Diagnostic Evidence Co-operatives (DECs)

Funded by the NIHR, 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
- Enable collaboration between the IVD industry, clinicians and other healthcare professionals, patients, 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.

Diagnostic Evidence Co-operatives Business Model

Each DEC provides a network of partners and collaborators who form a rich source of expertise and resources for IVD evaluation. The DECs will draw upon the most appropriate resources to match the needs of your project.

The DECs will work with you to put in place the legal and contractual documentation that is appropriate for the specific study being undertaken. Depending on the individual company needs, DECs can provide a variety of contracting options to clients, including fee for contract services, collaborative project services or risk reward type arrangements.

Charging for services of the DEC is dependent upon the nature of the project and its stage of development. The DECs will work with companies to determine the most suitable charging option. DECs can also offer expert opinion and can assist companies to identify and apply for relevant grant funding.

IVD Evaluation Methodology

The DECs are playing a key role in researching and developing evaluation methodologies for IVDs. This is predominantly in response to the needs of the NHS and the IVD industry, and aims to generate robust evidence in a more timely and cost effective manner.

All four DECs are collaborating, via the DEC Methodology Group, to work on common IVD evaluation methodologies, including study design, health economics and informatics. Additionally, each DEC will draw on expertise in specific disease and technology areas to make sure methodologies are developed for various different types of IVDs such as point of care tests, primary care diagnostics and laboratory assays.

The DEC Methodology Group includes representation from the National Institute for Health and Care Excellence (NICE) to help ensure that evidence generated through the DEC process is relevant to the NICE Diagnostics Assessment Programme.

Further information about NIHR Diagnostic Evidence Co-operatives

For more information about the DECs, or to understand how to work with the DECs, contact NOCRI.

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The NIHR DEC In Vitro Diagnostic Evidence Generation Pathway has been created to enable companies to generate the right evidence that will facilitate successful uptake of commercial IVDs.

At this stage the following will be considered:
- Potential new IVDs are taken.

The initial step is where early decisions on whether it will provide additional benefit(s) and what patient groups it could benefit are made.

All of the work in the evaluation phase will help development of evidence requirements for adoption of IVDs into the NHS. This includes:
- Health economic expertise
- Decision analytic modelling
- Health informatics
- Clinical decision algorithm development

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.

NIHR Diagnostic Evidence Co-operatives enable experts from across the NHS and industry to collaboratively generate clinical validity, clinical utility, cost-effectiveness and care pathway benefits of IVDs.

All NIHR DECs work closely with the NIHR Office for Clinical Research Infrastructure (NCORI) and link with other NIHR-funded research infrastructure.

DEC expertise includes:
- Analytical & clinical validity assessment
- Evaluate clinical utility
- Evaluate cost effectiveness
- Qualify analytical & clinical validity
- Patient benefit
- Economic benefit
- Health care system impact
- Output report

NIHR DEC Infrastructure Funding

DEC Methodological expertise and resources
- Pathway & economic modelling, evidence synthesis, clinical informatics

NIHR DEC Experts and Resources
- Pathology and clinical expertise to assess and qualify the assays in real life setting
- High quality biobanks with clinical data
- Pathway & economic modelling
- Evidence synthesis
- Clinical informatics
- Human factors and design evaluation (usability assessment, inclusive design, risk assessment / patient safety, system / process mapping and stakeholder analysis)
- Technical expertise
- Qualification procedures
- External quality assessment
- Assay validation e.g. precision and accuracy
- Assay comparison
- Decision analytic modelling
- Health informatics
- Clinical decision algorithm development
- Health economics
- Value of information analysis
- Development of open access scientific publications
- Feed into NICE Diagnostic Assessment Programme/guidelines
- AHSN adoption pilots

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

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- 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.

This level of collaboration has the potential to lead to improvements in healthcare services and the quality of life of NHS patients, by helping patients access the most appropriate treatments more quickly and help the NHS make the best use of its resources.

Stage in Pathway
- Evaluate cost-effectiveness
- Evaluate clinical utility
- Qualify analytical & clinical validity
- Assess current clinical care pathway and propose changes where appropriate

NIHR DECs include:
- Industry
- Academy
- NHS
- Research sites, biobank samples & data, databases
- NHS Pathology
- NHS Clinical Risk Management

Selection, modelling & prioritisation
- Analytical & clinical validity assessment

The initial step is where early decisions on whether it will provide additional benefit(s) and what patient groups it could benefit are made.

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DECs expertise includes:

- Analytical and clinical validity assessment
- Evaluate clinical utility
- Qualify analytical and clinical validity
- Evaluate cost effectiveness
- Output document / report

**DECS Methodological Expertise and Resources**

**Pathway & Economic Modelling, Evidence Synthesis, Clinical Informatics**

**NIHR DEC Infrastructure Funding**

**Stage in Pathway**

<table>
<thead>
<tr>
<th>DEC Expertise &amp; Resources</th>
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<th>Evaluate clinical utility</th>
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<th>Output document / report</th>
</tr>
</thead>
<tbody>
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**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 receiver operating characteristic (ROC) performance of the IVD.

**Evaluation**

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Diagnostic Evidence Co-operatives: NHS organisations and clinical themes

NIHR Leeds Teaching Hospitals NHS Trust DEC
Generating high quality evidence on protein and cellular biomarker-based IVDs for the clinical management of musculoskeletal, urological, liver and colorectal disease and oncology
www.leeds.dec.nihr.ac.uk

NIHR Newcastle upon Tyne Hospitals NHS Foundation Trust DEC
Generating high quality evidence for new diagnostics tests for cancer, cardiovascular, liver, musculoskeletal and respiratory diseases, stroke, genetics, infections and immunology
www.newcastle.dec.nihr.ac.uk

NIHR Oxford Health NHS Foundation Trust DEC
Generating high quality evidence for primary care IVDs and diagnostics for musculoskeletal diseases and improving ‘bench to bedside’ processes to implement IVDs into primary care
www.oxford.dec.nihr.ac.uk

NIHR Imperial College Healthcare NHS DEC
Generating high quality evidence for point-of-care in vitro diagnostic tests for gut health, primary and general care, respiratory disease, infectious disease, metabolic medicine, cardiovascular disease, cancer, women’s health and paediatrics
www.london.dec.nihr.ac.uk

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NOCRI provides a single point of contact to each of the four NIHR DECs to enable easy access to NHS expertise for the evaluation of in vitro diagnostics.
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