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

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

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

NOCRI
NIHR Office for Clinical Research Infrastructure

National Institute for Health Research
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
<table>
<thead>
<tr>
<th>NIHR Clinical Commissioning Facility (NIHR-CCF)</th>
<th>NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Invention for Innovation (i4i)</td>
<td>• Efficacy and Mechanism Evaluation (EME) Programme</td>
</tr>
<tr>
<td>• Programme Grants for Applied Research (PGfAR)</td>
<td>• Health Services and Delivery Research (HS&amp;DR) Programme</td>
</tr>
<tr>
<td>• Programme Development Grants (PDG)</td>
<td>• Health Technology Assessment (HTA) Programme</td>
</tr>
<tr>
<td>• Research for Patient Benefit (RfPB)</td>
<td>• Public Health Research (PHR) Programme</td>
</tr>
<tr>
<td>• Health Innovation Challenge Fund (HICF) – Co-funded between DH &amp; Wellcome Trust</td>
<td>• Systematic Reviews (SR) Programme</td>
</tr>
<tr>
<td></td>
<td>• NIHR Clinical Trials Unit (CTU) Support Funding</td>
</tr>
<tr>
<td>Broad research area</td>
<td>EME</td>
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<tr>
<td>------------------------------</td>
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</tr>
<tr>
<td>Public health</td>
<td>✓</td>
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<tr>
<td>Health services and organisation</td>
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<tr>
<td>Clinical evaluation and translation</td>
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<tr>
<td>Technology development</td>
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<tr>
<td>Types of evidence</td>
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<tr>
<td>Evidence synthesis</td>
<td>×</td>
</tr>
<tr>
<td>Evidence generation</td>
<td>✓</td>
</tr>
<tr>
<td>‘Programmes’ of research</td>
<td>×</td>
</tr>
</tbody>
</table>
### Research programme

<table>
<thead>
<tr>
<th>Calls and competitions (number of opportunities to apply per year)</th>
<th>EME</th>
<th>HS&amp;DR</th>
<th>HTA</th>
<th>i4i</th>
<th>PGfAR</th>
<th>PDG</th>
<th>PHR</th>
<th>RfPB</th>
<th>SR</th>
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<tbody>
<tr>
<td>Researcher-led</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3*</td>
<td>3</td>
<td>1*</td>
</tr>
<tr>
<td>Commissioned</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
<td>3*</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Themed</td>
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<tr>
<td>Frequency and participating programmes as advertised</td>
<td></td>
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</tr>
</tbody>
</table>

### Funding amounts and periods

<table>
<thead>
<tr>
<th>Funding limit**</th>
<th>No limit</th>
<th>No limit</th>
<th>No limit</th>
<th>No limit</th>
<th>No limit***</th>
<th>£100k</th>
<th>No limit</th>
<th>£350k†</th>
<th>£400k</th>
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<tbody>
<tr>
<td>Period of funding</td>
<td>No fixed period</td>
<td>No fixed period</td>
<td>No fixed period</td>
<td>Up to 3 years</td>
<td>No fixed period***</td>
<td>0-18 months</td>
<td>No fixed period</td>
<td>Up to 3 years</td>
<td>Up to 3 years</td>
</tr>
</tbody>
</table>

* denotes a smaller number per year of opportunities than usual, £ denotes £ sterling, and † denotes pounds sterling.
This pathway covers the full range of interventions - pharmaceuticals, biologicals, biotechnologies, procedures, therapies and practices - for the full range of health and health care delivery - prevention, detection, diagnosis, prognosis, treatment, care.
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?)
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
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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Deadline</th>
<th>Commissioning brief</th>
<th>Guidance notes</th>
<th>Apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/142 Mechanisms of action of health interventions*</td>
<td>7 October 2014, by 1pm</td>
<td>Access commissioning brief (pdf, 131.04 KB)</td>
<td>Access guidance notes (pdf, 360.59 KB)</td>
<td><a href="#">Apply</a></td>
</tr>
<tr>
<td>14/144 Bowel control and faecal incontinence in adults</td>
<td>7 October 2014, by 1pm</td>
<td>Access commissioning brief (pdf, 133.11 KB)</td>
<td>Access guidance notes (pdf, 304.14 KB)</td>
<td><a href="#">Apply</a></td>
</tr>
<tr>
<td>14/145 Pituitary and/or adrenal disorders and related diseases</td>
<td>7 October 2014, by 1pm</td>
<td>Access commissioning brief (pdf, 132.66 KB)</td>
<td>Access guidance notes (pdf, 304.14 KB)</td>
<td><a href="#">Apply</a></td>
</tr>
<tr>
<td>14/146 Renal failure resulting from intrinsic renal diseases</td>
<td>7 October 2014, by 1pm</td>
<td>Access commissioning brief (pdf, 132.97 KB)</td>
<td>Access guidance notes (pdf, 304.14 KB)</td>
<td><a href="#">Apply</a></td>
</tr>
<tr>
<td>14/147 Wound healing</td>
<td>7 October 2014, by 1pm</td>
<td>Access commissioning brief (pdf, 132.28 KB)</td>
<td>Access guidance notes (pdf, 304.14 KB)</td>
<td><a href="#">Apply</a></td>
</tr>
</tbody>
</table>
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: http://www.youtube.com/watch?v=ICtXbGgc5nU
• EME secretariat: contact us at info@eme.ac.uk or 02380 594304
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
Other Funding Streams
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.
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.

**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*.

**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 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

---

**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

---

**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
Funding call received

Assess eligibility and suitability

PI decides on who applies to what and when

Expression of interests (when applicable)

Draft Writing (multiple rounds)

Budgeting

Confirm internal and external collaborators

Internal peer review

Co-applicants (internal and external) approval

Final approved from the College

Application Deadline

3 months (12 weeks) in advance

Decision

10 weeks in advance

Grant preparation

1 week in advance

Submission

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

• View Open NIHR Funding Calls
  – http://www.nihr.ac.uk/funding-opportunities/
NIHR INFRASTRUCTURE TO SUPPORT EVIDENCE GENERATION
NIHR Research Infrastructure

Invention

Early-phase clinical research

NIHR Biomedical Research Centre
NIHR Biomedical Research Units
NIHR Clinical Research Facilities
Experimental Cancer Medicine Centres

Evaluation

Late-phase clinical research

Healthcare Technology Cooperatives
Diagnostic Evidence Cooperatives

Adoption

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
Biomedical Research Centres (BRCs)

£800 million Government investment to support NIHR Centres and Units - the largest ever commitment to early stage health research.
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
NEW MODELS FOR EFFECTIVE PARTNERSHIP
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
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.
NIHR Diagnostics Evidence Co-operatives (DECs)

- **Imperial College Healthcare NHS Trust**: Cancer, Cardiovascular disease, Gut health, Infectious diseases, Metabolic medicine, Primary Care, Respiratory, Gastrointestinal disease.
- **Newcastle upon Tyne NHS Foundation Trust**: Cancer, Cardiovascular disease and stroke, Genetics, Infection, Liver disease, Musculoskeletal disease, Respiratory, Transplantation.
- **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.
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)
Standardizes 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.
NIHR CRN Study start-up route map

Feasibility & eligibility for CRN support
- Early feedback on study design
- Suitable site identification for the study
- Application for CRN Portfolio eligibility decision
- Confirmation of CRN Portfolio inclusion & support (Site Intelligence)

When you have:
- A design concept, or
- Synopsis, or
- Draft protocol
- Contact CRN ‘Support My Study’ Team
- Confidential Disclosure Agreement (CDA)

Submit to Industry Application Gateway (IAG)

Cost & contract support
- Industry Costing Template completion
- Draft Model Clinical agreement

Complete CSP portfolio application form
- Initialise study in IRAS

Study Milestone Schedule (SMS) agreement
- Study performance management

R&D submission
- Ethics submission
- MHRA submission
- Other approval submissions

SSI submission
- All necessary approvals granted including NHS permission

Research study can start

Key
- CRN supported requirement
- CRN optional service or requirement
- Outside network support
How do I submit my study for support?
Case Studies

Alzheimer’s Plasma Biomarker Study

The National Institute for Health Research (NIHR) is collaborating with industry to develop a plasma biomarker test that has significant potential to transform the diagnosis and management of Alzheimer’s.

Blood test – a simple diagnosis for Alzheimer’s?

The NIHR is collaborating with industry to develop a plasma biomarker test that has significant potential to transform the diagnosis and management of Alzheimer’s.

NIHR Dementia Translational Research Collaboration

Dementia research is currently underresourced, with considerable methodological and disciplinary diversity. However, the main research questions require detailed, in-depth exploration of specific areas and global specialist expertise.

Industry Collaborations

Professor Simon Lovestone, Director of the NIHR Dementia Biomedical Research Unit at Maudsley, said, "This is the largest study of plasma biomarkers, which is now underway. A number of potential Alzheimer’s biomarkers are being investigated, and there is increasing need for gold-standard diagnostic and therapeutic markers to assess efficacy, cost-effectiveness, and safety.

The opportunity for collaboration in this new field is expected to increase as more patients with Alzheimer’s disease are diagnosed and receive the appropriate care and treatment.

The NIHR Dementia Translational Research Collaboration is a new and important part of the NIHR clinical research infrastructure and offers a unique opportunity to harness the significant NIHR investment in dementia translational research.

As a result of the new collaboration, industry leaders are encouraged to make more use of the new therapeutic and diagnostic approaches to identify and develop new tools for early diagnosis, treatment, and management of Alzheimer’s disease.

The collaboration is a vital component in the NIHR clinical research infrastructure and offers a unique opportunity to harness the significant NIHR investment in dementia translational research.
FUTURE PLAYERS

• MRC
  – Molecular Pathology ‘Nodes’
    • Regional centres
    • Discovery, Evaluation & Adoption!
  – Competition Open

• Innovate UK (TSB)
  – Precision Medicine Catapult
  – Still to be announced formally
DEC IN-VITRO DIAGNOSTIC (IVD) DEVELOPMENT PATHWAY
**In-Vitro Diagnostic Development Pathway - Stakeholders**

**Stage 1:** Selection, Modelling & Prioritisation
- IVD Developers Include:
  - Industry
  - Academia
  - NHS

**Stage 2:** Analytical & Clinical Validity Assessment
- DEC Clinical expertise and resources
  - Research sites, Biobank samples & data, Databases

**Stage 3:** Assess Existing & Propose Clinical Care Pathway
- DEC Clinical expertise and resources
  - Pathway & Economic Modelling, Evidence Synthesis, Clinical Informatics

**Stage 4:** Qualify Analytical & Clinical Validity

**Stage 5:** Evaluate Clinical Utility

**Stage 6:** Evaluate Cost-effectiveness

**Stage 7:** Output Document/Report
- NIHR DEC Infrastructure Funding

**Contributors to Discussion(s)**
- Patient Groups & Public
- NIHR Infrastructure
- DH Academic Health Science Centres (AHSCs)
- Trade Associations
- IVD Developers
- NIHR Horizon Scanning Centre
- NICE Scientific Advice

**Recipients of Output**
- Patient Groups and Public
- NICE Diagnostics Assessment Programme/Clinical Guidelines
- NHS Evidence
- NHS Providers of Pathology Services
- National Laboratory Medicine Catalogue (NLMC)
- NHS Trusts
- NHS England
- NHS commissioners
- NHS Supply Chain
- Academic Health Science Networks (AHSNs)

**Potential Stakeholders+++**
- • Patient Groups & Public
  - NIHR Infrastructure
- • DH Academic Health Science Centres (AHSCs)
- • Trade Associations
- • IVD Developers
- • NIHR Horizon Scanning Centre
- • NICE Scientific Advice
- • Patient Groups & Public
  - NIHR Infrastructure
- • 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
In-Vitro Diagnostic Development Pathway - Funding

### Stage 1: Selection, Modelling & Prioritisation
- IVD Developers Include:
  - Industry
  - Academia
  - NHS

### Stage 2: Analytical & Clinical Validity Assessment
- DEC access to Clinical expertise and resources
  - Research sites, Biobank samples & data, Databases

### Stage 3: Assess Existing & Propose Clinical Care Pathway
- DEC Methodological expertise and resources
  - Pathway & Economic Modelling, Evidence Synthesis, Clinical Informatics

### Stage 4: Qualify Analytical & Clinical Validity
- Pathway
- Utility

### Stage 5: Evaluate Clinical Utility
- Economic Benefit

### Stage 6: Evaluate Cost-effectiveness
- Healthcare System Impact

### Stage 7: Output Document/Report
- Patient Benefit

### Potential Funders
- RESEARCH COUNCILS – EPSRC (Stages 1,2,3), MRC (Stages 2,4,5)
- TSB – Biomedical Catalyst, Smart Awards
- NHS England - SBRI Healthcare – Specific Themed Calls
- Wellcome Trust / Dept of Health – Health Innovation Challenge Fund (HICF)
- NIHR i4i Product Development Awards
- NIHR i4i Challenge Awards (Stages 3, 5)
- NIHR HTA (Stages 4,5,6)
- NIHR Research for Patient Benefit (RfPB)
- NIHR/MRC EME (Stages 3,4,5)
- EU RELATED FUNDING (HORIZON 2020, FP7, ...)

### Industry Engagement
- Industry
- Academia
- NHS
To work with the Partnerships or any of the NIHR infrastructure contact the team at:

nocri@nihr.ac.uk

www.nocri.nihr.ac.uk