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Funding for diagnostic test development and opportunities to collaborate with academia.

Mr Ravi Chana
NIHR Office for Clinical Research Infrastructure (NOCRI)

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Overview

- RESEARCH FUNDING
- NIHR INFRASTRUCTURE TO SUPPORT EVIDENCE GENERATION
- MODELS FOR EFFECTIVE PARTNERSHIP

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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
  - ...

The central role of NIHR research in the innovation pathway

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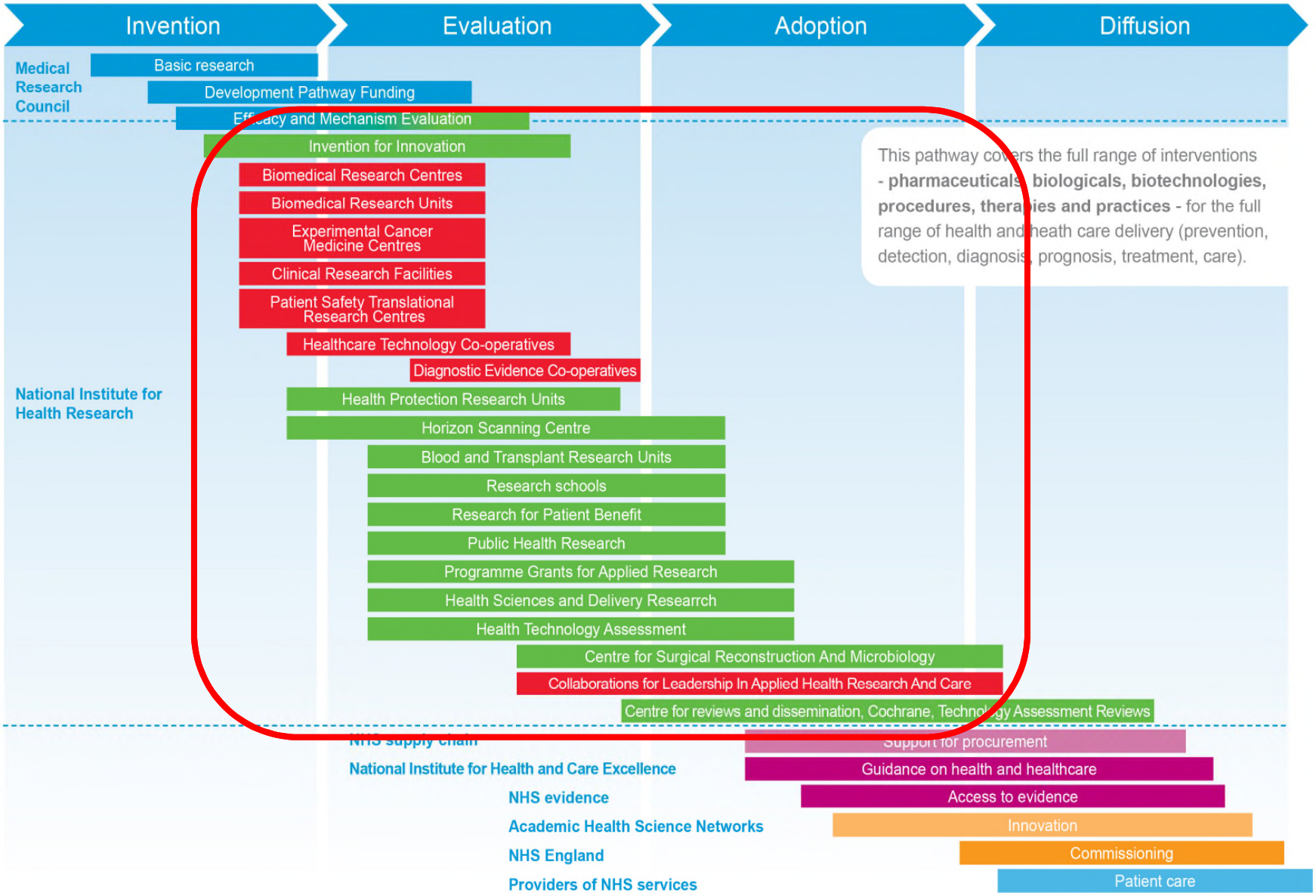

NIHR Research Programmes

- 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

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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
- Systematic Reviews

Research-Led Research

- Invention for Innovation (i4i) – Product Development Awards
- 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

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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

	Research programme								
Broad research area	EME	HS&DR	HTA	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	×	✓	×	×	✓	✓	✓	×	✓

	Research programme								
	EME	HS&DR	HTA	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

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

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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

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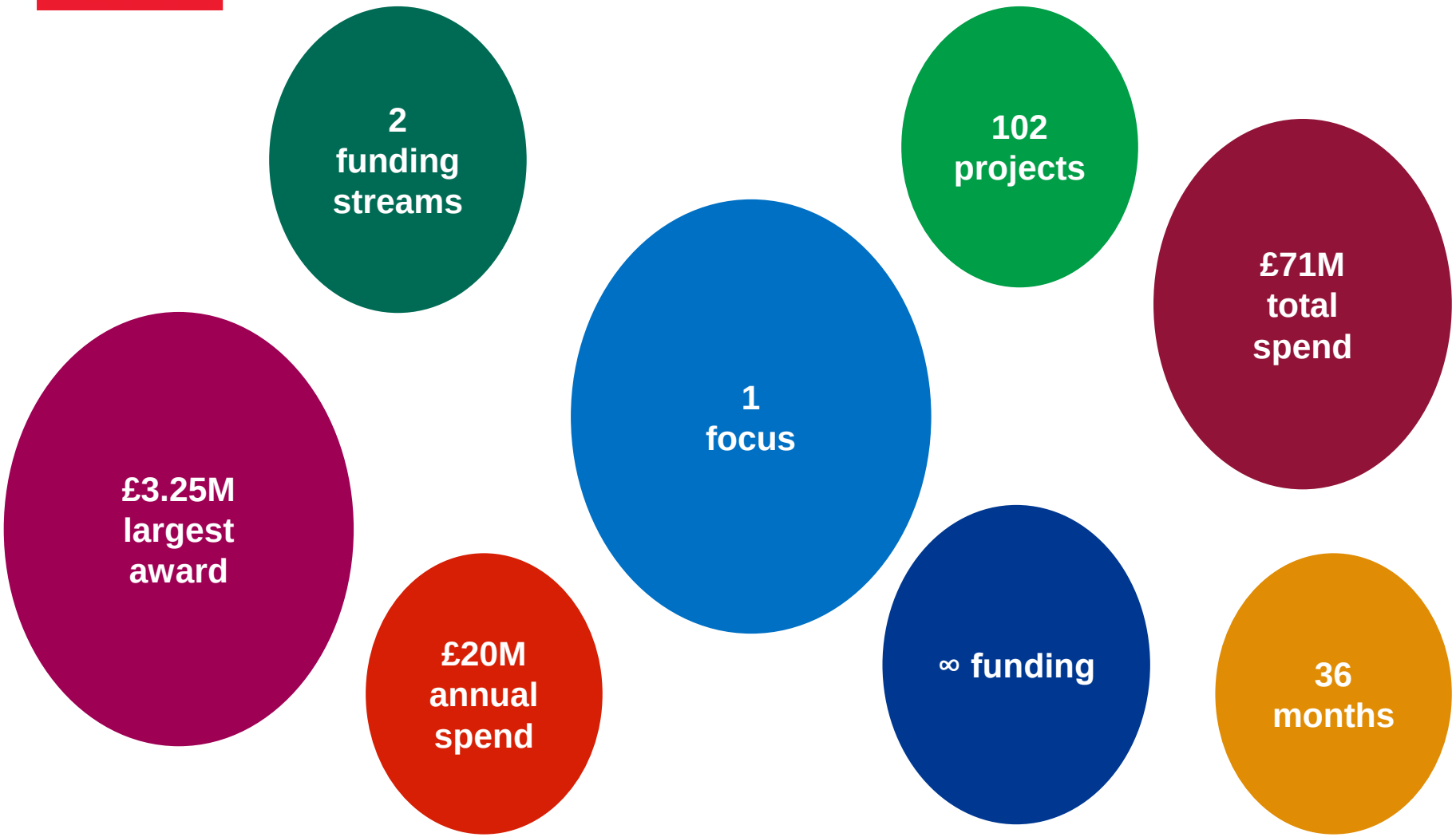
i4i facts & figures



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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)

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MRC-NIHR Efficacy and Mechanism Evaluation (EME)

The EME Programme is broadly aimed at supporting 'science driven' studies with an expectation of substantial health gain and aims to support excellent clinical science with an ultimate view to improving health or patient care.

The remit includes:

- evaluations of new treatments – includes therapeutics, small molecules and biologics
- psychological interventions
- Public Health interventions
- diagnostics and medical devices.

14 projects funded	19,346 participants in clinical trials

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

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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: http://www.youtube.com/watch?v=lCtXbGgc5nU
- EME secretariat: contact us at info@eme.ac.uk or 02380 594304

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NIHR Health Technology Assessment (HTA)

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NIHR Health Technology Assessment

Purpose and remit

- To deliver information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.

Types of studies funded:

- randomised controlled trials and non-randomised trials
- stand-alone pilot and feasibility studies (where there is evidence they will lead to a full trial)
- cohort studies (retrospective or prospective)
- adaptive designs and methodological studies
- evidence synthesis and modelling studies.

69 projects funded	67 published reports	206,174 participants in clinical trials

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

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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 NIHR Funding Streams

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NIHR Health Services & Delivery Research

Purpose and remit

- The NIHR Health Services and Delivery Research (HS&DR) Programme funds research to produce rigorous and relevant evidence on the quality, accessibility and organisation of health services.

43 projects funded	12 funding calls	29 published reports

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NIHR Public Health Research

Purpose and Remit

- The PHR Programme funds research that evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impact of non-NHS interventions intended to improve the health of the public and reduce inequalities in health.

Unique characteristics

- Non-NHS intervention evaluation.
- Wide range of methodologies supported.

17 projects funded	14 funding calls

NIHR Systematic Reviews

- Systematic Reviews provide decision-makers with the best possible information about the effects of tests, treatments and other interventions used in health and social care.
- supports the production/update of reviews through 2 main funding streams:
  - NIHR Cochrane Programme Grants scheme
  - NIHR Cochrane Incentive Awards scheme.

32 projects funded	2 funding calls

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Research for Patient Benefit

- Response-mode funding programme for small grants.
- Maximum award £350,000 for up to three years (£250,000 for feasibility studies).
- Awards made to **NHS bodies and other providers of NHS services in England** with subcontracts to academic partners.
- **Ten** Regional Advisory Committees.
- **Three** funding competitions per year.
- **Single stage** application process.
- **More than 650 awards made to date totalling over £145 million.**

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Programme Grants for Applied Research

- Response mode funding for programmes of research.
- **No** limit on funding amount or duration*.
- Awards made to **NHS organisations in England** with subcontracts to academic partners.
- **Two** funding rounds per year.
- **179 awards in 15 funding rounds totalling ~ £335m.**

**Amount and period of funding depends on nature of proposed work. Funding above £2.5 million and duration more than six years will be unusual.*

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Programme Development Grants

- **Sub-Programme** of PGfAR Programme.
- Response mode funding for small pieces of research needed to underpin future research programme.
- Individual awards for **£20,000 – £100,000** over a period of **6 – 18 months.**
- Awards made to **NHS organisations in England** with subcontracts to academic partners.
- **Two** funding rounds per year.

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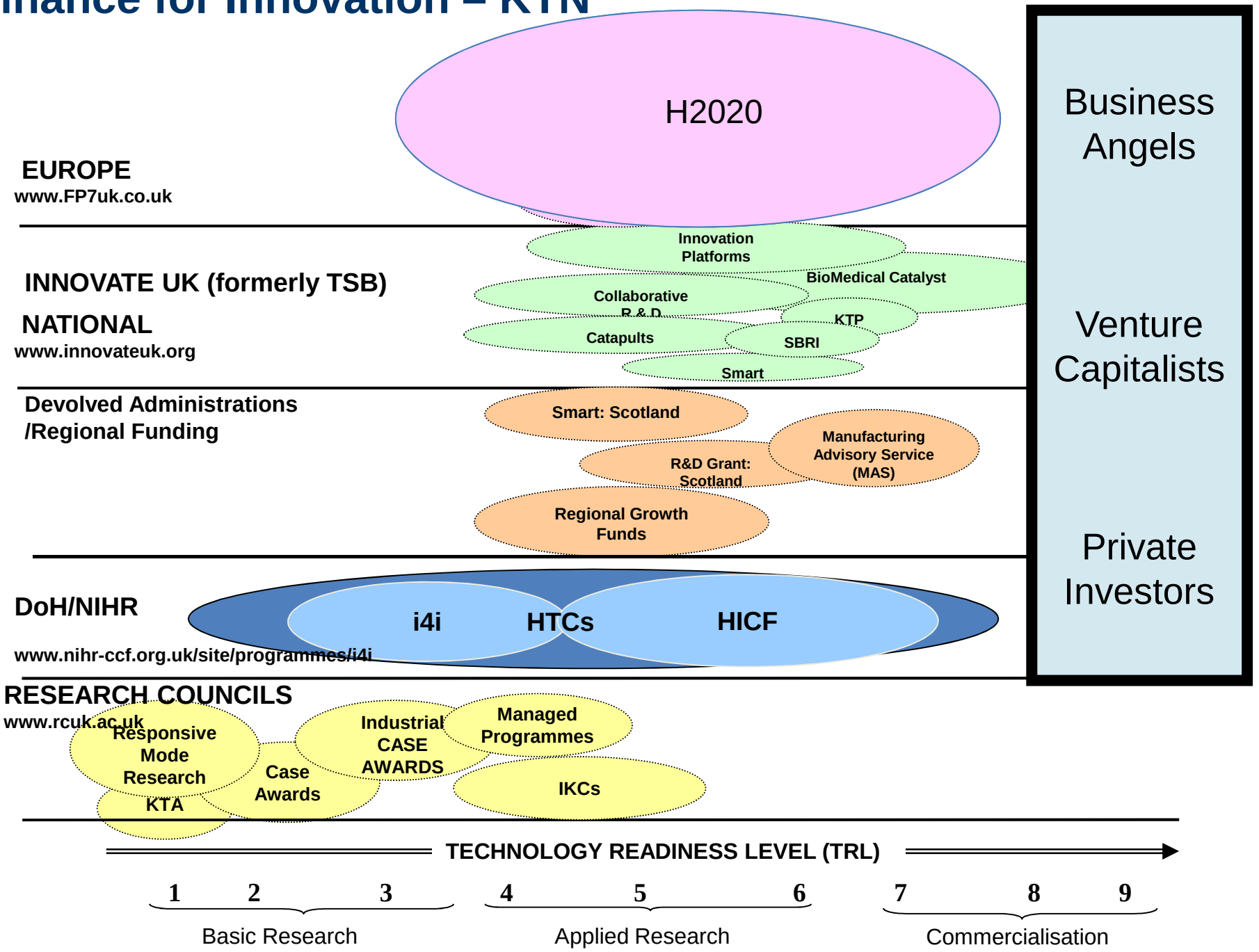
Non-NIHR Funding Streams

Finance for Innovation – KTN



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Innovate UK

Technology Strategy Board
Driving Innovation

MRC Medical Research Council

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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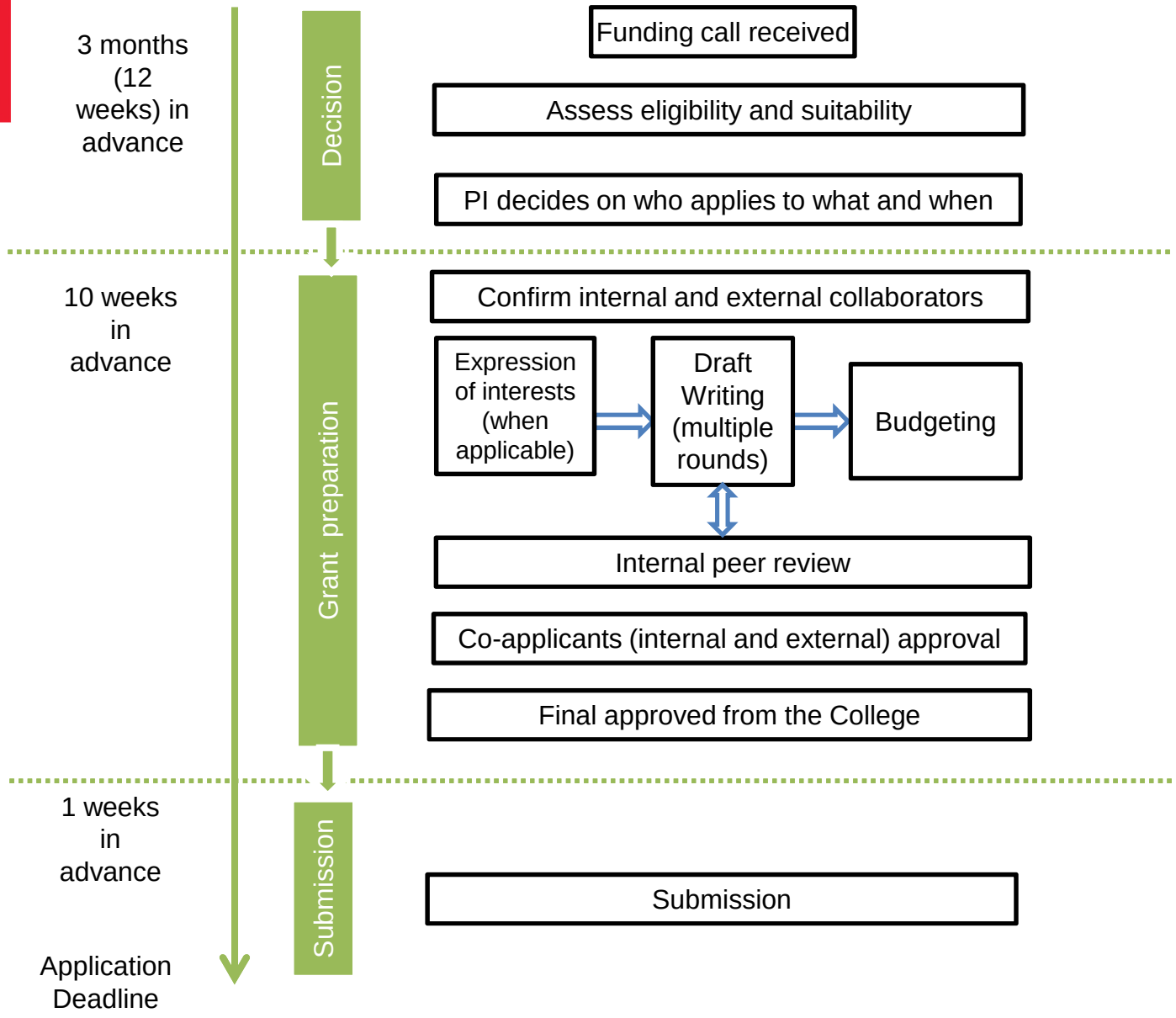

Common Issues with Applications

- 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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NIHR Research Infrastructure

Invention → 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
- Diagnostic Evidence Cooperatives

Late-phase clinical research

- 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

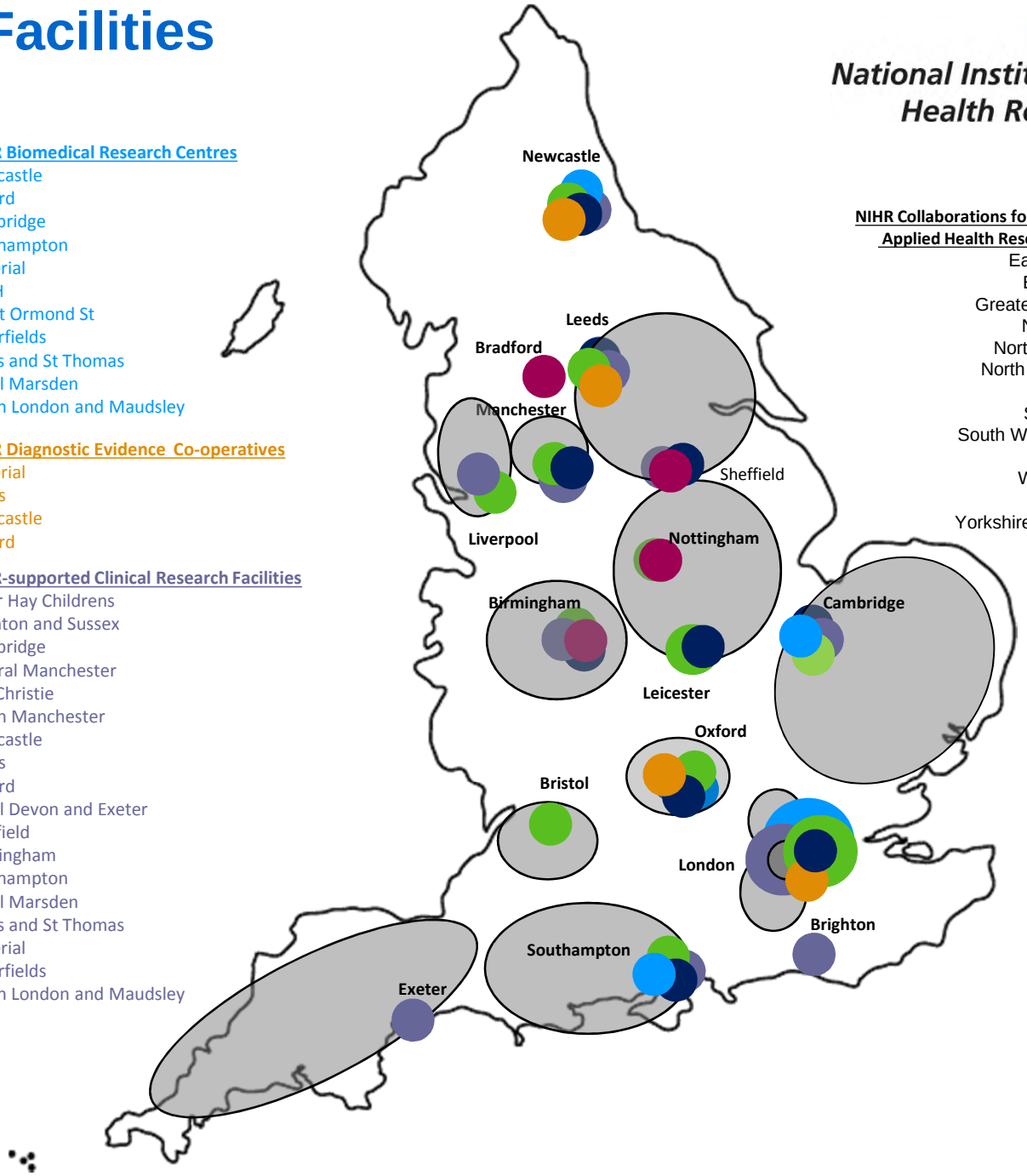
NIHR Healthcare Technology Co-operatives
Birmingham
Bradford
Leeds
Nottingham
Sheffield
Barts
Cambridge
Guy's & St Thomas'

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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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 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

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.

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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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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:

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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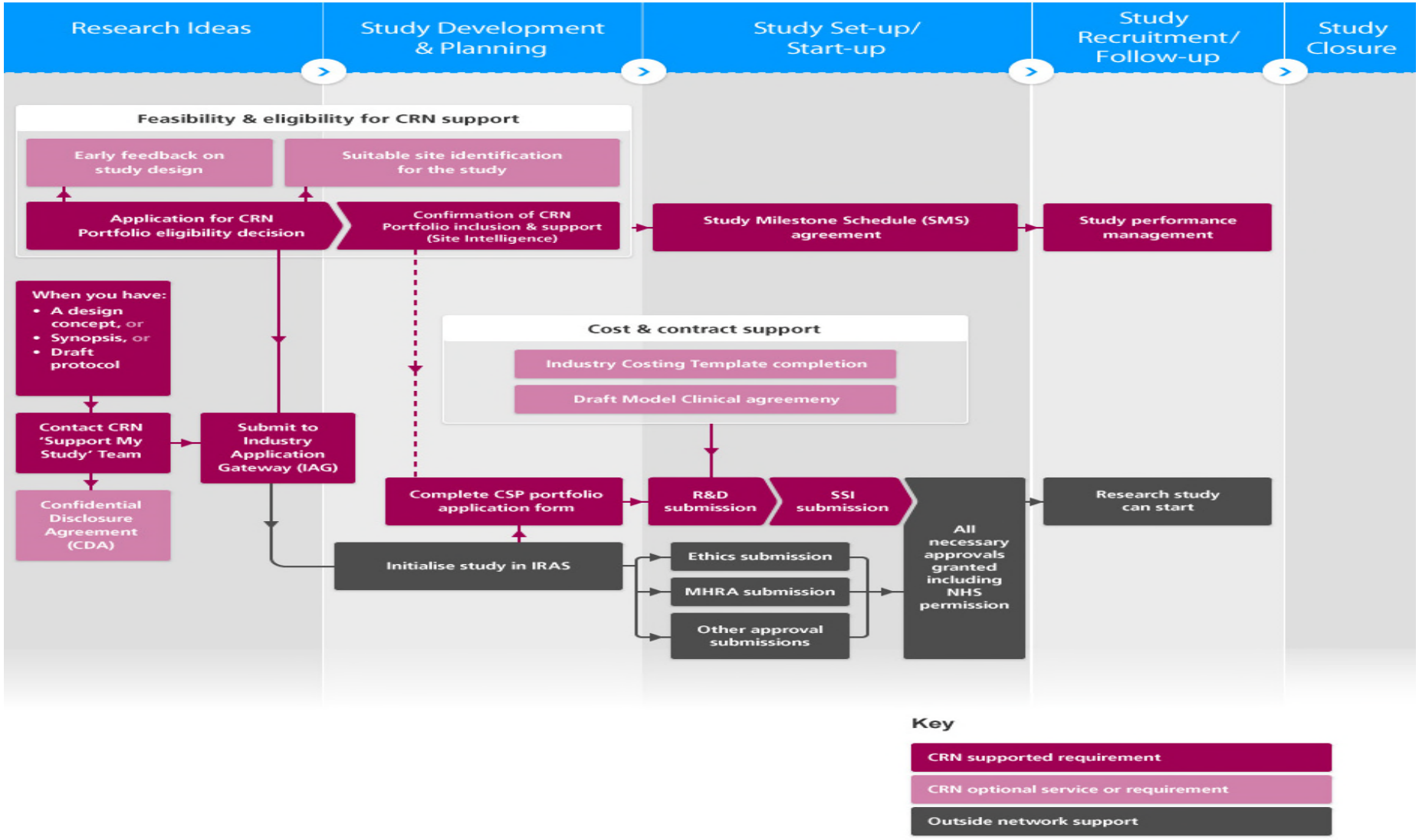
NIHR CRN Study start-up route map



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

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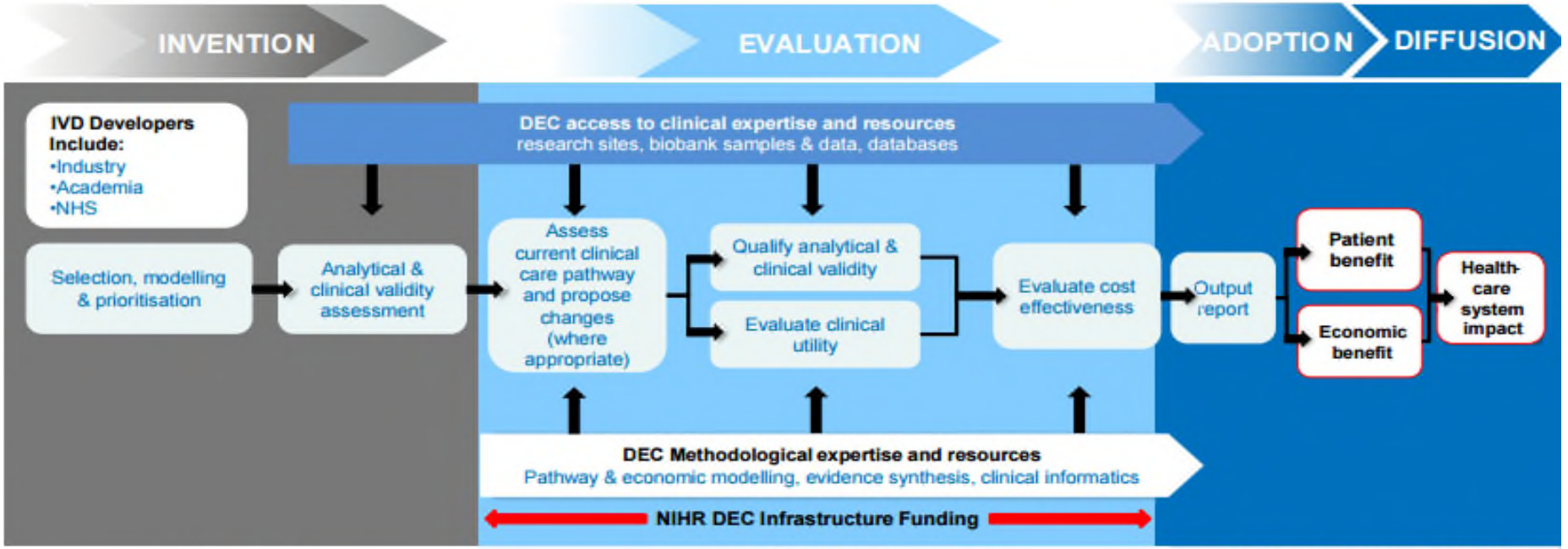
The NIHR DEC *In Vitro* Diagnostics Evidence Generation Pathway



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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Our industry engagement process

NOCRI provides industry partners with:

- **access to clinical expertise and capabilities at individual NIHR centres**
- **unique multi-centre collaborations in early technology design and clinical input enabling early phase clinical research in specific therapeutic areas.**

NOCRI industry engagement completed (non-confidential)

Meeting/telecon between company and NOCRI

NOCRI identifies relevant NIHR infrastructure and gathers expressions of interest
Meeting between company and investigators/ academic/clinicians

Industry/NIHR collaborative project initiated

Supported by standard agreements and templates

Facilitating rapid access to NIHR clinical research infrastructure

NIHR-Supported Facilities

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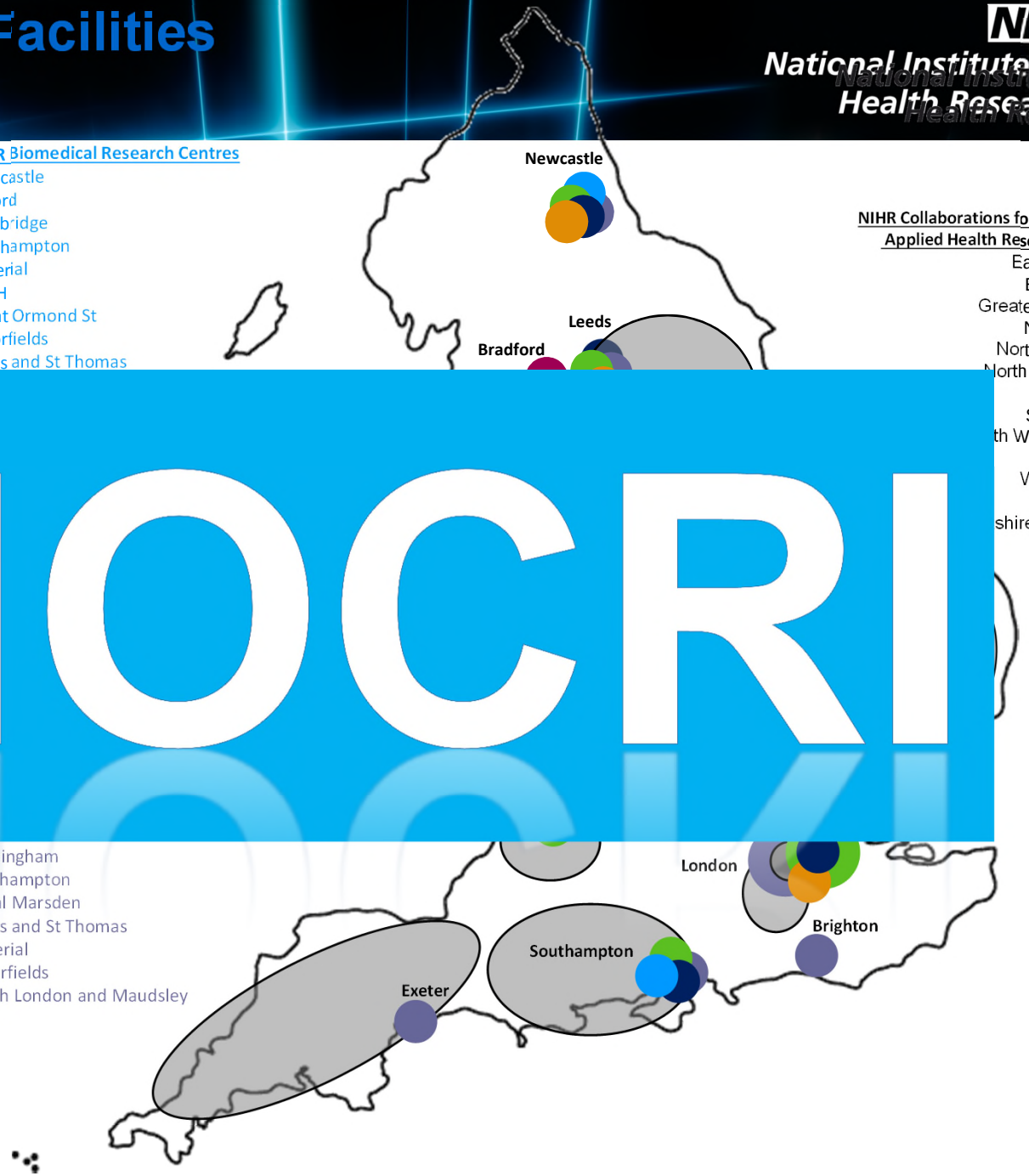
NIHR Biomedical Research Units
Newcastle – dementia
Leeds – [illegible]
Central Manchester – musculoskeletal
Liverpool – gastrointestinal
Nottingham – hearing/respiratory/gastrointestinal
Leicester – cardiovascular/respiratory/nutrition
Birmingham – gastrointestinal
Bristol – cardiovascular/nutrition
Oxford – musculoskeletal
Southampton – respirat
London Imperial – cardi
Barts – cardiovascular
UCL – dementia
South London and Mau

NIHR Healthcare Techno
Birmingham
Bradford
Leeds
Nottingham
Sheffield
Barts
Cambridge
Guy's & St Thomas'

NIHR Experimental Can
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

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
th West Peninsula
West
West Midlands
Wessex
shire and Humber

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Diagnostic Evidence Co-Operative Leeds

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Deputy Director

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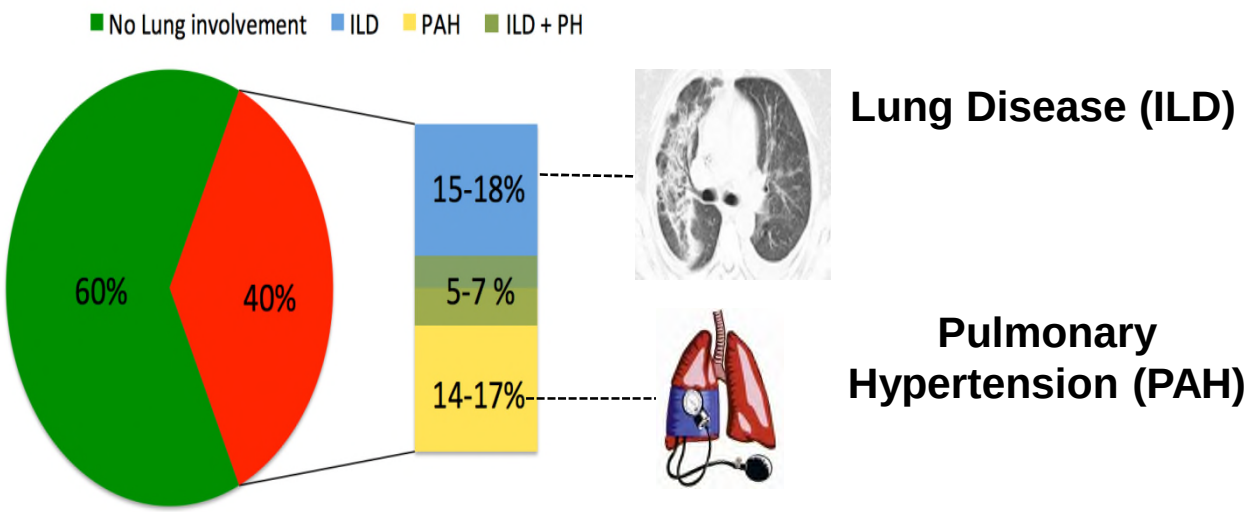
NIHR DEC Leeds

Since September 2013, the NIHR DEC Leeds and it's partners have:

- established a network of more than **90** commercial and more than **100** non-commercial partners
- developed **56** active or completed projects at various stages
    - involving **37** companies
- submitted **37** project proposals for funding:
    - **twenty-one** funded (involving **27** companies)
    - **ten** not funded
    - **six** under review
- leveraged funding:
    - **more than £8.5 million** from government
    - **more than £700,000** from industry.

Stratifying patients with scleroderma

- Systemic Sclerosis (SSc) or Scleroderma, is a rare fibrotic autoimmune condition with an approximate prevalence of 6,000 patients per year in the UK.
- Costs for the NHS currently exceed £200 million per year.
- In partnership with Siemens and Myriad RBM, Dr Del Galdo has secured over £1.5 million in funding to develop and evaluate new diagnostic tests to stratify and manage the 40% of patients who are at risk of developing lung and heart complications.



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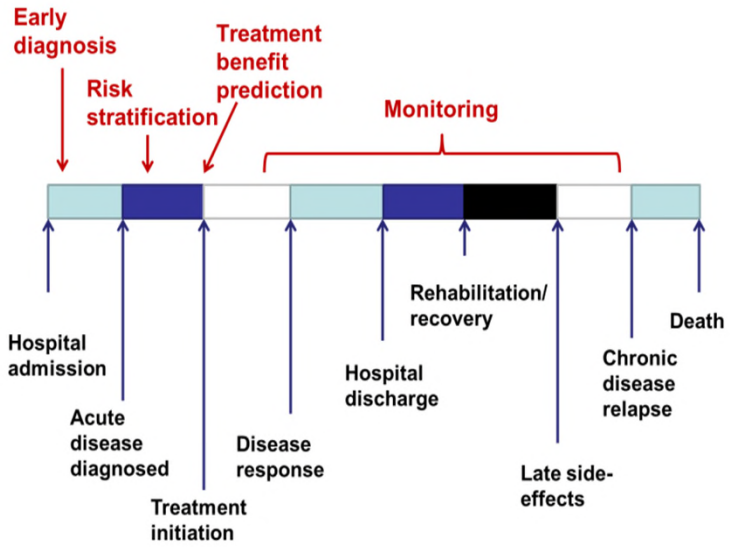
Acute kidney injury (AKI) Diagnostics

- NICE estimate that AKI costs the NHS £620 million per year.
- Adequate care of AKI could avoid 42,000 deaths every year.
- Andy Lewington and Peter Hall are leading research to:
  1. evaluate the potential for AKI diagnostics to enhance the NHS care of patients admitted to critical care
  2. identify the priorities for further diagnostics development and propose efficient designs for relevant future research.

Research Plan:

1. systematically review evidence
2. describe the care pathway
3. identify decision points
4. evaluate clinical and cost effectiveness
5. characterise uncertainties
6. prioritise tests
7. identify efficient study designs.



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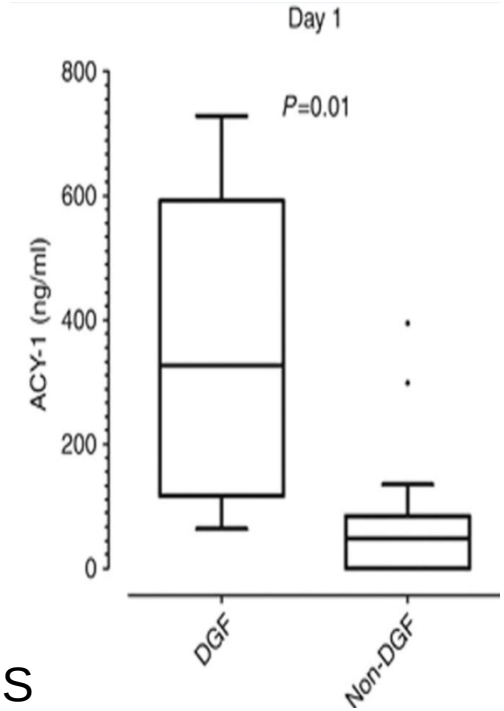
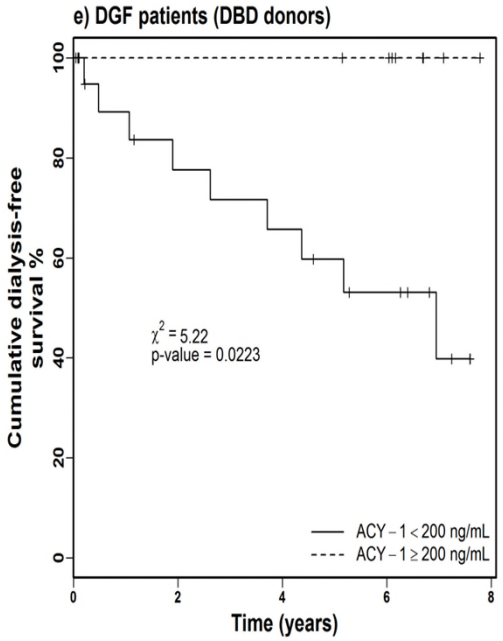
Technology transfer of Aminoacylase (ACY-1) to a clinical diagnostic test

- ACY-1 was discovered by researchers at the University of Leeds.
- Following kidney transplant, ACY-1 blood concentrations can both diagnose delayed graft function and prognose for poor outcomes.
- Researchers and patients collaborated with Randox to transfer the assay onto their clinically proven Biochip technology.
- ACY-1 could potentially save the NHS approximately £1.7 million per year.





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NIHR DEC London

- The NIHR DEC London initiative began in August 2013. One of four DECs in the country (Leeds, London, Newcastle and Oxford) hosted at St. Mary's Hospital, Imperial College London.
- Successful Biomedical Catalyst Award with Ingenza for £1 million to develop a new test for nasogastric (NG) feeding tube placement. If implemented, this would increase patient safety for NG tube feeding and potentially save the NHS more than £120 million per year.

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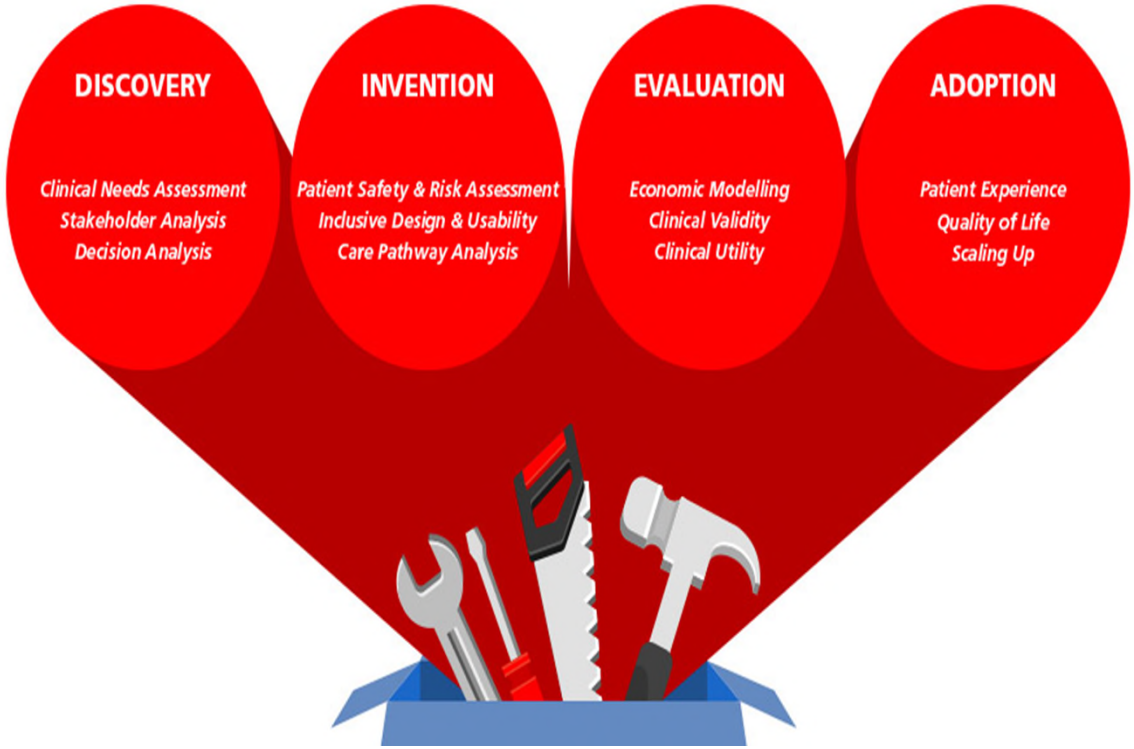
Evidence in Diagnostic Design Process

Support the product design process as it goes through the iterative process of invention, design development and evaluation using our diagnostic evidence toolkit.



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Nasogastric (NG) Feeding Tube Test

- In an industry collaboration with Ingenza, part of a team developing a new enzyme-based test for NG feeding tube placement.
- At least 1 million NG tubes are used in the NHS each year. The gold standard test is an x-ray, which is expensive and subject to misinterpretation. Consequences of erroneous feeding tube placement can be severe.
- NIHR DEC London is generating evidence on clinical validity, clinical utility, cost effectiveness and human factors for the improved test.
- Potential impact of the test is for patient care to be safer, cheaper, more efficient, and is likely to become the new standard of care.

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Breath Test to Diagnose Cancer

- Researchers at Imperial College London are developing a new Point of Care breath test to diagnose oesophageal and gastric cancer by detecting VOCs (Volatile Organic Compounds).
- These cancers are usually diagnosed in the advanced stages using an endoscopy procedure, leading to poor long term survival rates.
- However, early diagnosis can improve survival rates as well as reduce the number of invasive endoscopies carried out on patients.
- The test has produced encouraging results in a clinical study facilitated by NIHR DEC London, and will now be tested in a larger trial involving three hospitals in London.

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NIHR DEC Newcastle

- The NIHR DEC Newcastle was formed in September 2013.
- Hosted by the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) in collaboration with Newcastle University.
- Work closely with the Academic Health Science Network North East and North Cumbria (AHSN-NENC), who have provided additional funding for the DEC to support regional SMEs as part of their Innovation Pathway initiative.
- Handled enquiries for the evaluation of approximately 80 tests from over 40 companies. We have four completed or live studies, five studies in advanced development, and six studies in early development.

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Validating a regional model of Familial Hypercholesterolaemia genetic diagnosis and cascade testing

- Aim of the study is to improve the identification of patients at highest genetic risk of Familial Hypercholesterolaemia (FH).
- FH is a genetic disorder characterised by high LDL-cholesterol levels causing premature cardiovascular disease.
- Study is undertaking cascade testing of relatives of patients with genetically confirmed FH for early identification of undiagnosed individuals – as recommended in NICE guidance (2008).
- The DEC is working with the Northern Clinical Commissioning Groups, Northern Genetics Service (NHS), local company NewGene and AHSN-NENC to develop a regional genetic diagnostic testing service for FH.

Clinical evaluation of near patient testing for influenza A and B using the ALERE™ rapid nucleic amplification technique versus standard laboratory based real time PCR

- The aim of the study is to evaluate the clinical utility and cost effectiveness of a near patient test for flu compared to the standard PCR test.
- Deploying a rapid diagnostic test would enable the improvement of patient turnaround time, administration of effective treatment and instigation of infection control practice.
- This test has not been evaluated against standard PCR test.
- The impact of shorter time to diagnostic confirmation on important hospital resources like isolation facilities and bed capacity will be assessed.
- The data from the study is in the process of being analysed (827 recruited patients) and a budget impact analysis undertaken.

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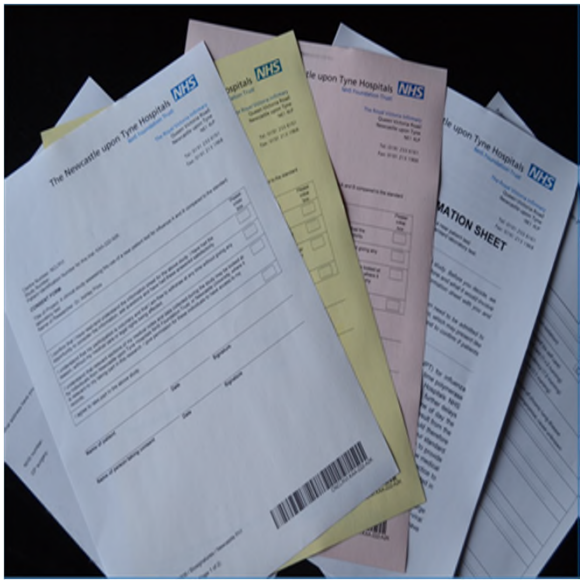
DEC Work Packet System (WPS)

- Aim of this project was to develop a bespoke software system for evaluation study management.
- The development of a purpose built system to manage DEC studies will enable it to deliver them more quickly and in a secure manner.

- With one-click, produces full recruitment packs, each coded with a unique study ID.
- Reduces the administrative workload of the research nurse.
- Anonymised data is uploaded via a custom-built website to a secure cloud server.
- Enables data sharing between sites, and easy access to data for analysis by the DEC.



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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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Developing a new screening tool for colon cancer

- E&B Devices engaged NOCRI with a prototype and early stage concept for testing for blood in stool samples that was ‘hands-free’.

- Through the NIHR Leeds DEC and Colorectal Therapy HTC, the company had access to clinical experts, clinical biochemists, health economists and product design specialists.

- E&B Devices were also able to raise funding from venture capitalists based in the US.

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Fuel3D Eyekona Camera

- Fuel3D camera provides much more information than a standard camera including wound size, depth, volume and colour indicative of type of tissue.

- In partnership with Fuel 3D, NIHR WoundTec HTC helped secure a successful grant application of £685,000 from the NHS England Small Business Research Initiative (SBRI) fund to increase the functionality of the camera.

- NIHR WoundTec HTC is supporting the testing and evaluation phase of the updated Eyekona camera system.

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