



National Institute for
Health Research

NIHR – Supporting the development of innovative diagnostic technologies

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NIHR Innovation Programmes**

 @NIHR_NOCRI

 /nihr-office-for-clinical-research-infrastructure

Contents

A horizontal bar composed of several colored segments: green, dark green, orange, purple, red, dark blue, and light blue.

- Where the NIHR fits in the landscape
- NIHR's translational infrastructure
 - BRCs
 - MICs
- NOCRI Signposting Service
- Project Delivery
 - CRN Study Support Service

Partnership

- Between Government, Charity and Industry
- Between NHS and University
- Between research leaders and research facilitators
- Between different health care professions
- Between different research disciplines
- Between researchers and patients

A Health Research System

The Innovation Pathway

INVENTION

EVALUATION

ADOPTION

DIFFUSION

Creation

- new things
- new ideas
- new techniques
- new approaches

Assessment

- new things
- new ideas
- new techniques
- new approaches

Uptake

- new things
- new ideas
- new techniques
- new approaches

Spread

- new things
- new ideas
- new techniques
- new approaches

Basic Research

**MRC & Charities,
Inventors**

Applied Research

NIHR

Commissioning

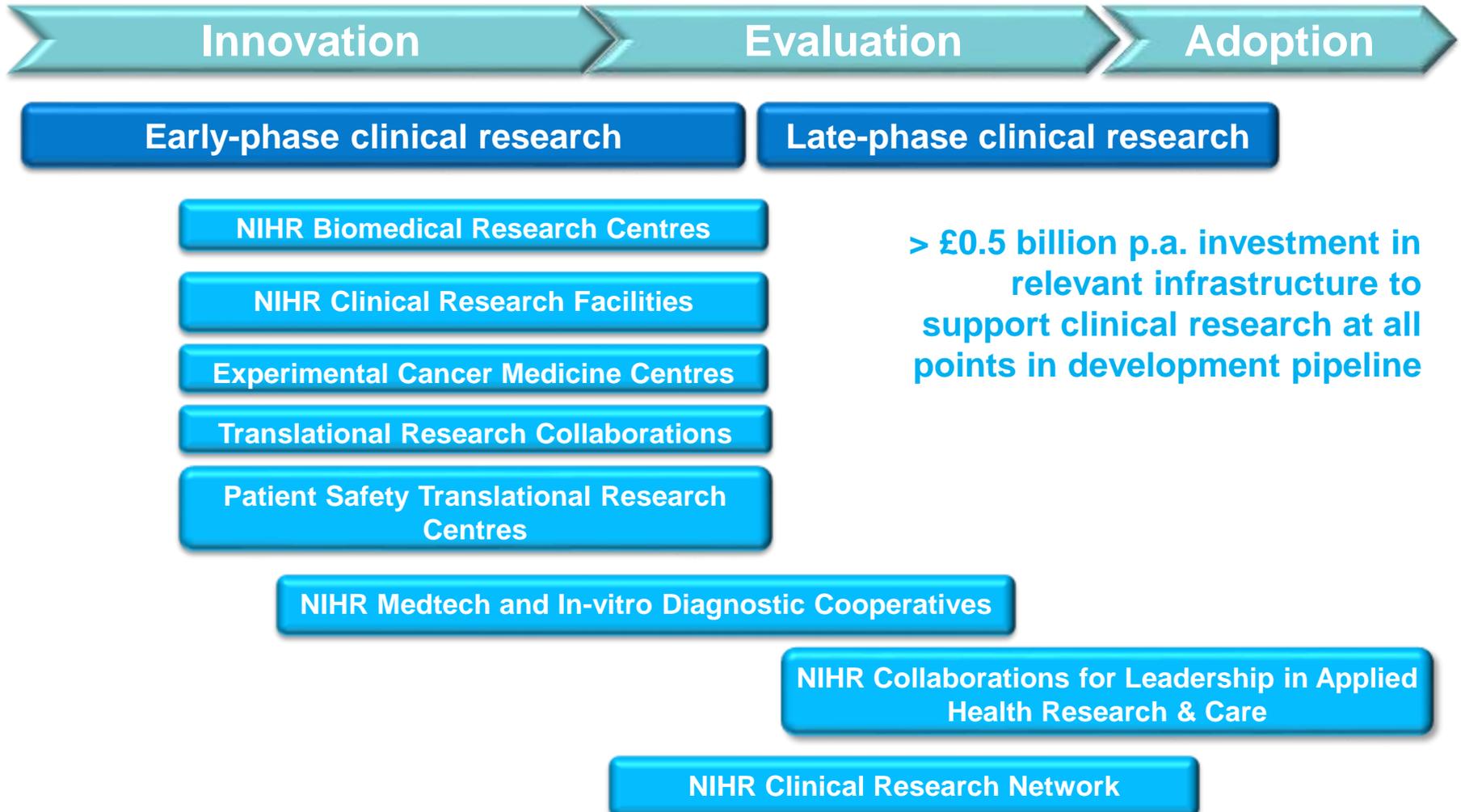
**NHS
Commissioners**

Patient Care

**Providers of NHS
services**

- Better Quality
- Better Value

NIHR Clinical Research Infrastructure





The NIHR has transformed the research landscape by investing in biomedical research facilities and establishing collaborations that drive innovation in key areas.

This infrastructure works collaboratively with the life sciences industry, including SMEs.

NIHR Biomedical Research Centres

Commenced April 2017

**New £816 million
investment in health
research**



NIHR Biomedical Research Centres

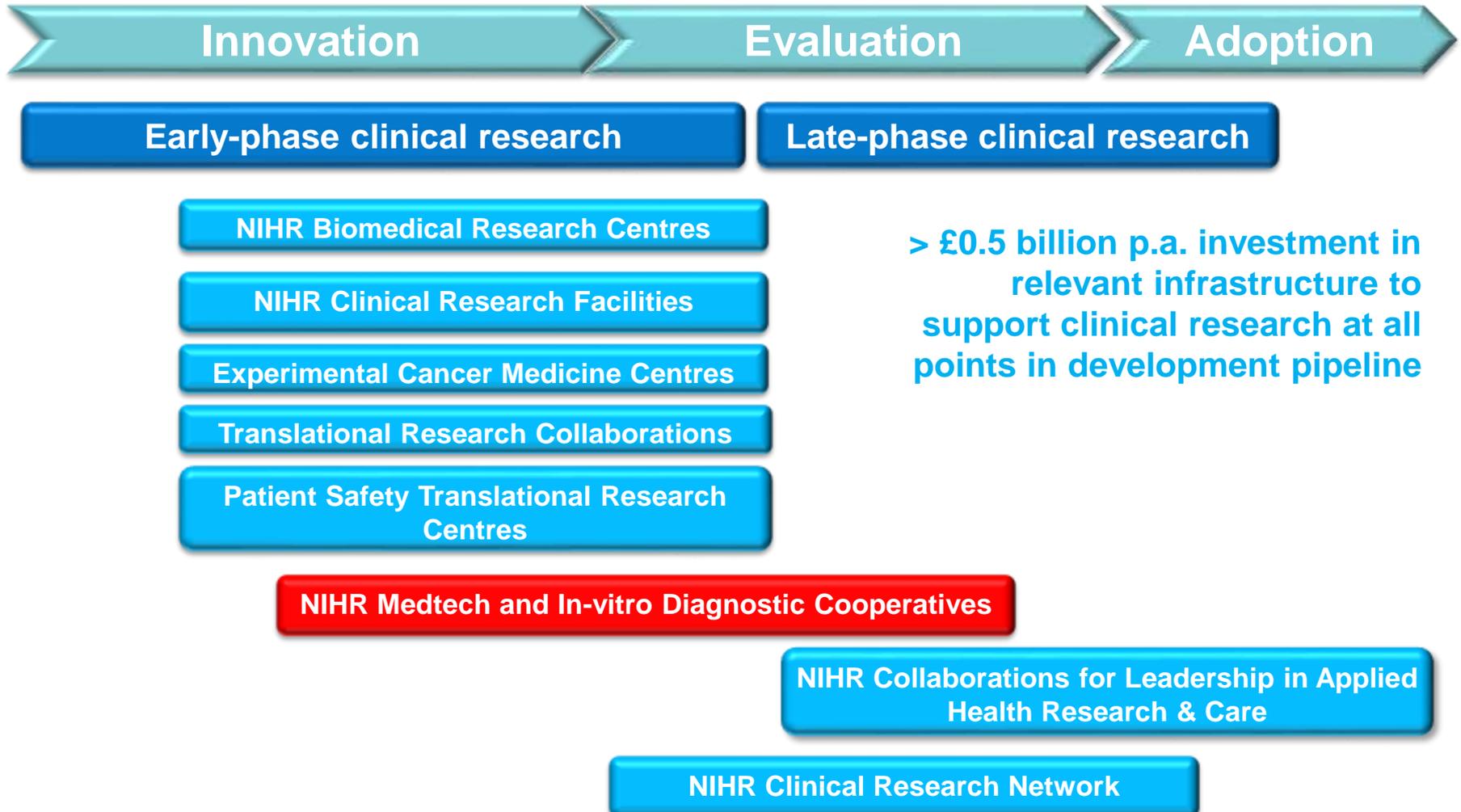


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NIHR Biomedical Research Centres will continue to provide a strong foundation for expertise and leadership in translational research across a broad range of disease and therapy areas, including:

- Antimicrobial resistance
- Cancer
- Cardiovascular disease
- Child health
- Dementia and neurodegenerative disease
- Eye disease
- Endocrinology and metabolic medicine
- Gastrointestinal disease
- Hearing health
- Infection and immunity
- Liver disease
- Mental health
- Musculoskeletal disease
- Nutrition and lifestyle
- Respiratory disease

NIHR Clinical Research Infrastructure



NIHR Medtech and In vitro diagnostic Co-operatives (MICs)

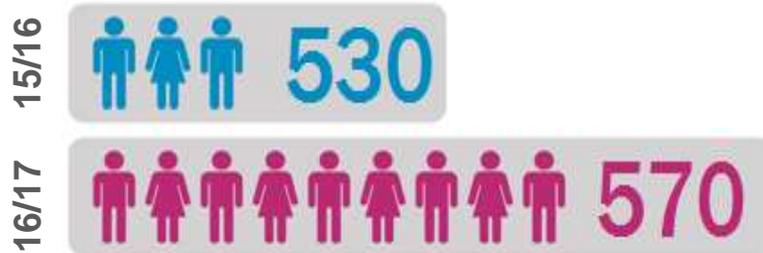
- Centres have been chosen that focus on:
 - the development of medical technologies in areas of high patient morbidity and
 - evidence for diagnostic tests leading to benefits in healthcare services and the quality of life of NHS patients.
- New funding of £14.25m over 5 years started in January 2018.

NIHR Medtech and In vitro diagnostic Co-operatives (MICs)



Impact of the DECAs and HTCAs

NUMBER OF COMPANY
COLLABORATIONS:



NUMBER OF ACTIVE
PROJECTS:



2016/17

TOTAL MONEY
SECURED TO SUPPORT
MEDTECH
PROJECTS:

£28.5
million



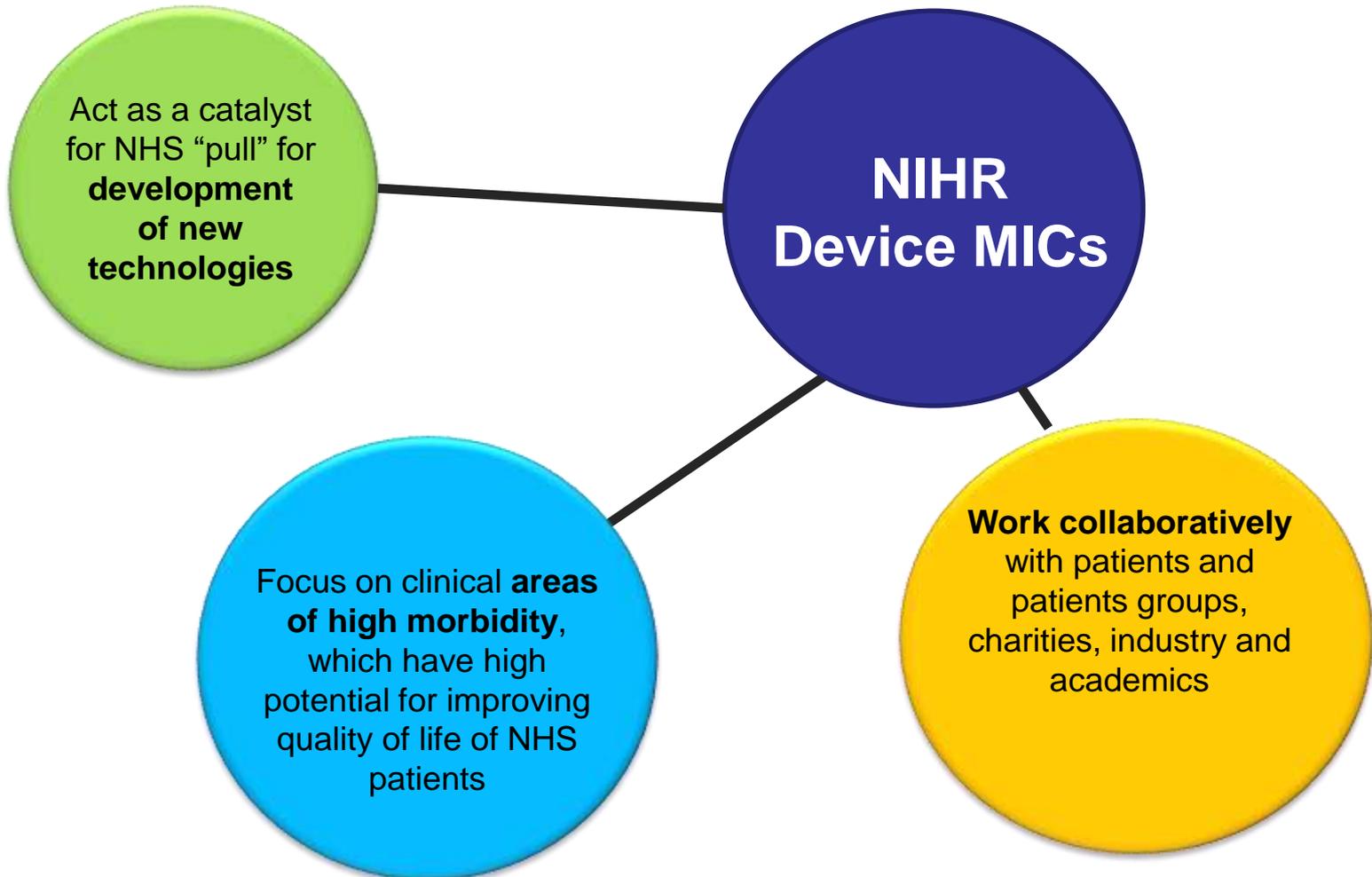
15/16

£37.5
million



16/17

NIHR “Device MICs”



Case study: A New Screening Tool For Bowel Cancer

E&B Devices, a medtech startup, required support for the development of their new prototype technology for bowel cancer screening.

NOCRI provided advice to the company and connected them with the relevant NIHR experts to support the development of their technology from prototype to product.

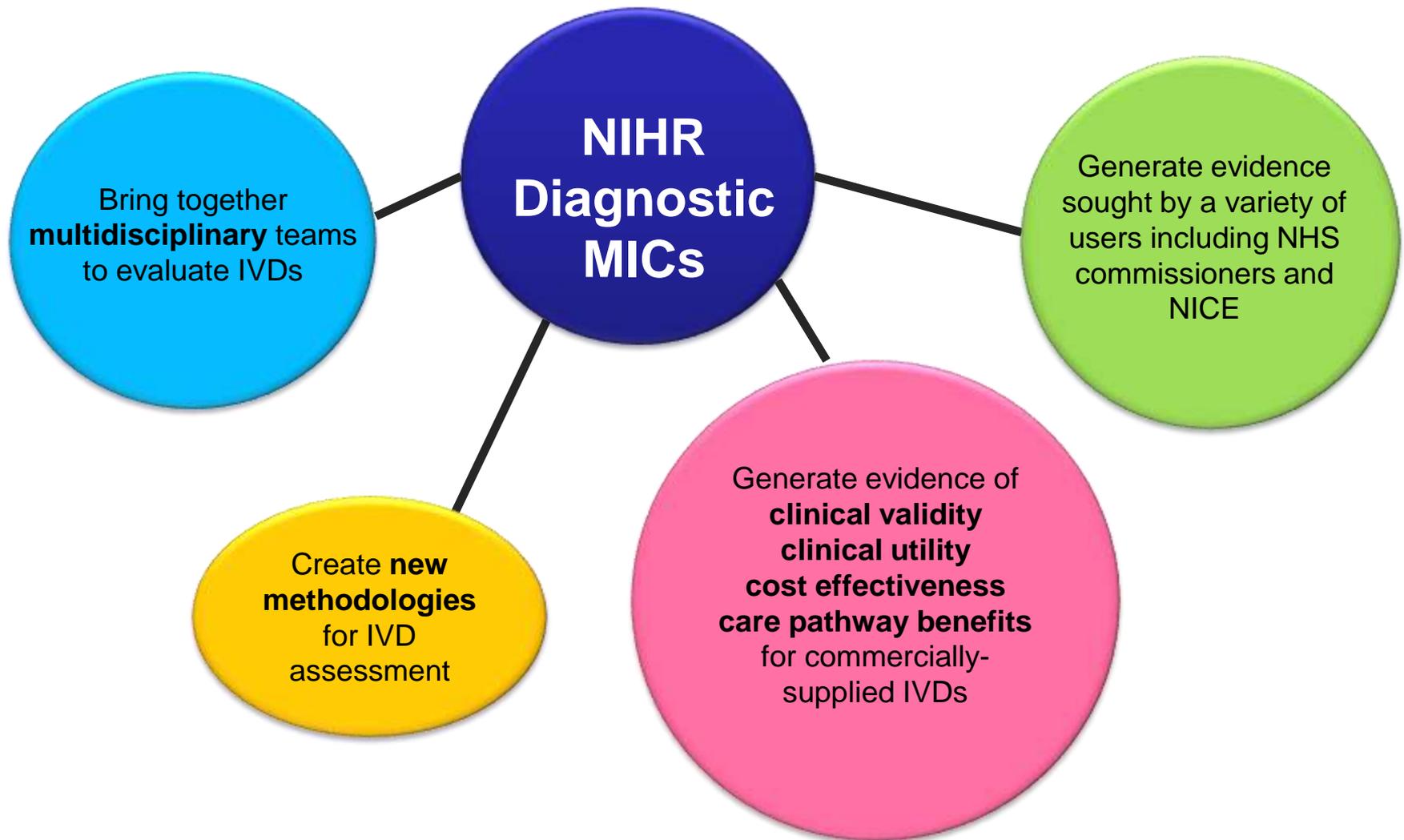
The NIHR Leeds Colorectal Therapy Healthcare Technology Co-operative worked with E&B Devices on the development and design of the technology to ensure the sensitivity of the device was appropriate.



Impact:

- Take-up of the current standard test is currently only around 55-60%
- The new technology detects extremely low amounts of blood in the stool directly in the toilet bowl, without the need to collect a sample
- Potential as an alternative test that would be more acceptable to the public

NIHR “Diagnostic MICs”



Case study: A new diagnostic test for acute exacerbations of COPD



MOLOGIC LTD, a UK-based SME has developed a urine-based test system 'HeadStart' which enables chronic obstructive pulmonary disease (COPD) patients to monitor their disease status at home for early indications of exacerbation..

It will test the levels of key biomarkers in the urine, interpret them and identify imminent acute exacerbation and cause in 10 minutes.

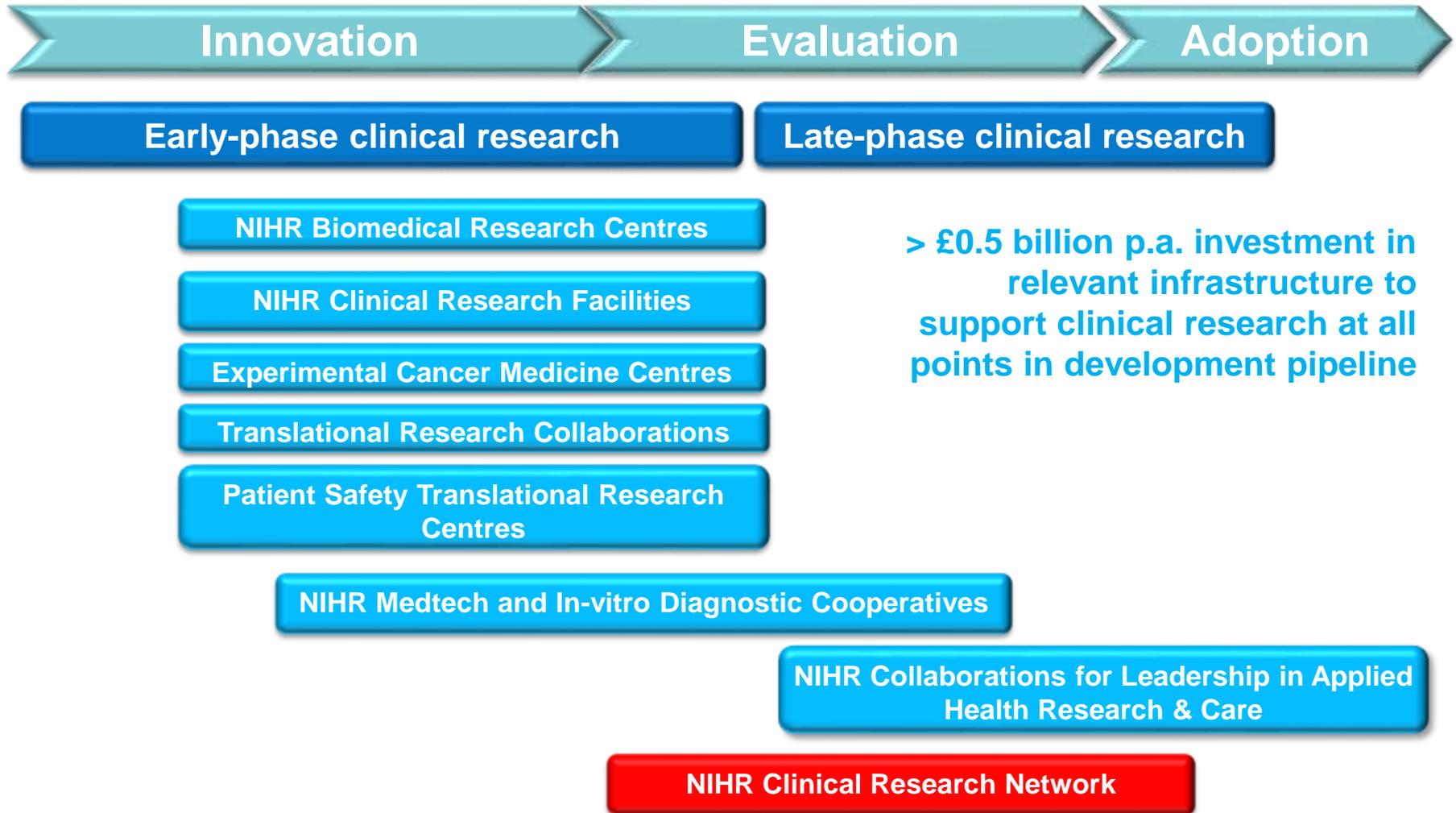
In collaboration with the NIHR Diagnostic Evidence Cooperative (DEC) Newcastle, MOLOGIC LTD was awarded a £100k Small Business Research Initiative (SBRI) contract to further develop the HeadStart test and to prepare an application for a Phase 2 contract to provide robust evidence on clinical utility and cost-effectiveness of the test.

The NIHR DEC is leading on the care pathway modelling work, with pathway descriptions will be developed through interviews with clinical experts. It is known that there is variability in practice throughout the UK, and this study will focus on understanding the management of COPD within the Newcastle and North East area.

NOCRI Signposting Service

- The NIHR provides industry with access to academic and clinical experts who can provide input **early on** in the development of new technologies.
- Also as potential collaborators on applications for funding
- **Navigating the NHS is complex**, even more so when you include other related organisations
- NIHR will **signpost you directly** to the best people to help you on your journey
- Service is **simple and free of charge**

NIHR Clinical Research Infrastructure



NIHR Clinical Research Network



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- Research active engaged clinicians across all 30 therapy areas
- Detailed understanding of care pathways
- 15 Local Clinical Research Networks (LCRNs)
- Allows flexible deployment of resources
- Links with rest of UK



Some stats

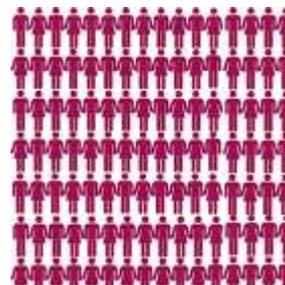
Financial year 2016/17:



Of the
729 commercial
new studies
added last year
12% were
medtech
= 88 studies



Of the
1008 commercial
studies that were
open to recruitment
15% were medtech
= 148 studies

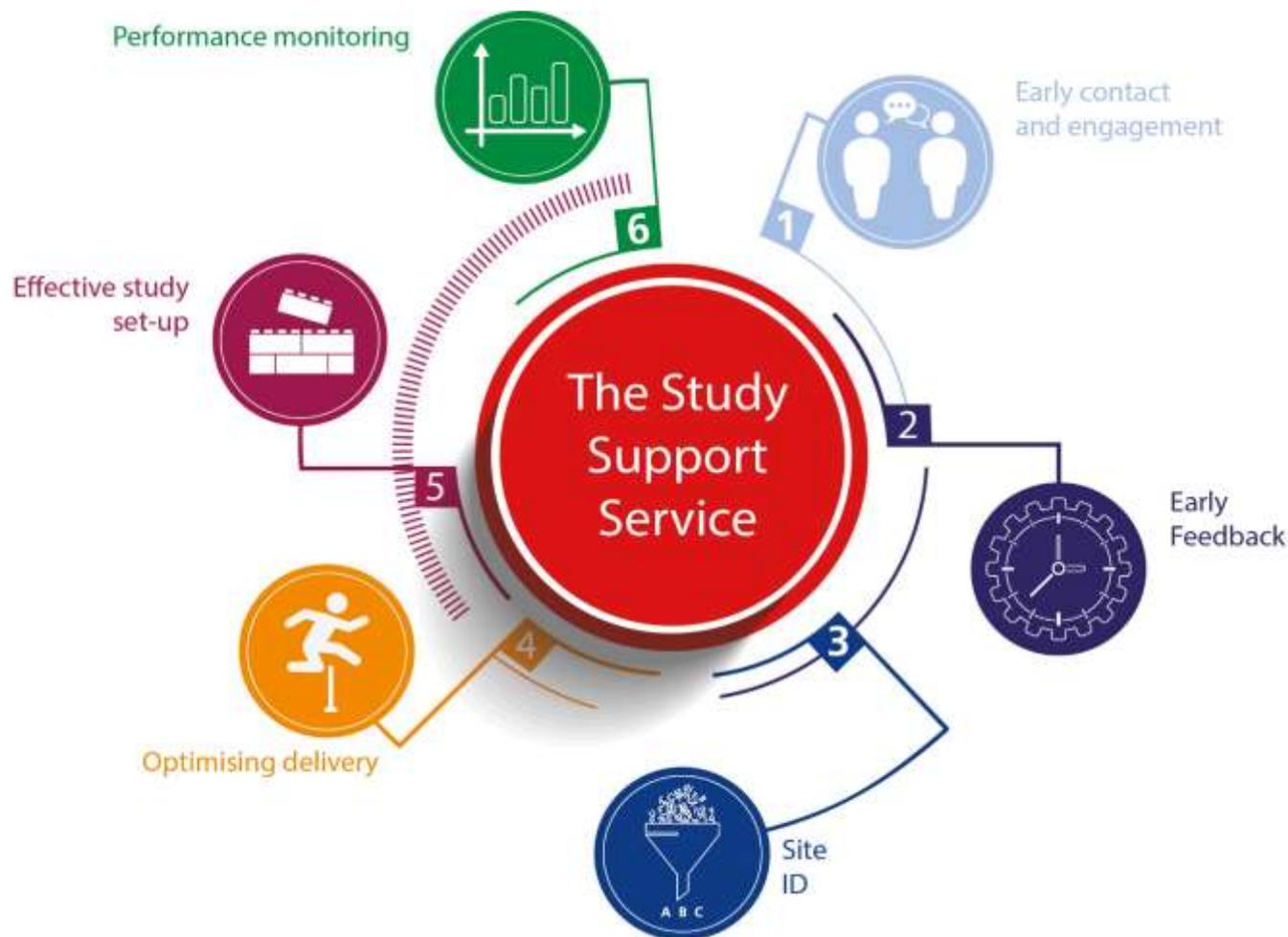


666,630+
patients recruited
34,648 recruited
into commercial
studies
27% into medtech
= 9297 patients



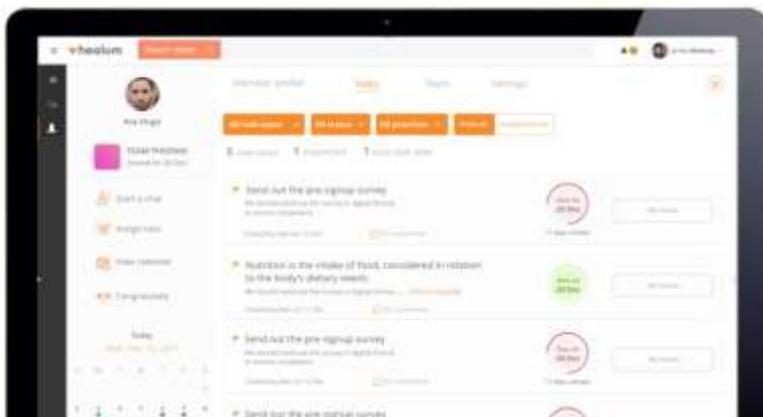
99.9% NHS
trusts research
active
79% commercial

Service summary



Case study: Healum

- UK medtech SME company
- Creates digital solutions that enable healthcare professionals to empower, support and motivate their patients to make healthier choices to tackle chronic diseases
- The product is a digital solution formed of two parts:
 1. online software for use by GPs which is linked to
 2. a mobile app for use by patients on their phone, tablet or laptop
- Pilot - product it has been customised to help manage type 2 diabetes



Case study: Healum



Early Feedback

- confirmed that the study would be feasible in the NHS
- highlighted some potential problems to avoid



Site Identification

- seeking 20 sites
- used single online submission
- returned 117 expressions of interest meeting company criteria
- included clusters and CCG = total 130 sites



Effective Study Set-up

- guided in using the Primary Care Costing Template
- company reduced the number of sites to stay within budget

Case study: Healum



Cassandra Baiano, Research Lead and Partnerships Manager for Healum:

“The response was huge, more than we expected. Some of the expressions of interest were from clusters of practices and even one CCG, which meant the total number of practices interested in piloting our app was over 130. This was great because immediately we knew there was an appetite out there and a clinical need to be met....We now have a strong list of sites we intend to work with.”

“The Network team in Manchester helped us to complete the costing template which was invaluable. We quickly realised we needed to reduce the number of sites from 20 to 15 to stay within planned budget.”

Thrombolysis: “Time is brain”

NIHR supported research has played an important role in the decision to commission this revolutionary treatment, which will have a significant impact on quality of life after a stroke.

Professor Christine Roffe, NIHR National Lead for Hyperacute Stroke Research Centres

- April 2017 NHS England announcement - commissioning mechanical thrombectomy
- Two NIHR-supported studies informed the decision
 - PISTE confirmed the benefit and safety of thrombectomy in the NHS
 - PEARS estimated 8,000 patients will benefit in coming years.

Thrombolysis: “Time is brain”

- Further related NIHR-supported research
 - STABILISE - looking into the efficacy and safety of a new device for thrombectomy
 - PISTEi - will test different imaging strategies to identify patients who are most likely to benefit from thrombectomy

...time is brain. Now that we know that thrombectomy is effective, we need to find ways of ensuring the treatment is given as soon as possible after patients develop symptoms of stroke.

Professor Christine Roffe, NIHR National Lead for Hyperacute Stroke Research Centres

What NIHR offers to SMEs

- Easy and rapid connections to the country's leading experts and research facilities through NOCRI
- Support with study feasibility, set-up and delivery through CRN
- Clinical input into study design
- Steer on technology development to ensure it meets clinical need
- Early go/no go decisions
- Links to non-clinical experts e.g. engineers, statisticians, IT experts, health economists, patient and public involvement (PPI)
- Funding through research programmes
- **Clinical evidence generation throughout the research pathway**



Patients



Funding



Expertise

supportmystudy@nih.ac.uk



Training



Study Support