



DIAGNOSTIC EVIDENCE CO-OPERATIVES

Introduction

The vision of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research.

This document sets out how the NIHR Diagnostic Evidence Co-operatives (DECs) contribute to this vision. Information about other elements of the NIHR clinical research infrastructure can be found in companion documents.

Overview

The need to improve the way diseases are diagnosed is an important health priority. In vitro diagnostic medical devices (IVDs) have the potential to address this need. However, many existing and newer IVDs require evidence of clinical validity, clinical utility, and cost effectiveness and care pathway benefits to enable informed patient, clinician and NHS commissioning decisions to be made. This is needed to assess the effectiveness and cost-effectiveness of the product itself as well as to assess its impact in care pathways. In addition, consideration is being given to inclusion of clinical validity within the regulatory requirements for placing IVDs on the market in Europe.

The NIHR has established DECs to act as centres of expertise to catalyse the generation of evidence on IVDs that is required by the NHS and by IVD manufacturers, enable patients to access the most appropriate treatments more quickly and help the NHS make the best use of its resources.

This initiative supports the Government's Strategy for UK Life Sciences, which aims to provide a better environment for life sciences, improve the lives of patients and contribute to the UK's economic growth, enabling patients to access novel treatments earlier.

Aims

NIHR DECs focus on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of in vitro diagnostic medical devices (IVDs) has the potential to lead to improvements in healthcare services and the quality of life of NHS patients. Led by a Clinical Director, and

involving multidisciplinary teams, they facilitate collaborative working with clinicians and other healthcare professionals, the IVD industry, staff of at least one accredited provider of NHS pathology services, NHS commissioners, academic researchers including health economists, and patient-groups.

The Diagnostic Evidence Co-operatives:

- **Act as catalysts** 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
 - the NICE Diagnostic Assessment Programme.
- **Enable collaboration** between clinicians and other healthcare professionals, patients, 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 DECs also work closely with the NIHR Office for Clinical Research Infrastructure (NOCRI), link with other NIHR-funded research infrastructure and engage effectively with the emerging structures for the delivery of innovation in the NHS, such as the Academic Health Science Networks and local showcase hospital programmes.

Designation and Funding

Four NIHR DECs were selected by open competition in 2013. Applications were assessed by an independent selection panel using the following criteria:

- The potential of the proposed clinical area(s) or theme(s) for generating evidence on IVDs leading to improvements in healthcare services and quality of life of NHS patients
- The track record of generating evidence of clinical validity, clinical utility, cost effectiveness and care pathway benefits of IVDs
- The strength of the strategic plan
- The strength of the strategic partnerships
- The track record in high quality multidisciplinary research in areas relevant to the proposal

- Value for money.

The NIHR is providing £4 million funding to the DEC's over four-years from 1 September 2013. The amount of funding allocated to each DEC has been determined by the scale, nature and quality of the research activity to be conducted by that DEC.

In order to ensure critical mass, funding was awarded to a single NHS Organisation to meet the NHS research infrastructure costs incurred by the NHS in facilitating collaboration, including the funding of core staff (e.g. project management, relationship management, clinical contributors, research leads, administration). However, a number of DEC's are working with other NHS Trusts as partners to deliver their work programmes.

The performance of each DEC is monitored and reviewed by the NIHR Central Commissioning Facility. Collaborations, which are not performing at the required standard, will first be put on notice, and if the required standard is not achieved within a defined time-scale, funding will be withdrawn.

NIHR DEC's Clinical Areas and Themes

DEC's focus on the following clinical areas and themes as detailed on the table below

NHS Organisation	Clinical Themes/Areas
Imperial College Healthcare NHS Trust	Cancer, Cardiovascular diseases, Gut health, Infectious diseases, Metabolic medicine, Primary Care, Respiratory 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.
Leeds Teaching Hospitals NHS Trust	Liver Diseases, Musculoskeletal Diseases, Renal Diseases, Colorectal Diseases and Oncology.
Newcastle upon Tyne Hospitals NHS Foundation Trust	Cancer, Cardiovascular disease and stroke, Genetics, Infection, Liver Disease, Musculoskeletal Disease, Respiratory, Transplantation.

Future funding for Diagnostic Evidence Co-operatives

A new, open competition to designate and fund **NIHR MedTech and In Vitro Diagnostic Co-operatives (NIHR MICs)** was announced in September 2016.

The scheme will aim to provide NIHR research infrastructure funding for leading NHS Organisations to act as centres of expertise

- I) to develop new concepts, demonstrate proof of principle studies and devise research protocols for new medical devices, healthcare technologies or technology-dependent interventions that are applicable across the NHS. This will address clinical areas or themes of high morbidity and unmet need for NHS patients and healthcare technology users, which have not benefited from a high degree of innovation; **and/or**
- II) to catalyse the generation of evidence on commercially-supplied IVDs that is required by the NHS and by industry. This will be developed through follow-on research funded from other sources and includes evidence which demonstrates the benefit to patients and the healthcare service. The focus here will be on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of IVDs has the potential to lead to improvements in healthcare services and the quality of life of the NHS Patients.

NIHR MICs will replace the current NIHR HTCs and NIHR Diagnostic Evidence Co-operatives, but will incorporate and retain the remits of both schemes.

Funding of £14.25m will be available for the NIHR MICs from 1 January 2018 for five years. The outcome of the competition will be announced in summer 2017.

Further information

Further details about HTCs are available on the [NIHR website](#) or contact the NIHR Office for Clinical Research Infrastructure at nocri@nihr.ac.uk

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