

Collaboration for Leadership in
Applied Health Research and Care
East Midlands

NHS
*National Institute for
Health Research*

NIHR CLAHRC East Midlands

Industry Strategy 2014 - 2018





1. Introduction

This strategy has been developed to outline CLAHRC EM's commitment to promoting a close collaboration between industry, research and healthcare to support high quality patient care above and beyond what may be delivered by any party in isolation. We recognise that industry is critical to delivering innovation in healthcare and that information received from healthcare is critical for industry to understand and support developments in clinical practice.

We recognise the unique contribution that NIHR CLAHRC EM can make to the local healthcare economy. NIHR CLAHRC EM has a range of internationally renowned leaders in the field of health science covering all of the major areas of chronic disease and public health. It is also at the hub of excellent networks that cross academia, the

NHS and industry. This places CLAHRC EM in a unique position to facilitate effective cross sector working.

CLAHRC EM will maintain and build on the positive relationships that LNR and NDLP predecessor CLAHRCs had with industry. Both organisations proactively engaged with commercial organisations across a range of clinical areas, particularly in diabetes, respiratory disease, mental health, cardiovascular disease and chronic kidney disease. CLAHRC EM will work seamlessly with EMAHSN, universities, other NIHR infrastructure (BRUs, CTUs and Networks) and commercial collaborators across the innovation pipeline, from discovery to adoption.

We need a new relationship with industry based on partnership not just transactional. We will work with

industry to develop a better 'value proposition' for the NHS. Together, we will scope problems and develop solutions to key health challenges.

The Government's 'Plan for Growth' (March 2011) together with two other key publications, 'Innovation, Health and Wealth, Accelerating Adoption and Diffusion in the NHS (December 2011)' and 'Strategy for UK Life Sciences' (Department for Business, Innovation and Skills and the Office for Life Sciences, December 2011) form a comprehensive strategy to transform the UK health innovation and life sciences sectors. Therein, the Department of Health clearly defines the scale of the future challenge together with their vision of how the NHS and Industry should respond. This has been summarised in this document.



2. Background: The Challenge

Throughout its history the NHS has faced increasing demands: a growing population with an extending lifespan, an increase in its own capability fuelled by advances in knowledge, science and technology and ever-increasing expectations from the people it serves (World Class Procurement in the NHS, Department of Health 2012).

We must meet these demands from within our current cost envelope whilst at the same time improving quality. This means that doing more of what we have always done is no longer an option. We need to radically transform the way in which we deliver services. Research and innovation must become core business to meet this challenge.

Searching for and applying innovative approaches to delivering healthcare must be an integral part of the way we

do business Strengthening Leadership and Accountability for Innovation, NHS England 2013). Doing this consistently and comprehensively will improve the quality of care and services for patients. It will deliver the productivity savings we need to meet the growing demand for services and will support the role of the NHS as a major investor and wealth creator in the UK.

NHS success in adopting innovation helps support growth in the life science industries. This, in turn, enables these industries to invest in developing the technology and services the NHS needs for its development. Our ambition is for an NHS defined by its commitment to innovation demonstrated both in its support for research and its success in the rapid adoption and diffusion of transformative, innovative

ideas, products, services and clinical practice. Innovation, Health and Wealth, Accelerating Adoption and Diffusion in the NHS (Department of Health, December 2011).

3. Setting the Context: Building for the future

The environment in which we operate is changing and we must adapt so that we can rise to the challenge. We must capitalise on its strengths: its world-class science and clinical research, talent base of pioneering life science researchers, and the NHS, where discovery can be translated into results for patients. In the future, the NHS will need to play a more active role in realising innovation. It will be the 'pull' behind the industry "push" for new therapeutic interventions. At the heart of this will be the patient. Patients will be offered new choices to participate in the development of novel treatments, with the support of their clinicians. This will mean they gain earlier access to new treatments and improve their chances of recovery. Strategy for UK Life Sciences' (Department for Business, Innovation and Skills and the Office for Life Sciences, December 2011).

The Government recognises these opportunities and challenges and is determined that industry and healthcare/research charities thrive in the UK; researchers and clinicians have a vibrant, exciting and world-class environment in which to work; and patients have access to leading-edge treatments early (Department for Business, Innovation and Skills and the Office for Life Sciences, December 2011).

4. Mission, Vision, Values and Strategic Objectives

This strategy has been developed in line with CLAHRC EM's Mission, Vision, Values and Strategic Objectives as detailed below:

4.1 Mission

Collaboratively generate and apply evidence in prevention and management of Long Term Conditions (LTC) to achieve healthier living for longer.

4.2 Vision

To improve the health of the EM population by carrying out and implementing world class research in prevention and management of LTCs.

4.3 Values

CLAHRC EM operates in line with an agreed set of values, 'PARTNERS'

- P - Patient focused
- A - Accountable
- R - Responsive
- T - Transparent
- N - Novel and Innovative
- E - Excellence
- R - Respect Diversity
- S - Sustainable

4.4 Strategic Objectives

CLAHRC EM has developed the following objectives:

1. Collaboratively co-produce and co-conduct translational research for healthcare improvement
2. Co-produce and enable a sustainable research-receptive culture in partner organisations
3. Increase research capacity across the EM to carry out applied research
4. Increase public engagement and involvement in applied health research amongst all EM communities
5. Sustain and develop successful partnerships across health, industry and academia to improve health outcomes and positively contribute to the local economy

5 National Institute of Health Research (NIHR)

Through the NIHR, the government has committed to working with the life sciences industry to deliver first class clinical research in the NHS. To achieve this, the NIHR is funded to manage a broad research infrastructure including expert individuals, research facilities and technology platforms. In support of the life sciences industry, the NIHR provides dedicated teams through which companies have a direct route to work with the country's leading investigators, research facilities and technology platforms, and the NHS.

5.1 Industry Sectors

CLAHRC EM is required by NIHR to report progress against its strategy for engaging with industry in the following sectors: with

- i. Pharma
- ii. Biotech
- iii. Medtech/devices
- iv. Diagnostics
- v. CROs
- vi. Non-life sciences companies

Industry sectors are described as follows:

Pharma - a company which develops, produces, and/or markets drugs or pharmaceuticals licensed for use as medicinal products.

Biotech – a company which is primarily concerned with the development, production and/or marketing of biological products

Medtech/Device - a company that makes and/or sells medical devices or other healthcare technology products. The term medical devices covers products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability excluding in-vitro diagnostics and software as well as licensed medicinal products.

Diagnostic - a company which develops, produces and markets in-vitro diagnostics. In-vitro Diagnostics are defined as diagnostic tests which are used to analyse a sample taken from the body e.g. blood, urine, sputum.

CRO (Contract Research Organisation) - a commercial organisation contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

Non-life sciences company – a company that is not defined as pharma, biotech, medtech/device or diagnostic according to this guidance e.g. software companies, design companies

5.2 Small and Medium Enterprises (SMEs)

CLAHRC EM is required to report the total number of UK SMEs we work with. This includes contract commercial trials, industry collaborative research studies, other academic commercial research and studies which are under discussion with UK SMEs where a non-disclosure agreement has been signed. SMEs are defined as follows: Headcount<250, Turnover<41m and Balance Sheet Total <£35.2m

5.3 Other

CLAHRC EM is required to report key examples of studies including Contract commercial trials, Industry collaborative research studies and other academic commercial research. We are committed to developing partnerships or studies with industry which lead to further industry, public or charity research funding, including as part of consortia. We will strive to increase the number of agreements we hold with Industry e.g. Non-Disclosure Agreements and Model Trial Agreements, including mCRA and mCTAs

6. What can CLAHRC EM offer Industry?

As a successful and forward looking organisation CLAHRC EM has a comprehensive and extensive offer for potential and existing industry partners. This includes:

- World class NHS active researchers with a track record of leading successful projects and collaborations that have positively impacted on patient outcomes and the health economy. Researchers from CLAHRC EM have successfully collaborated with a range of commercial companies, including Bristol Myers Squibb, AstraZeneca, Sanofi, Lilly, NOVO, Merck and Roche, QbTech Ltd, Buddy Enterprises, Red Embedded Systems Ltd, and Buzz3D Ltd.
- Proactive engagement with commercial organisations across a range of clinical areas, particularly in diabetes, respiratory disease, mental health, cardiovascular disease and chronic kidney disease. CLAHRC EM has already secured approximately £1.2m in agreed funding from industry and commerce.
- CLAHRC EM sits at the apex of a translational pipeline that has the expertise to take an idea from generation to dissemination and implementation in clinical practice. CLAHRC EM works seamlessly with EMAHSN, Universities, other NIHR infrastructure (BRCs, BRUs, HTCs, DECs, CTUs and CRN) and commercial collaborators across the innovation pipeline, from discovery into widespread adoption. The CLAHRC facilitates the development of NHS 'pull' on commercial activity, changing the relationship with industry from suppliers and sponsors to development partners.
- A history of successful product development that includes software to identify patients at risk from disease; education programmes and support tools for patients with health problems.

7. What can Industry Partners offer CLAHRC EM?

CLAHRC EM understands the benefit that industry partners can bring to our work.

The Life Sciences industry is a crucial element of the broader UK health research framework that includes the NHS, government bodies (such as the NIHR that fund research), academia, NHS partners and public and patient involvement groups. The Life Sciences industry employs over 150,000 people in the UK and invests approximately £5billion in research and development each year.

Industry partners provide invaluable resources, intelligence and an in-depth understanding of the overall markets for our innovative research. They often have access to revenue outside of that available to a health research centre as well as commercial expertise from which CLAHRC EM can benefit.

Industry also plays a crucial role in developing innovative solutions for patient management. Collaboration between industry and the CLAHRC will enable suitable technologies to be brought into the NHS.

Finally, we understand the benefits offered by joint applications for public funding with industry partners where we can carry out mutually beneficial research in line with our strategic aims. We know that some potential industry partners, particularly within the SME, Device and Diagnostics sectors may have limited funds for companies to access through their existing businesses. CLAHRC EM can help with joint applications to funding streams such as NIHR, Horizon 2020 and the Technology Strategy Board to support the development of cutting edge solutions to current and future health care problems and priorities.

8. How has CLAHRC EM engaged with Industry to date?

8.1 Nottinghamshire, Derbyshire and Lincolnshire (NDL)

- CLAHRC NDL's work with industry supported and piloted work that led to the successful NIHR Mindtech HTC application, the only national NIHR funded centre dedicated to working with industry on the use of digital health care in mental health and dementia.
- The "Clinical utility and economic case of QbTest in ADHD" project is working closely with QbTech Ltd. QbTech Ltd, a small to medium private healthcare company specialising in ADHD assessments, is providing £120,000 in-kind support, including test equipment and licenses.
- The MOSAIC study team worked in partnership with QbTest to develop and evaluate a computerised continuous performance test for ADHD
- The Upper Limb study collaborated with 3 industrial partners to develop rehabilitative technology games (Saebo, Vivo Medical Devices, IM ABLE)
- Johnson and Johnson already work with IPS in the USA; discussions regarding extending the current programme across the UK are ongoing.
- The Stroke Rehabilitation Theme worked with the Nottingham New Business Accelerator Programme to provide workshops around unmet clinical need as a focus for innovative start-up companies and entrepreneurs
- The Older People's Theme worked with Glaxo Smith Kline to support the roll out of fracture liaison services to reduce incidence of second fractures in an already vulnerable population

8.2 Leicestershire, Northamptonshire and Rutland (LNR)

CLAHRC LNR successfully engaged and worked collaboratively with industry across all of its themes throughout the funding period and was able to secure funding support for a range of studies and other activities. Highlights included:

- NB Group, which is a marketing and communications group, are working with us on our "Healthy Schools Programme" project provided £20,000 in matched funding support.
- The Walking Away from Diabetes study is working closely with GE Health Care which has installed a state of the art dual-emission X-ray absorptiometry machine for use on this study. To date over 300 individuals have been scanned. In addition, ongoing collaboration with Unilever (£150,000) has resulted in the analysis of novel biomarkers through the Walking Away study
- An ultrasound scanner for Use of Dynamic Plaque Indices was supplied to our Reduce Stenosis Risk study below retail price saving us an estimated £90,000

- Worked closely with Unilever across a number of studies who provided £157,000 to support our work.
- Researchers at the Leicester Diabetes Centre are working on an international study, funded by Novo Nordisk, entitled Diabetes Attitudes, Wishes and Needs (DAWN2) which is the largest ever global study on the unmet needs of those with diabetes and is a collaboration between the International Diabetes Federation (IDF), the International Alliance of Patient Organizations (IAPO), the Steno Diabetes Center and a range of national, regional and global partners.
- Researchers from the Rehabilitation Theme are members of a national consortium involving the pharmaceutical sector and academia - COPD MAP (MRC, Academia and Pharma). The consortium comprises four work packages and is jointly funded by the Medical Research Council and the pharmaceutical industry. Its aim is to secure more rapid and effective drug treatment for COPD. The researchers are leading two trials in Work Package Four and Novartis and Glaxo SmithKline are represented on the work package steering committee. Data and samples from our REACH trial have been shared with the consortium and made available for analysis.
- Baxter Healthcare funded a CKD nurse (value >£110,000) to work with Leicester City and West Leicestershire CCGs to implement a CKD management programme based on the IMPAKT tool used in the PSP-CKD study. The IMPAKT tool has also been presented to the Association of Renal Industries.
- Merck, Sharp and Dohme provided support to the value of £75,000 to the Pharmacy based screening for high risk Individuals using Stepwise Methods (PRISM) study that enabled the study to recruit and train pharmacists and their staff.
- Pharmaceutical companies continue to provide financial support for the Leicester Diabetes Centre's primary care involvement groups; Diabetes Update and the Diabetes and Cardiovascular Interest Group. Their support helps to bring together researchers and the primary care community.

8.3 Current Industry Relations in CLAHRC EM

Company	Amount of Funding	Project Funded	Theme
QbTest Ltd	£123,767	QbTest	EMH
MSD	£15,000	Ambulance Hypo	COPSS
Janssens	£20,000	CVD Risk Prevention	PCD
Boeringher Ingelheim - Lilly	£10,000	GP Prompt	MCD

There is clear evidence of CLAHRC EM developing and extending positive relations with industry. A number of existing CLAHRC EM projects have attracted investment from industry most notably the QbTest project in the EMH theme which has attracted funding from QbTest Ltd for £123,767, the Ambulance Hypo study in our COPSS Theme which has received £15,000 from MSD and CVD Risk Prevention in our PCD Theme which has received £20,000 from Janssens. Finally, Boeringher Ingelheim - Lilly are funding £10,000 for our GP Prompt study in our MCD theme which will pay for the educational element of the study.

We are also in the process of formalising an industry partnership arrangement between project and corporate social responsibility arm of Nike (Designed to Move) for our Healthy Schools project in the PCD theme. If feasible, in kind contribution or marketing time will be given by DTM to help with the development of intervention resources. DTM will help disseminate the finalised teacher resource (e.g. web platform, training materials) through 'Active Schools' documents, Facebook page, DTM website etc. DTM, where appropriate, may promote and/or facilitate discussions with their wider network of stakeholders and policy makers.



9. How will CLAHRC EM engage with Industry going forward?

NIHR CLAHRC EM has already shown that it views developing positive and successful partner relations seriously by appointing a high profile and senior Director of Partner Relations to build partnerships with industry. The Director of Partner Relations has responsibility for the delivery of this strategy and will act as a central point of contact for information exchange. This will include access to model agreements, costing templates and directories of expertise. Our Theme Managers will act as a conduit between the Director of Partner Relations and individual research teams.

CLAHRC EM makes the following commitments to ensure the delivery of our Industry strategy:

- We will establish a 'single point of contact' for each industry partner. CLAHRC EM will work closely with named contacts to determine how CLAHRC EM can most effectively engage with and involve our partners in our programmes of work.
- We will develop a model contract for working with industry partners based on mICRA developed by the NIHR as a model contract.
- We will review our existing and proposed projects to ensure that we are maximising potential partnerships, actively seeking new opportunities where there are perceived gaps.
- We will develop a brochure for industry outlining the NIHR CLAHRC EM 'offer' in terms of our academic specialisms and experience and our ability to act as a 'gateway to the East Midlands health economy. This brochure will be available for all existing and potential industry partners as well as NOCRI and any other organisation that can assist us in developing and extending positive working relations with industry.
- We will evaluate all partnership arrangements with industry partners as part of the general evaluation of our implementation and partnership model which is based on co-production.

In addition, CLAHRC EM has developed a 'Getting Involved' leaflet. This is now available on the CLAHRC EM website and has been made available to partners via our July newsletter. The document provides information related to capacity development, research support and evaluation, patient and public involvement as well as highlighting the vital role that industry plays in driving forward the research agenda.

10. Intellectual Property

The NHS Trusts and Universities involved in the CLAHRC have arrangements in place to access appropriate support for IP exploitation. CLAHRC EM will work with IP specialists and commercial partners to maximise the IP opportunities available. All relations with industry in this area will be conducted in an open and fair manner to ensure mutual benefit which the CLAHRC believes is the basis for all collaborative working.

However, we understand that our industry partners will also have considerable IP expertise which we may be of mutual benefit.

11. Collaborative working with EMAHSN

CLAHRC EM will build on existing industry relationships and develop new ones across its research themes. An important component of the CLAHRC's industry engagement strategy will be its relationship with the EMAHSN. The AHSN has established an Industry Advisory Panel with representatives from organisations including ABPI, ABHI, Medilink East Midlands, BIVDA and local SMEs. The EMAHSN Commercial Director will work within CLAHRC themes to develop joint CLAHRC/AHSN/commercial partnerships. This joint working will ensure effective and rapid spread of innovative practice.

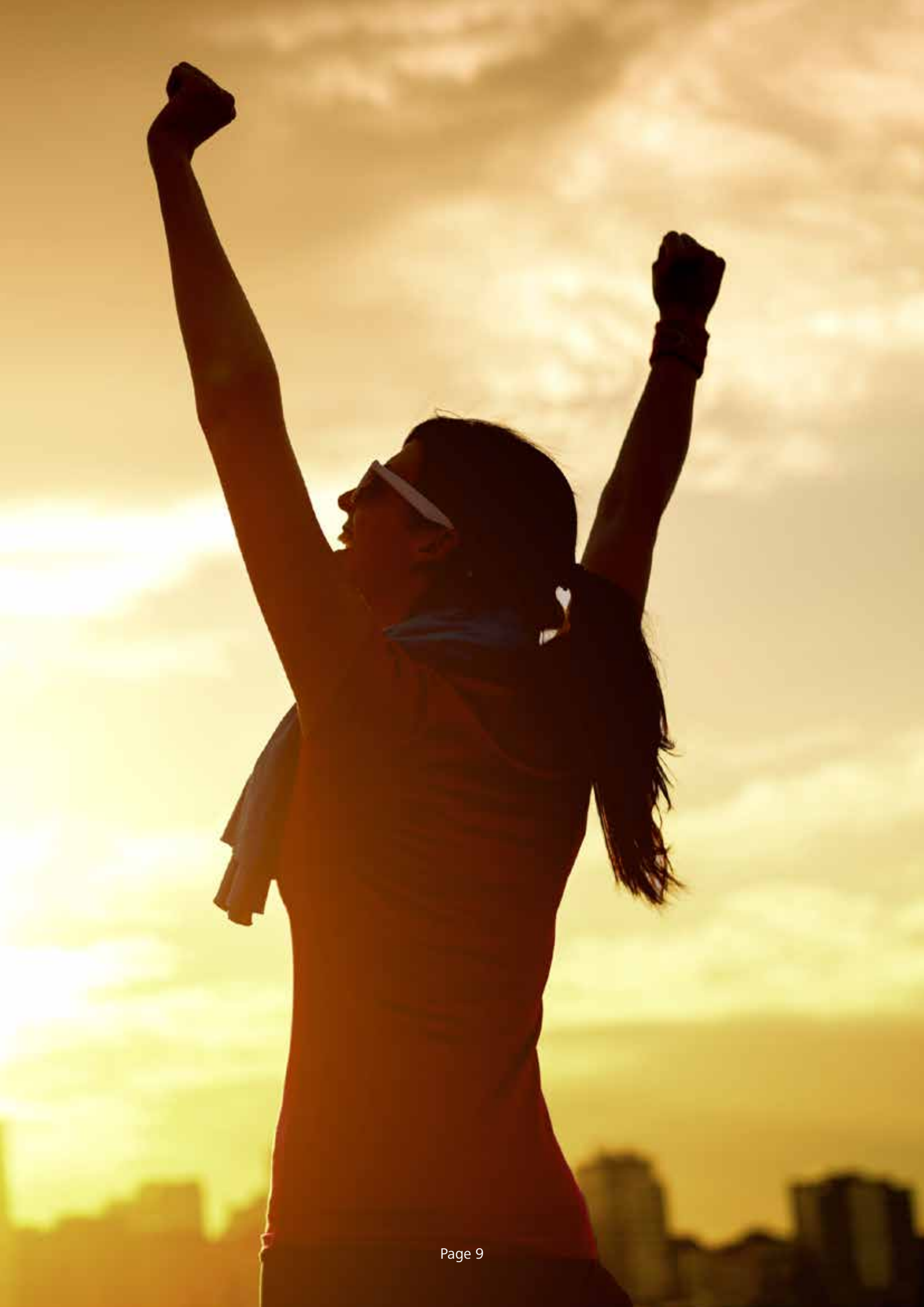
The CLAHRC will also work with the AHSN to create new industry focused roles, building on previous local experience of developing NHS-academic boundary spanning roles. Supported by both EMAHSN and EMCLAHRC, these individuals will accelerate the flow of information

between industry, academia and the NHS. They will also increase the commercial skill level within the NHS and academic communities. By spanning professional boundaries, the AHSN and CLAHRC will be able to identify unmet needs, develop new commercially relevant research questions and test and apply commercially developed innovations.

The Director of Partner Relations will lead this cross co-ordination of joint working in this area with EMAHSN.

12. Monitoring and Reporting

Progress against this strategy will be reported to the CLAHRC EM Governance Board on a quarterly basis as well as forming part of our Annual Report.



13. Glossary of Terms

- ABHI Association of British Healthcare Industries
- ABPI Association of the British Pharmaceutical Industry
- AHSN Academic Health Science Network
- BIVDA The British In Vitro Diagnostics Association
- BRC NIHR Biomedical Research Centre
- BRU NIHR Biomedical Research Unit
- CLAHRC Collaboration for Leadership in Applied Health Research and Care
- CLAHRC EM Collaboration for Leadership in Applied Health Research and Care East Midlands
- CRO Contract Research Organisation
- CTU Clinical Trials Unit
- DEC NIHR Diagnostic Evidence Cooperative
- EM East Midlands
- EMAHSN East Midlands Academic Health Science Network
- HTC NIHR Healthcare Technology Cooperative
- IP Intellectual Property
- LNR Leicestershire, Northamptonshire and Rutland
- mCTA model Clinical Trial Agreement
- mICRA model Industry Collaborative Research Agreement
- NDL Nottinghamshire, Derbyshire and Lincolnshire NOCRI NIHR Office for Clinical Research Infrastructure (NOCRI)
- NIHR National Institute for Health Research
- SME Small and Medium Enterprises

**“Healthier living
for longer”**

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