
East Midlands
Greater Manchester
North Thames
North West Coast
North West London
Oxford
South London
South West Peninsula
West
West Midlands
Wessex
Yorkshire and Humber

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NIHR CLINICAL RESEARCH NETWORK

- The NIHR CRN Structure:
  - ONE Network
  - Operating across 15 areas
  - Each covering all study delivery in all therapy areas

- Boundaries align with AHSN areas, but roles are different
  - CRN – research study delivery
  - AHSN – dissemination of innovation

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Clinical Research Network support along the study lifecycle

Draft protocol → Identify site / Investigators → Site / investigator feasibility → Site selection → Regulatory submissions (CA/IRB) → Application for hospital permission → Agree cost and contract with sites → All necessary approvals granted → Site initiation → First patient in → Last patient out

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:

1. Provides a single point of access, via the Integrated Research Application System (IRAS) for investigators applying for NHS permission
2. Defines and carries out checks that only need to be done once, and those that are required for each NHS location/organisation
3. 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-the-shelf", 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.

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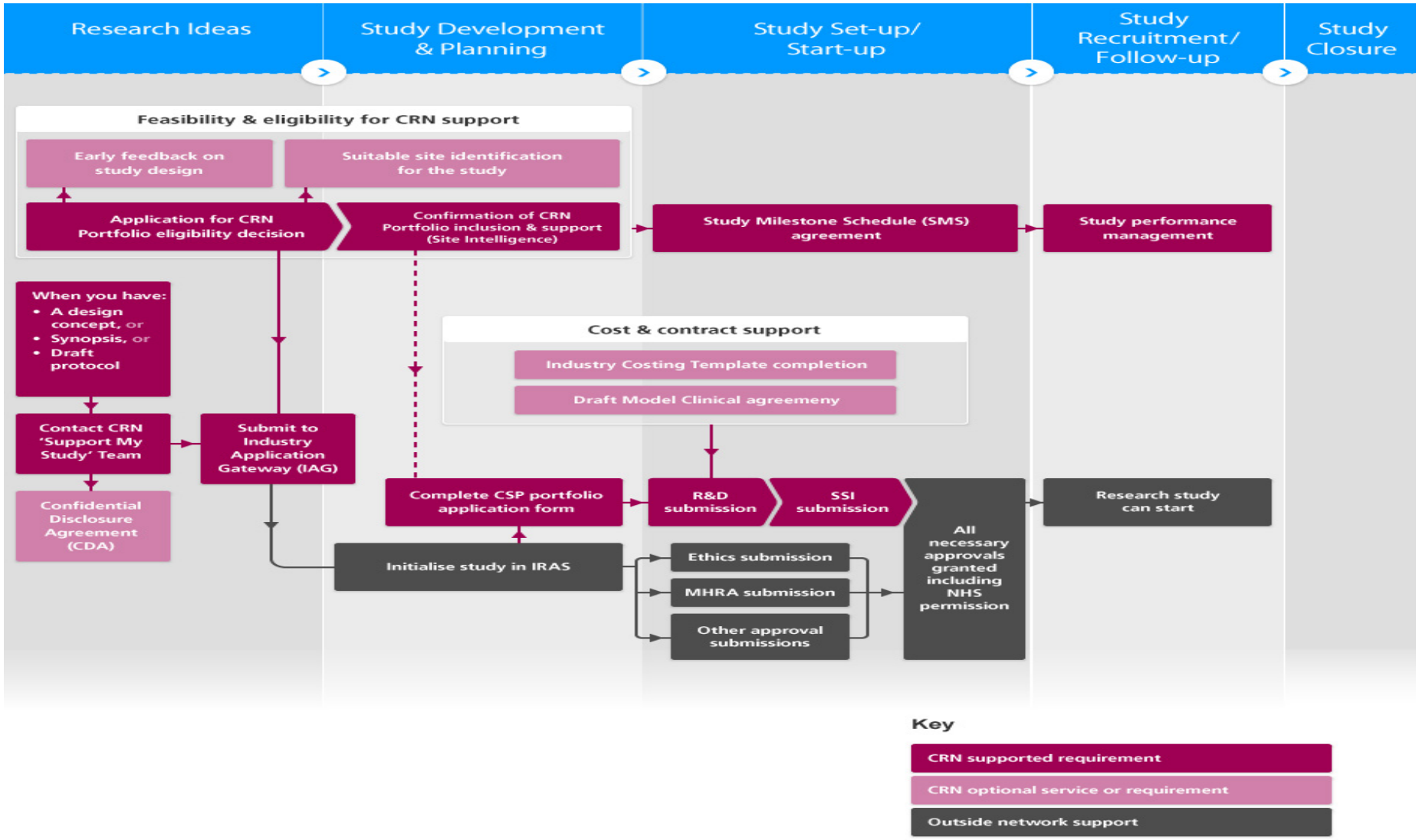
NIHR CRN Study start-up route map



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MODELS FOR EFFECTIVE PARTNERSHIP
Medical Devices and Diagnostics

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

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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 clinical validity, clinical utility, cost effectiveness and care pathway benefits 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

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NIHR Diagnostics Evidence Co-operatives (DECs)

Leeds Teaching Hospitals NHS Trust
Liver diseases, Musculoskeletal diseases, Renal diseases.

Newcastle upon Tyne NHS Foundation Trust
Cancer, Cardiovascular disease and stroke, Genetics, Infection, Liver disease, Musculoskeletal disease, Respiratory, Transplantation.

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.

Imperial College Healthcare NHS Trust
Cancer, Cardiovascular diseases, Gut health, Infectious diseases, Metabolic medicine, Primary Care, Respiratory diseases.

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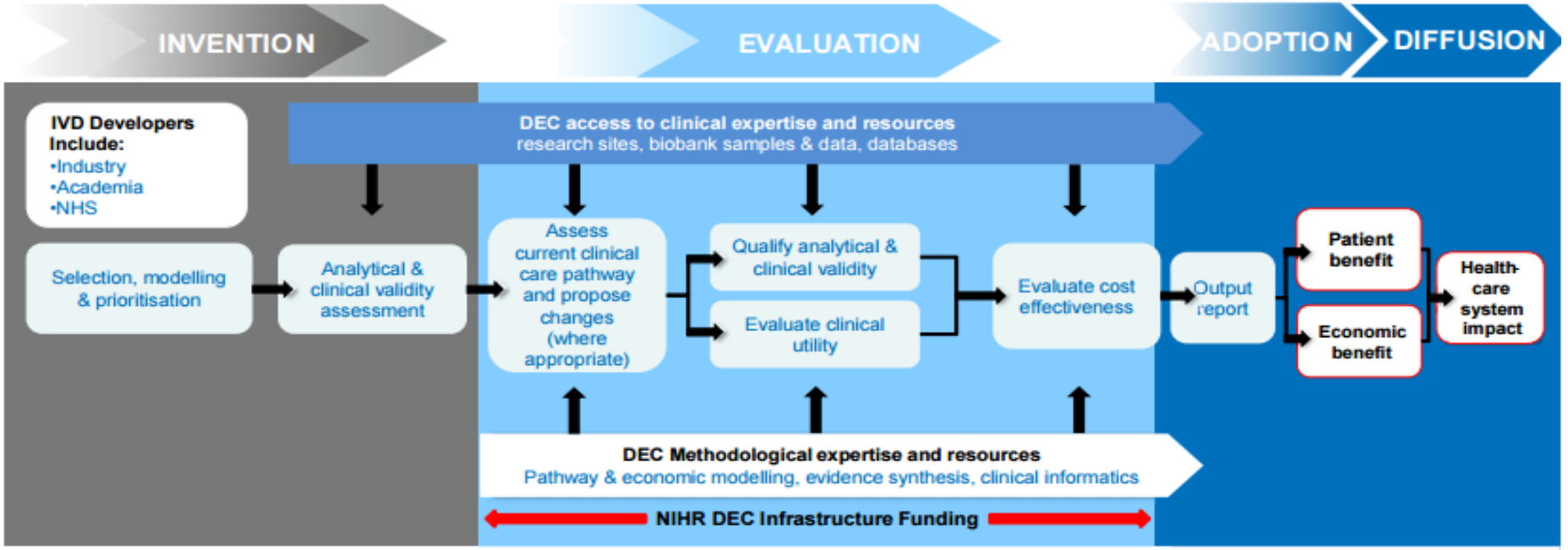
The NIHR DEC *In Vitro* Diagnostics Evidence Generation Pathway



INVENTION

The initial step is where early decisions on potential new IVDs are taken.

At this stage the following will be considered:

- what the IVD test measures
- which patient groups it could benefit
- whether it will provide additional benefit(s) over existing practices.

The analytical and clinical validity should also be confirmed, providing an indication on the sensitivity and specificity and Reciever Operating Characteristic (ROC) performance of the IVD.

EVALUATION

To get the true value of the IVD it is important to assess where it fits into the **clinical care pathway** and to generate appropriate data to assess the **clinical utility** and **cost-effectiveness** of the IVD.

The NIHR DECs include **clinical expertise, pathology expertise** and **health economic expertise**, all of which are important disciplines in bringing together the true benefit of the IVD.

All of the work in the evaluation phase will help development of **new methodologies for IVD evaluations**, with a particular focus on the evidence requirements for adoption of IVDs into the NHS.

ADOPTION / DIFFUSION

NIHR DEC funding does not support adoption of technology. DEC-generated evidence can influence decisions on adoption and implementation of IVDs. Outputs are designed to meet the needs of relevant stakeholders:

- clinical utility of the IVD will give clinicians confidence to use the test
- health economic data will provide NHS procurement and commissioning staff with information to inform decision making based on healthcare systems benefits
- patient pathway modelling will allow efficient use of resources in healthcare settings.

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NOCRI – SUPPORTING COLLABORATION

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Initial Company Engagement

Industry Engagement Form/Questionnaire – Non-Confidential Information

Meeting/Teleconference between Company and NOCRI Industry Team

5-7 days

NOCRI Industry Team & Infrastructure Team gain Expressions of Interest from NIHR Investigators/Academics/Clinicians

7-14 days

Meeting/Teleconference between Company and Investigators/Academics/ Clinicians

Diary Dependent
Aim 14-21 days

Industry/NIHR Collaborative Project

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NOCRI – CASE STUDIES

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Alzheimer's Plasma Biomarker Study

- The NIHR Maudsley Biomedical Research Centre (BRC) for Mental Health, in collaboration with Proteome Sciences and Merck Millipore, successfully concluded a **1,000 sample Alzheimer's disease biomarker validation study.**
- Preliminary data suggest that blood proteins biomarkers **could help to identify dementia in preclinical phase**, **or to predict progression from mild cognitive impairment to dementia.**
- The NIHR, Merck Millipore and Proteome Sciences have tested biomarker panels of between 11 and 16 proteins in a very large replication study. These biomarkers have significant potential **to form the basis of a series of simple blood tests for the diagnosis and management of Alzheimer's**.

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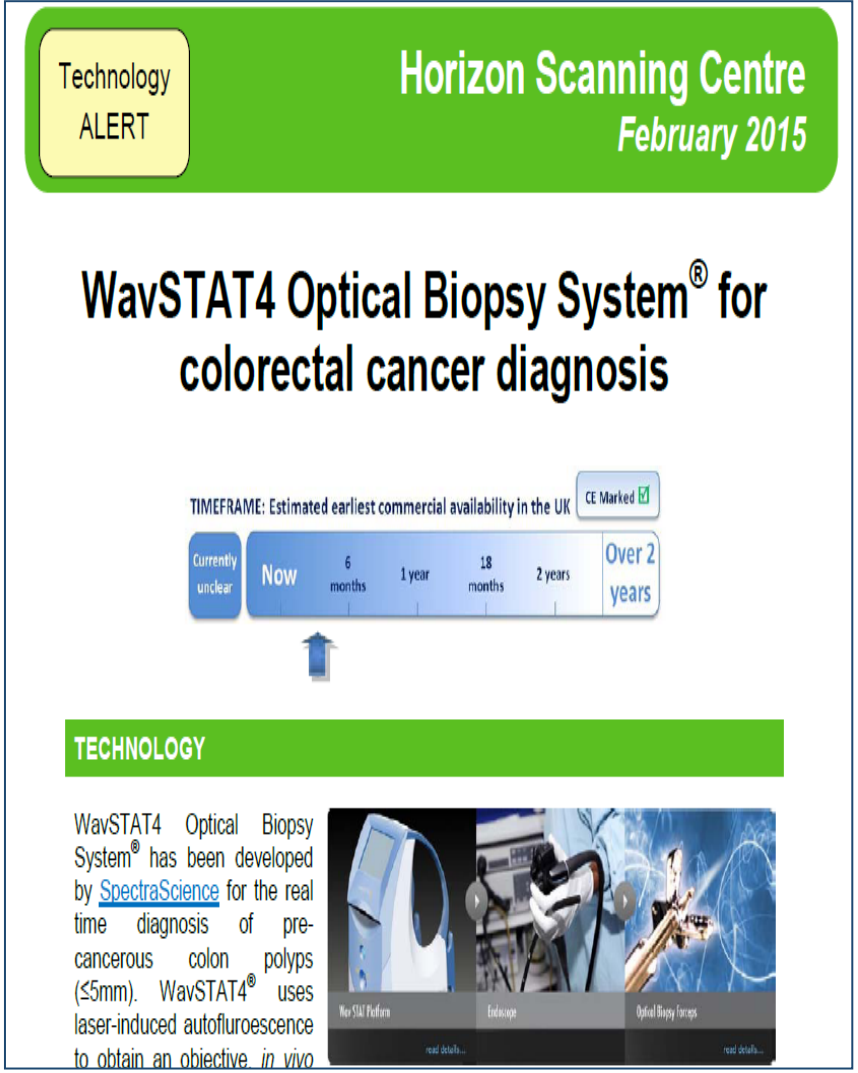
WavSAT4 Case Study

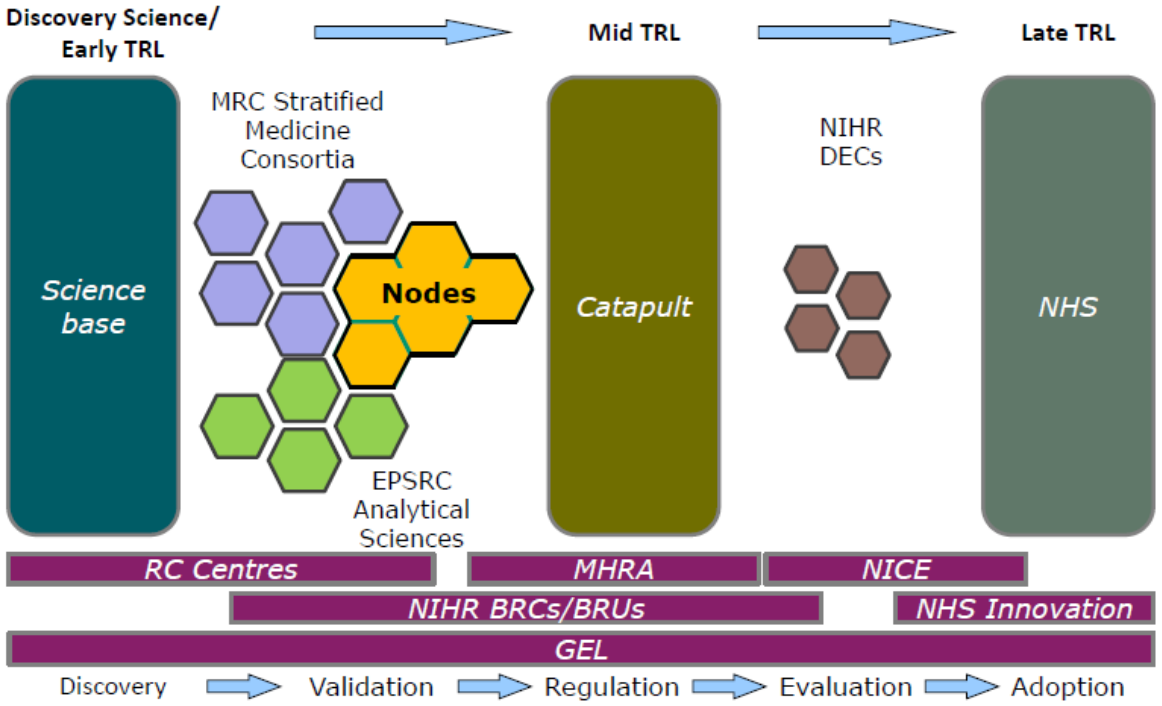
- NOCRI facilitated initial discussions between **Spectra Science and the NIHR Colorectal Healthcare Technology Cooperative (HTC)** in April 2014.
- WavSTAT® has been developed through the National Institute for Health Research (NIHR) Colorectal Therapies Healthcare Technology Co-operative (HTC).
- **NIHR Horizon Scanning Report** produced to highlight the technology to NHS Commissioners and Procurement ahead of formal launch of the product (February 2015).



NEW DEVELOPMENTS

New developments – MRC Molecular Pathology Nodes

The nodes will work as a network and complement partner investments

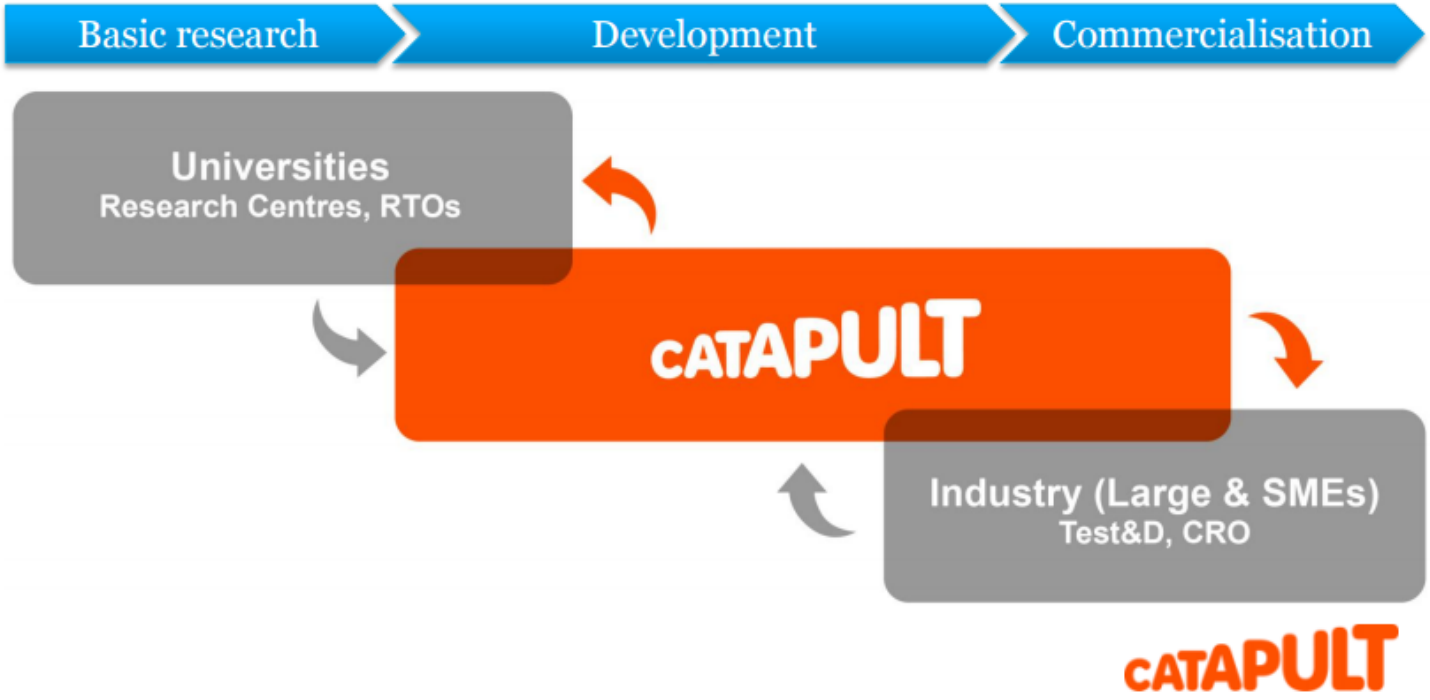


Precision Medicine Catapult

What are Catapults?

Technology and Innovation Centres

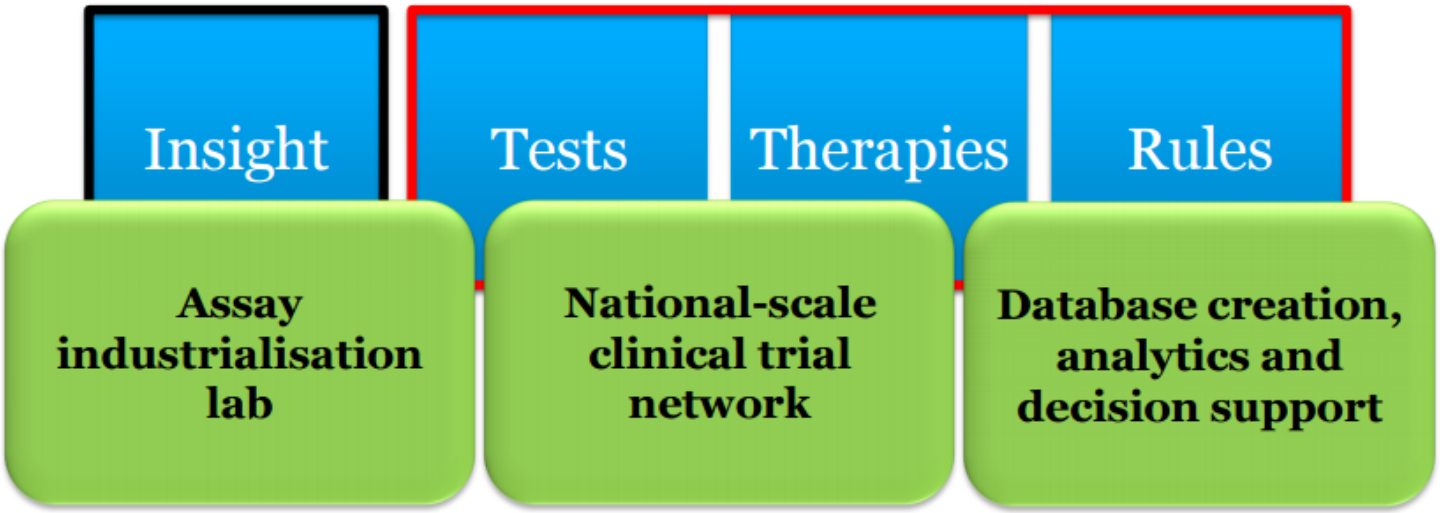
- Tackling the translational gap, bridging research & market
- Catalysing development



Precision Medicine Catapult

Why a Catapult for Precision Medicine?

- **Precision medicine is simple to understand**
  - but complex to execute



CATAPULT

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To work with the NIHR infrastructure contact the team at:

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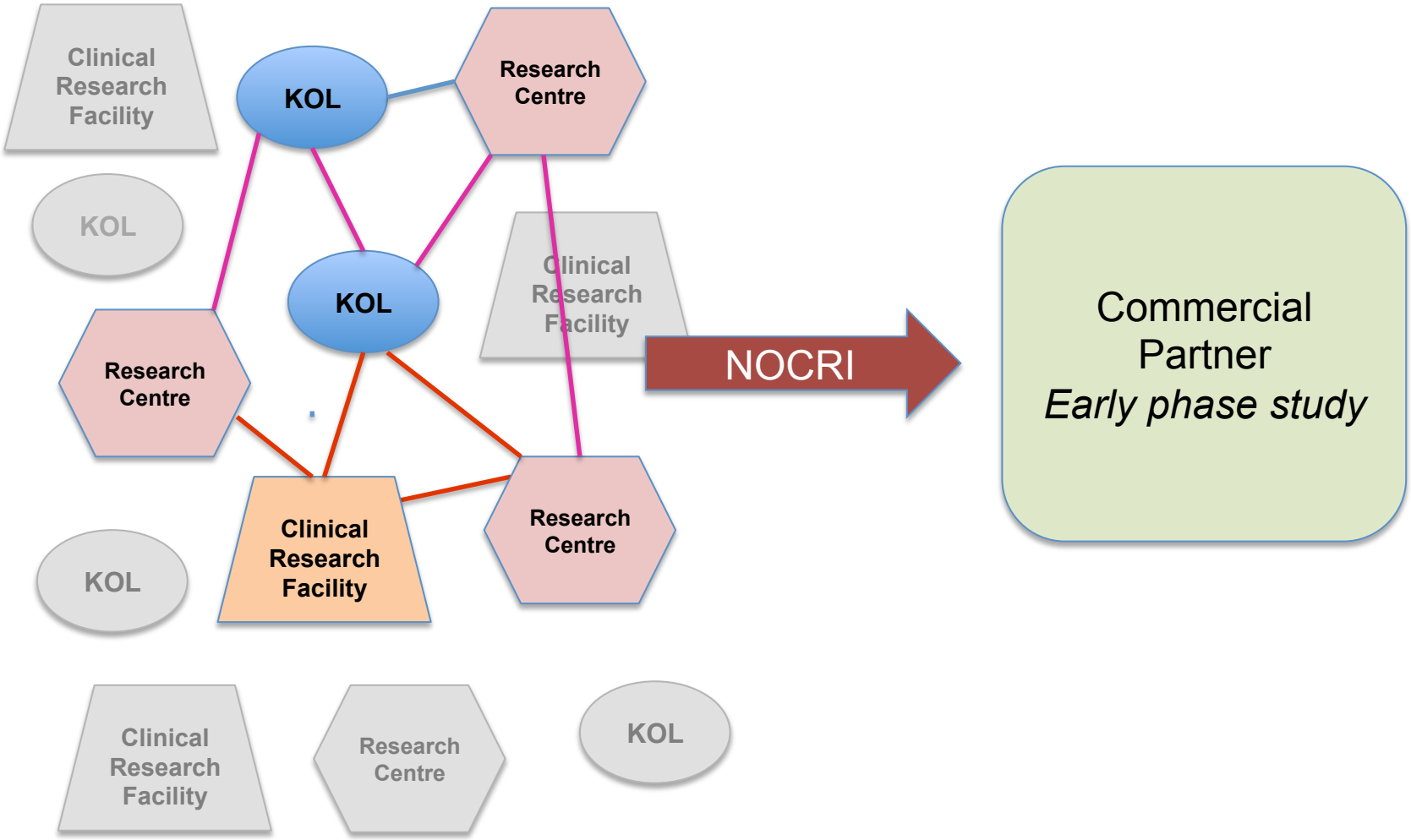
Supporting collaboration with UK research infrastructure and experts



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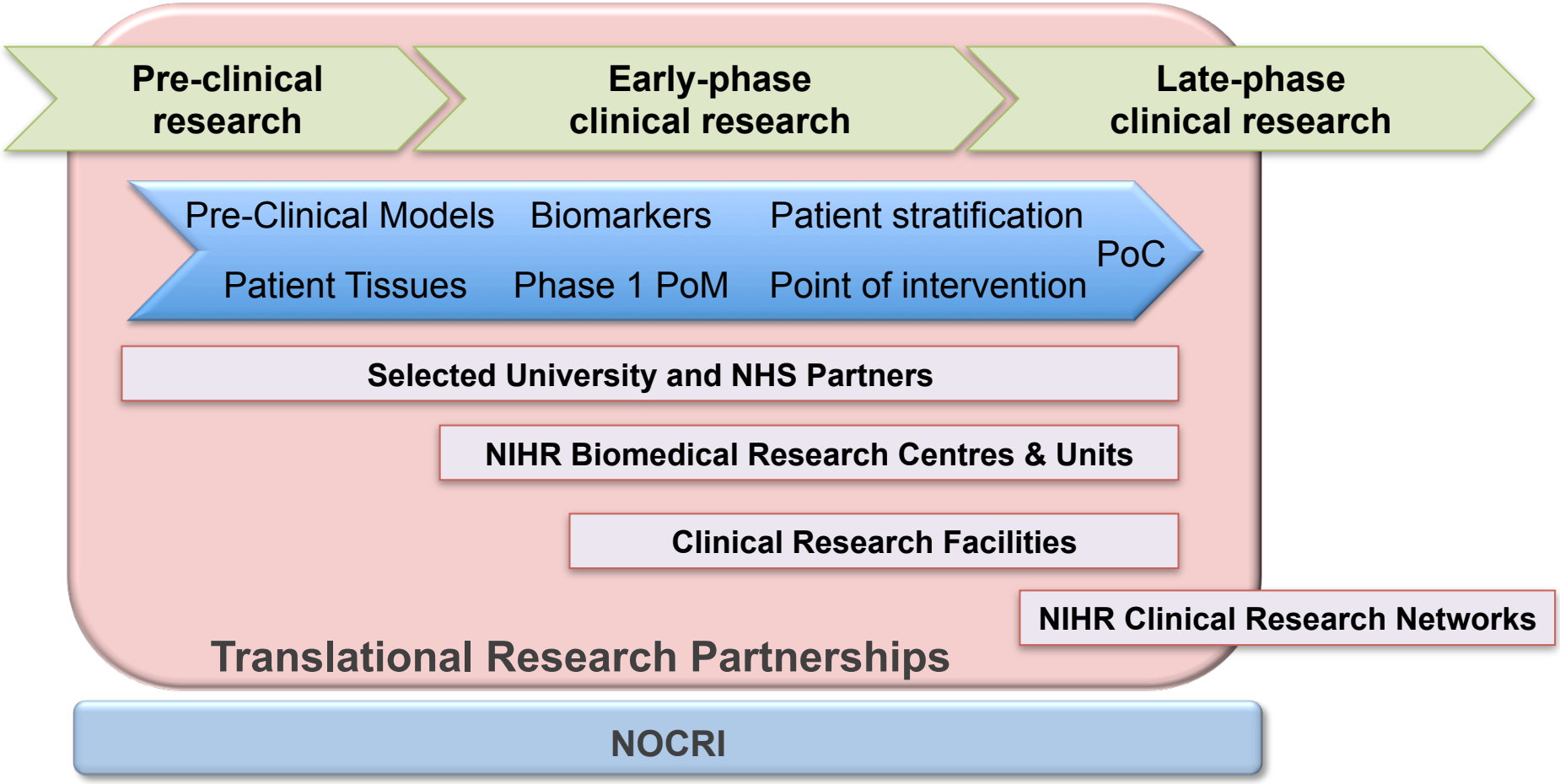
NIHR Translational Research Partnerships (TRPs)



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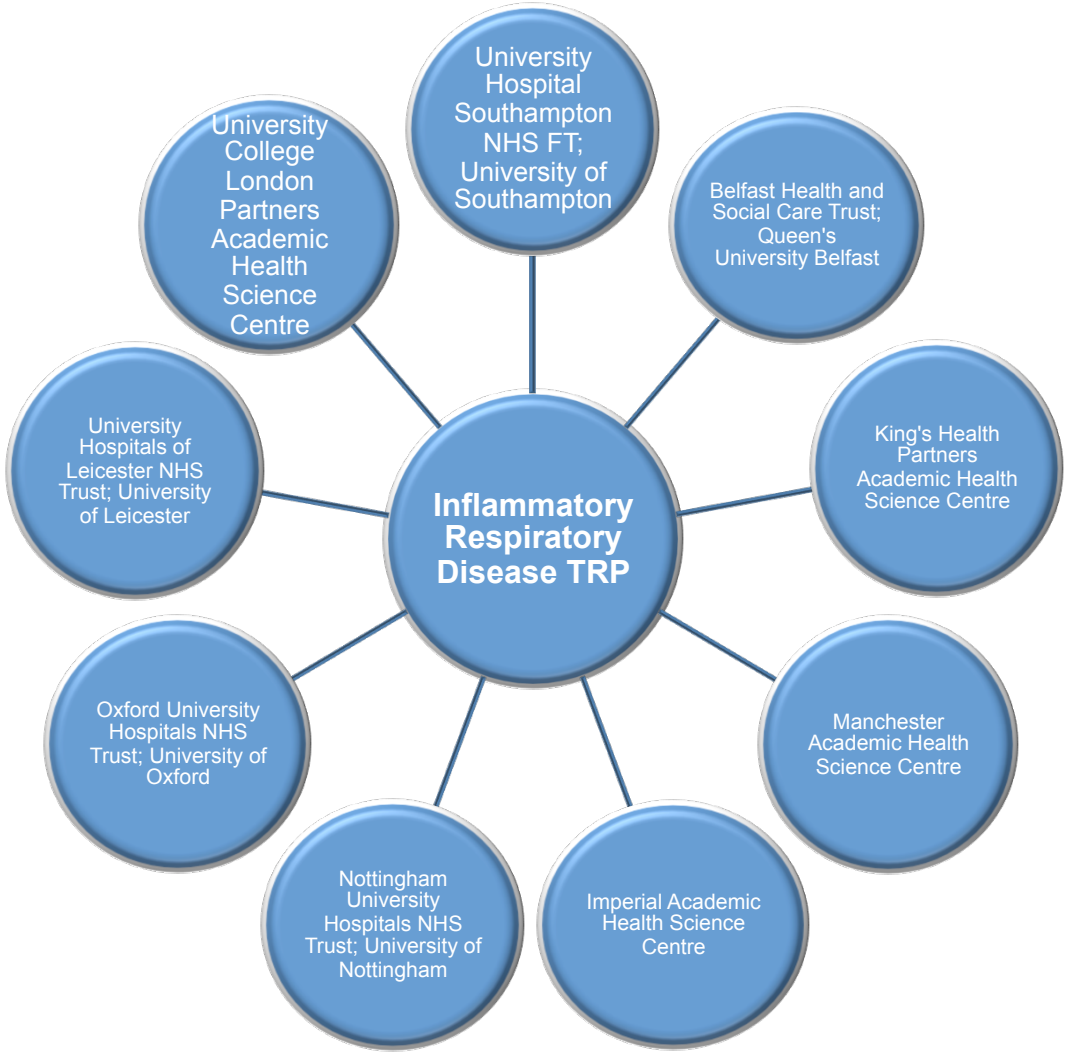
Inflammatory Respiratory Disease TRP

Inflammatory Respiratory Disease Expertise

- Acute lung injury
- Airway inflammation
- Allergy
- Asthma
- COPD
- Cystic Fibrosis
- Idiopathic Pulmonary Fibrosis
- Respiratory infection



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Biomedical Research Centres (BRCs)

£800million Government investment to support NIHR Centres and Units - the largest ever commitment to early stage health research

- Newcastle upon Tyne
- Cambridge
- Imperial
- University College
- Great Ormond St*
- Moorfields*
- Guy's and St Thomas'
- Oxford
- Marsden*
- Maudsley*
- Southampton

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Biomedical Research Units (BRUs)

Leeds – Musculoskeletal

Manchester – Musculoskeletal

Liverpool – Gastrointestinal

Birmingham – Gastrointestinal

Oxford – Musculoskeletal

Bristol – Cardiovascular, Nutrition, Diet, Lifestyle

Maudsley – **Dementia**

Southampton – Respiratory

Newcastle upon Tyne - Dementia

Nottingham – Hearing, Gastrointestinal

Leicester – **Cardiovascular**, **Respiratory**, **Nutrition, Diet, Lifestyle**

Cambridge – Dementia

University College – **Dementia**

Imperial – **Cardiovascular**, **Respiratory**

Barts & London – **Cardiovascular**

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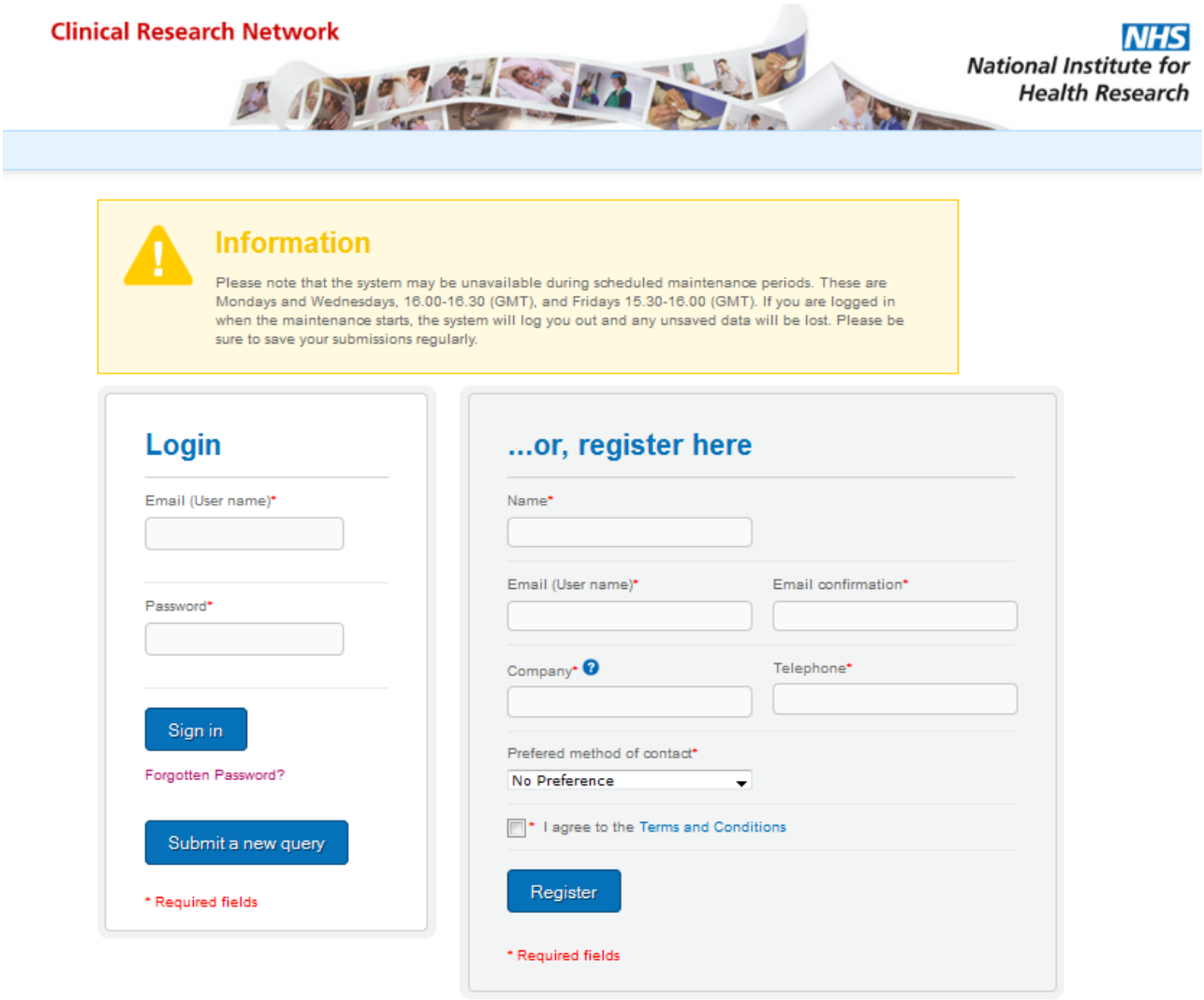
How do I submit my study for support?



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How it works for industry

- Single national "way in" to access the Network service

- www.supportmystudynihr.ac.uk
  - Email: supportmystudy@nihr.ac.uk
  - Phone: +44(0)113 34 34 555

- Triage out to therapy-area specialists – retaining all the specific expertise previously offered by the Network, but through a single easy route

- **NEW**: Industry Operations Manager in each of the 15 Local Clinical Research Networks
  - Provides local single point of contact once study is in play
  - Can escalate any delivery issues

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

NIHR Diagnostics Evidence Co-operatives (DECs)

- Aims of the DECs

  – Enable collaboration between clinicians and other healthcare professionals, patients and the **IVD industry**, 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.

Collaborations for Leadership in Applied Health Research and Care (CLARHCs)

- **Aims of the CLARHCs:**
  - Conduct applied health research and translating research findings into improved outcomes for patients;
  - Create a distributed model for the conduct and application of applied health research linking researchers with practitioners across the health community covered by the Collaboration;
  - Create and embed approaches to research and its dissemination that are specifically designed to take account of the way that health care is increasingly delivered across sectors and across a wide geographical area;
  - Increase country's capacity to conduct high quality applied health research focused on the needs of patients, and particularly research targeted at chronic disease and public health interventions;
  - Improve patient outcomes across the geographic area covered by the Collaboration.

The central role of NIHR research in the innovation pathway

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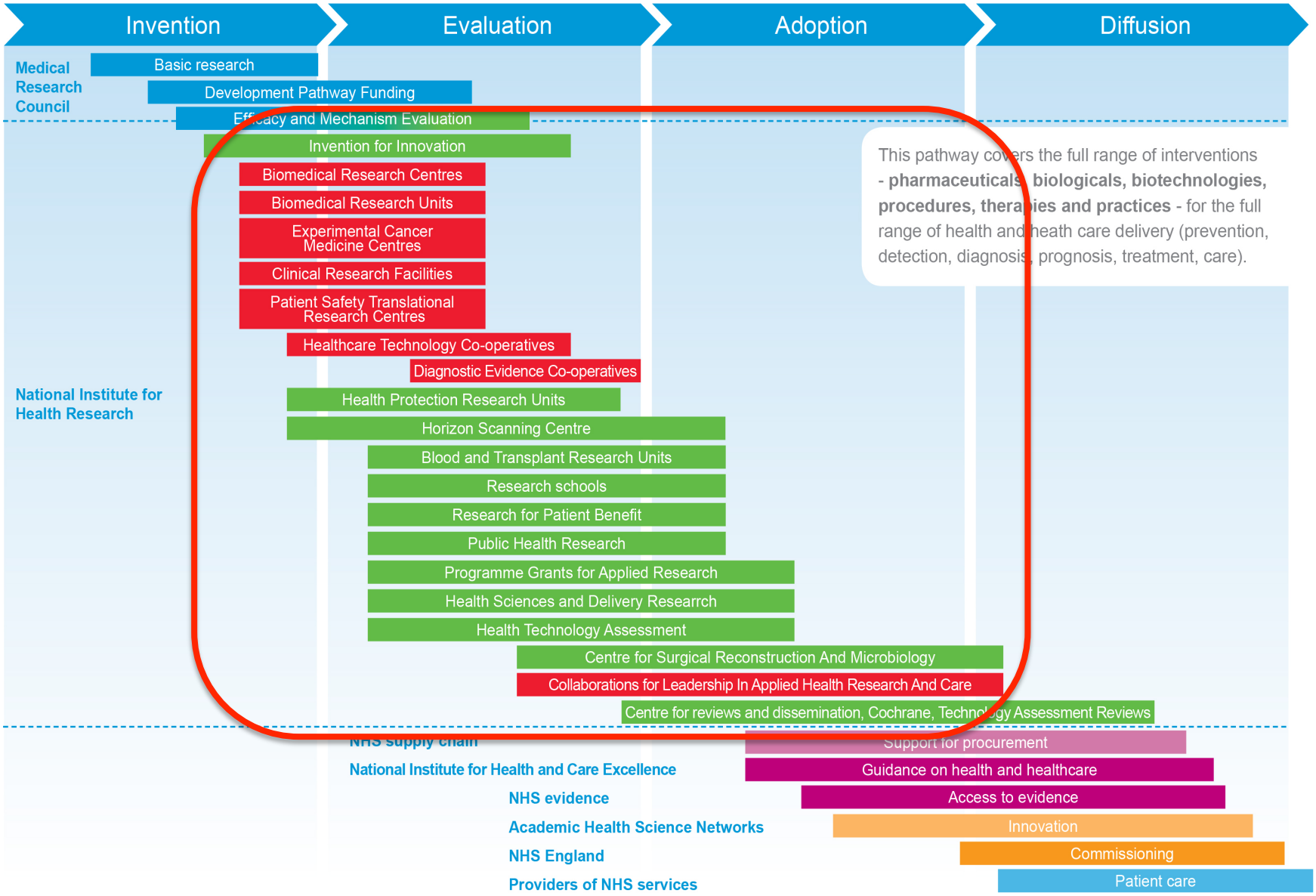

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Collaborations for Leadership in Applied Health Research and Care (CLARHCs)

NIHR CLARHC Greater Manchester – Salford Royal NHS FT
Patient-centred care, Community services & primary care.

NIHR CLARHC North West Coast – NHS Liverpool Clinical Commissioning Group
Public health, Mental health, long term conditions, personalised healthcare.

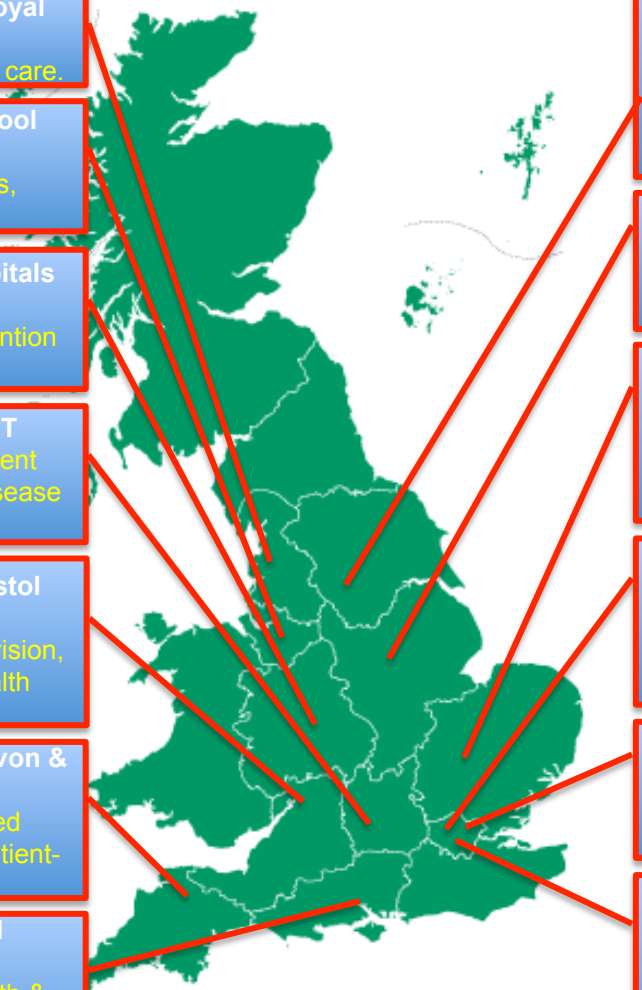
NIHR CLARHC West Midlands – University Hospitals Birmingham NHS FT
Maternity & child health, Youth mental health, Prevention & detection of illness, Chronic diseases.

NIHR CLARHC Oxford - Oxford Health NHS FT
Mental health & dementia, Health behaviours, Patient experience & patient reported outcomes, Chronic disease self-management.

NIHR CLARHC West - University Hospitals Bristol NHS FT
Chronic diseases (e.g. Dementia, musculoskeletal, vision, kidney, pain, depression, Parkinson's), Public health intervention.

NIHR CLARHC South West Peninsula – Royal Devon & Exeter NHS FT
Mental health & dementia, Diagnostics & stratified medicine, Healthy people, Healthy environments, patient-centred care.

NIHR CLARHC Wessex – University Hospital Southampton NHS FT
Respiratory health, Ageing & dementia, Public health & primary care, Chronic liver disease, long term conditions, organisational behaviour.



NIHR CLARHC Yorkshire & Humber – Sheffield Teaching Hospitals NHS FT
Healthy children & families, Public health & inequalities, Telehealth & care technologies, Older people, long term conditions, Mental health.

NIHR CLARHC East Midlands – Nottinghamshire Healthcare NHS T
Chronic disease, Older people, Stroke, Mental health.

NIHR CLARHC East – Cambridgeshire & Peterborough NHS FT
Dementia, frailty & end of life care, Enduring disabilities & disadvantage, Patient safety, Patient & public involvement.

NIHR CLARHC North West London – Chelsea & Westminster Hospital NHS FT
Breathlessness, Frailty, Mental health, Public health.

NIHR CLARHC North Thames – Bart's Health NHS T
Mental health, Child & adolescent health, long term conditions.

NIHR CLARHC South London – King's College Hospitals NHS FT
Alcohol, Diabetes, Infection, Palliative & end of life care, Psychosis public health, Stroke, Women's health, Patient & public involvement.

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Scale of opportunity for industry

Access *via a single point of entry* to world class science in world leading institutions and patients across the NHS

NOCRI supports industry through:

- **sign-posting**
- **introductions**
- **establishing collaborations**
- **managing relationships**