NIHR | Research Design Service East Midlands

NIHR Research Design Service East Midlands

Dr Rachel Evley

NIHR Mission

Partnering with other public funders, charities and industry
to maximise the value of research to patients and the economy

Funding, supporting and delivering high quality research
that benefits the NHS, public health and social care

Investing in world-class infrastructure and a skilled delivery workforce
to translate discoveries into improved treatments and services

Engaging and involving patients, carers and the public
in order to improve the reach, quality and impact of research

Attracting, training and supporting the best researchers
to tackle the complex health and care challenges of the future

NIHR Funding Streams

- Efficacy & Mechanism Evaluation (EME)
- Health Services & Delivery Research (HS&DR)
- Health Technology Assessment (HTA)
- Programme Grants for Applied Research (PGfAR)
- Public Health Research (PHR)
- Research for Patient Benefit (RfPB)
- Invention for Innovation (i4i)

NIHR Funding Streams

3 Main NIHR funding streams for biomedical discoveries (therapies, devices & diagnostics)

Invention for Innovation (i4i)

- Connect
- Challenge
- Product Development Award

Efficacy & Mechanism Evaluation (EME)

Health Technology Assessment (HTA)

NIHR Funding 2017-2018

Total Funding
all
NIHR Programmes
£226 974 907

Invention for Innovation (i4i)
£19 226 270

Efficacy & Mechanism Evaluation (EME)
£16 194 479

Health Technology Assessment (HTA)
£91 060 448

Invention for Innovation (i4i) - **Connect**

- Aimed at small-to-medium-sized enterprises (SMEs) - funding boost to reach next stage in the development pathway.
- Help SMEs get to a point where they can apply for further funding, in particular for an i4i Product Development Award.
- Aims to de-risk projects at any stage of the translational research and development pathway to support follow-on investment.
- i4i Connect is researcher-led and does not specify topics for research.
- Lead applicants to i4i Connect **MUST** be from an SME.

£50,000-£150,000 over a 6-12 month period, One call per year

i4i – **Product Development Award**

- Support innovations at any stage of the translational research and development pathway, including the clinical development of laboratory-validated technologies or interventions.
- This funding stream is researcher-led and does not specify topics for research.
- Research proposals must include applicants from two organisation types: an NHS Trust, higher education institution or small-to-medium-sized enterprise (SME).
- No upper funding limit for Product Development Awards BUT usually less than £1.5 million
- Projects can be up to three years in duration.
- Two funding calls per year.

i4i – what is funded?

The Product Development Awards & Connect will support:

- Research and development of medical devices, active implantable devices and in vitro diagnostic devices as defined by the relevant EU directives, across all areas of existing or emerging healthcare needs.
- Product or technology development required to enable a technology for clinical use, which may include manufacturing, intellectual property protection, freedom to operate and market analysis or business case development.
- Research and development of techniques or technologies from a different industry sector that could have a potential impact if applied in a healthcare setting.
- Feasibility studies, if a technology from a sector other than health is being developed.

i4i – what is funded

- Studies to provide data relating to safety and effectiveness of a device, including first-in-man and pivotal studies.
- Health economic analyses and clinical utility studies looking at a device's real-life implementation and use.
- Research to support CE mark applications and other regulatory requirements, including any associated safety trials.
- Activities associated with the adoption of new technology.
- Training associated with the implementation of new technology.

Invention for Innovation (i4i) - **Challenge**

Commissioned on an ad hoc basis in areas of existing or emerging healthcare need.

The expected output is a disruptive technology with the potential to offer improved outcomes for NHS patients.

2019 call - Assessment of Medtech innovations in real-world healthcare settings.

The aim is to shorten the evidence gap between the safety/preliminary efficacy studies typical of a newly CE marked technology and what is required for decisions by commissioners and regulators.

Invention for Innovation (i4i) - **Challenge**

Who can Apply?

- Small-to-medium-sized enterprises (SMEs), NHS trusts, NHS service providers and higher education institutions.
- A minimum of two organisations must be involved, and the proposal must include at least one collaborator from an NHS trust or NHS service provider.

Funding & Timeline

- No upper funding limit, but costs must be fully justified.
- No limit on project duration. Timelines will need to be commensurate with the requirements of the project and the delivery of outputs, in terms of potential healthcare uptake and patient benefit.

Efficacy & Mechanism Evaluation (EME)

Three calls per year – research led and commissioned calls

- Primarily supports clinical trials, and other robustly designed studies that test the efficacy of interventions.
- The interventions should have the potential to improve patient care or benefit the public.
- Only supports studies where there is sufficient evidence that the intervention might work in man, i.e. that there is ‘proof of concept’.

Efficacy & Mechanism Evaluation (EME)

Supports:

- Research to determine proof of clinical efficacy, size of effect, and long-term safety in a well-defined population.
- The evaluation of a broad range of interventions that have the potential to maintain health, treat disease or improve recovery.
- Hypothesis-testing research based on an efficacy study, to explore the mechanisms of action of interventions, causes of differing responses or disease mechanisms. These studies use data or samples obtained and stored from both treatment and control groups of a clinical study, to arrive at conclusions that would not arise from a simple cohort study.

Health Technology Assessment (HTA)

Some evidence needs to already exist to show that a technology can be effective.

Research will establish the clinical and cost-effectiveness for the NHS in comparison with the current best alternative(s).

Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to direct benefit to NHS patients.

- The researcher-led does not specify topics for research as long as they are within the programme's remit.
- The commissioned workstream is for research on specific questions which have been identified and prioritised for their importance to the NHS and patients.
- Proposals may include primary research, evidence synthesis, or feasibility and pilot studies when requested within the commissioning brief.

Health Technology Assessment (HTA)

“Technologies” mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care.

Not confined to new drugs, includes any intervention used in the treatment, prevention or diagnosis of disease.

The technology doesn't need to exist in current NHS practice, but a study would need to show that it could.

HTA Examples

- Procedures
- Drugs
- Devices
- Diagnostic tests
- Settings of care
- Screening programmes

HTA Investigates

- Does the technology work?
- For whom?
- At what cost?
- How does it compare to alternatives?

NIHR Links

Intellectual Property & Commercialisation Guidance

https://www.nihr.ac.uk/documents/intellectual-property-and-commercialisation-guidance-contract/12260

Case Study: Collaborating for Innovation

https://www.nihr.ac.uk/documents/case-studies/collaborating-for-innovation/21211

i4i Case study: A magnetic filter to remove pathogens from the bloodstream

https://www.nihr.ac.uk/documents/case-studies/a-magnetic-filter-to-remove-pathogens-from-the-bloodstream/21471

i4i Case study: Virtual reality for mental health

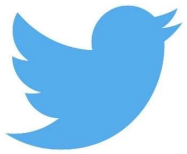
https://www.nihr.ac.uk/documents/case-studies/virtual-reality-for-mental-health/20177

East Midlands RDS Contact Details

Leicester: 0116 252 3276
Nottingham: 0115 970 9310

rds.em@nihr.ac.uk

www.rds-eastmidlands.nihr.ac.uk



follow @NIHR_RDSEM