

THE NEXT WAVE
OF HEALTH
INNOVATION:
POWERED BY
PARTNERSHIPS



Lilly



Public Policy Projects

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FOREWORD

Rt. Hon. Stephen Dorrell,
Chair, Public Policy
Projects

The UK is at the forefront of a wave of scientific progress with world-class universities, talented researchers and a flourishing life sciences sector. The range of treatment options is ever expanding, with not only new medicines, but also new digital and wearable technologies to monitor health. Alongside this, new 'omics' from genomics to proteomics are rapidly advancing, generating large amounts of data which needs to be collated, interpreted and used to further benefit research.

Over recent months, Government have published some important blueprints for the health service, in particular the Life Sciences Industrial Strategy and the NHS Long Term Plan. Together they set out a bold and ambitious vision for the future of the NHS and the biosciences sector. The NHS cannot achieve these goals alone, and there needs to be true partnership and collaboration between the health service, industry and academia to overcome the challenges faced by the health system and establish the UK as a world leader in healthcare. Examples of cross-sector collaboration have demonstrated that combining expertise, experience and resource has the potential to improve patient care, drive more efficient use of NHS resources and support the UK's life sciences sector.

This report outlines many of the challenges and opportunities of this healthcare revolution and identifies where the Government and all stakeholders should do more to reduce the barriers to partnership working and foster collaboration. All stakeholders must acknowledge and act on these recommendations as a matter of urgency. Only then will patients truly benefit from the next wave of innovation.

Stephen Dorrell

Lilly has an 85-year heritage in the UK of which we are exceptionally proud. London was host to our first office outside of the United States of America in 1934, closely followed by the company's first overseas manufacturing site, which opened in Basingstoke in 1939. Lilly's research facility at Erl Wood, just outside of London, opened in 1967 and has grown to become Lilly's Global Centre of Excellence for neuroscience research. Over the past decade we have spent over £1.9 billion on our UK research operations and today we are conducting more than 60 clinical trials across 118 UK study locations, in areas including oncology, diabetes, immunotherapy, pain, and neurodegeneration. Our work in the UK has been awarded both the Prix Galien and the Queen's Award for Innovation. Around the world, we continue to invest in innovation outside of our labs to access the newest technology, ideas and pathways that will deliver future treatment options for patients. Our focus on innovation is undiminished, and we are committed to bringing life-changing medicines to those who need them by launching at least 20 medicines in the 10 years from 2014 to 2023.



FOREWORD

Dr Arash Tahbaz,
Senior Medical Director,
Lilly UK

New medicines bring new hope. Lilly has always pushed the boundaries of science to make conditions that are incurable today, treatable tomorrow. You could say its in our DNA.

The promise of science to change people's lives has never been greater than today. Recent progress in understanding biology, including the unlocking of the human genome, has unleashed new insights, allowing scientists at Lilly and our partners more power and precision to treat disease.

As Senior Medical Director at Lilly UK, and a former Consultant in the NHS, I want to make sure that UK patients can realise the benefits of the newest medicines. Our vision is to change patients' expectations, to provide a new sense of hope for people suffering from some of the world's most debilitating diseases.

This report explores how scientific discovery must be matched with system change to ensure the opportunities in medical innovation can be realised, building on the work of the NHS Confederation and the Association of the British Pharmaceutical Industry (ABPI) to support cross-sector collaboration and partnership working between academia, industry and the NHS. Realising the significant potential that collaboration can bring, this report delves deeper into how partnership working can continue to drive the next phase of research and innovation; ensure the UK has the capability, skills, and talent to progress medical innovation; and help ready the healthcare system to embrace innovation at every stage of the patient journey.

Lilly is keen and ready to work with the Government, the NHS and all partners, to ensure the system is ready to face the challenges of the future. We have the same goal in mind: to deliver the best possible healthcare for patients. We believe that collaboration and partnership between the NHS, industry, and academia at every stage of the innovation journey, from pre-clinical research to system change, is essential to discovering and developing long term solutions that support a twenty-first century health service in delivering innovation solutions for patients at its heart.







FOREWORD

**Piers Ricketts, Chair,
The AHSN Network,
Chief Executive,
Eastern AHSN**

Healthcare systems throughout the world are facing the same series of complex issues: an aging population with a corresponding rise in complex co-morbidities, increasing consumer expectations and flat or declining budget to fund our health and care. At the same time advances in medicines and technology are enabling us to solve some of these issues but they are frequently developed in isolation from those at the front line in the delivery of care.

The AHSN Network was established by the NHS to meet this need by convening all partners in the health and care sector to speed the adoption of proven innovations with the belief that citizens, academia, health services, and industry will achieve more working together than they will in isolation. Our purpose is to turn great ideas into positive health impact. We do this by helping innovators navigate complex systems, generate value propositions, and convene stakeholders to overcome challenges together.

Since our formation in 2013, the AHSN Network has demonstrated that by convening the right people we can create the right conditions to diffuse great ideas across health and social care to improve patient outcomes and support the message that this report puts forward, that the UK has a unique opportunity to drive forward medical innovation by building bridges across academia, industry and the NHS. We have already seen a rise in the number collaborations between industry the NHS and the AHSN Network has recently signed a Memorandum of Understanding (MoU) with the Association of the British Pharmaceutical Industry (ABPI) to govern how we work together.

However, in order to deliver the recommendations of the NHS Long Term Plan, academia, industry, and the NHS need to collaborate on a greater scale than has previously been the case. This report makes some interesting recommendations, which need to be reflected on with wider stakeholder input. We hope that it will encourage a conversation about what can be done to foster an environment that is more consistently supportive of partnership working on the challenges and opportunities we face if we are to make the most of new scientific opportunities. Only by working more effectively together can we create a culture where good ideas can come alive and are spread at pace and scale so that our citizens can benefit from the next wave of innovations.

However, in order to deliver the recommendations of the NHS Long Term Plan, academia, industry and the NHS need to collaborate on a greater scale than has previously been the case.

Piers Ricketts

**FROM ALEXANDER FLEMING'S
DISCOVERY OF ANTIBIOTICS TO
UNDERSTANDING THE STRUCTURE
OF DNA, THE UK HAS A LONG
AND DISTINGUISHED HISTORY
IN DRUG DISCOVERY AND HAS
ESTABLISHED ITSELF AS A
WORLD LEADER IN PRODUCING
EFFECTIVE AND INNOVATIVE
TREATMENTS.**

The UK is unique in being able to draw on the country's world-class universities, a strong pharmaceutical and biosciences sector, and one of the largest single healthcare systems in the world, with anonymised data representing 65 million people¹; assets that together make the UK a world leader in life sciences.

By combining our unique combination of academic, NHS, and industry assets, we can continue to build on our strengths and maintain our position as a global life sciences hub. The benefits of combining these strengths are clear; excellence in research leads to improved medical care, attracts global investment into UK research and development (R&D), and improves healthcare services.

This ecosystem could create the opportunity for the UK to deliver truly innovative medical research at a time of unprecedented scientific opportunity. We are on the cusp of a scientific revolution, with new medical breakthroughs constantly around the corner. We have witnessed the realisation of highly targeted, personalised medicines. Gene editing is now within the realm of the possible. We have seen the first CAR-T therapies be made available for UK patients, allowing people with late-stage cancer to harness their own natural defences. We are seeing the rise of digital health; from health apps to the use of wearable technologies that can monitor vital signs and environmental conditions, such as blood glucose levels and air quality.





Taking advantage of these opportunities will mean overcoming substantial challenges in the years ahead:

- **Demand for healthcare services** has been growing steadily since the NHS was first established more than 70 years ago, with no sign of slowing down. Advances in medicine and healthcare mean that the demand to treat illnesses such as tuberculosis, and infection has been replaced by the need to support people living with long-term conditions, such as diabetes, cancer, dementia, and auto-immune conditions. The combined impact of treating long-term conditions is a significant driver of demand, accounting for approximately 50 per cent of all GP appointments, 64 percent of all outpatient appointments and over 70 percent of all inpatient bed days. Treatment and care for people with long-term conditions is estimated to cost £7 in every £10 of total health and social care expenditure.² These costs and demands on the NHS continue to rise; the number of people with more than three long-term conditions rose from 1.9 million in 2008 to 2.9 million in 2018.²
- **Workforce instability**, caused by high turnover and low recruitment, further hampers the UK's ability to meet demand. There were nearly 94,000 full-time equivalent staff vacancies in hospital and community services between July and September 2018. This equates to a shortfall of 8%, representing around 1 in 12 posts.³
- **Access to the latest innovations** remains a pressing issue. The UK has historically lagged behind international peers on providing people with access to new, innovative treatments. This disadvantages people in need of life-changing treatments, and impacts the country as a whole by reducing our global competitiveness. Substantial efforts have been made to speed the delivery of the newest treatments to patients, such as the Early Access to Medicines Scheme and Accelerated Access Collaborative, but 2019 Office for Life Sciences (OLS) data revealed that the situation remains unresolved.⁴ UK uptake of approved medicines in the first year after launch stood at 21% of the median uptake of comparator countries, despite commitments in the Voluntary Scheme for Branded Medicines Pricing

and Access (VPAS) for the UK to reach the upper quartile of uptake for the five highest health gain categories during the first half of the five-year scheme.

- **NHS budgets have been constrained** in recent years, with many NHS Trusts reporting a deficit.⁵ In 2018, the Government announced an additional £20.5 billion would be made available for the NHS in England by 2023/24, which is the equivalent of a 3.4 per cent increase per year. However, inflation is anticipated to be approximately 2.9 per cent by 2020/21, consuming much of the additional funding on offer leaving a net increase of just 0.5%.

Collaboration is vital to overcome these country-wide challenges and establish an ecosystem in which expertise and resources can be pooled to develop new medical innovations, harness the strengths of different stakeholders, and ensure effective new treatments are taken up swiftly throughout the NHS to benefit people across the UK.

The uncertainty caused by Brexit makes the need for collaboration more urgent than ever. If the UK is to maintain its world-leading position at the forefront of global R&D, we must harness the power of working in partnership. This will support the Government in reaching its targets for R&D investment, encourage economic growth, and improve health outcomes. Breaking down barriers between universities, life science companies, and the NHS to unite our combined expertise will be essential to seizing new scientific opportunities and positioning the UK as one of the best countries in the world for medicines innovation.

This paper serves as Lilly's contribution to the debate and seeks to explore opportunities for partnership working, across three broad themes:

- Partnering for research
- Partnering for capability development
- Partnering for system change

Case study examples of effective partnerships have been included where appropriate. While far from being an exhaustive list, we hope these act as an effective catalyst for debate and demonstrate the power of effective partnership.

CHAPTER 1

PARTNERING FOR RESEARCH

The world's most challenging medical conditions, such as Alzheimer's disease and cancer, will not be overcome by one person, organisation or company alone. To develop medical innovation and breakthrough technologies, we must combine our resources and knowledge, leverage the best available data, invest outside of our own laboratories and walls, and share the considerable risk, to have the best possible chance of discovering the medicines we need for the future. Collaborating in medical research can include multiple partners, and take many different forms, including:

Pre-competitive research collaborations

Public-private partnerships

NHS data research collaborations

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"A key element of our strategy is to invest in innovation outside of our labs to access new technology, ideas and pathways. We're increasing our access to new disease targets, treatment modalities and discovery tools. Our acquisitions of Loxo Oncology and ARMO BioSciences, and our numerous collaborations with external partners, will help us continue to bring in new technologies and new target identification strategies."⁶

Eli Lilly and Company, 2018 Integrated Summary Report

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Pre-competitive research collaboration

The UK's universities are world-leading; their research capabilities stretch the boundaries of science. This capability has been long-recognised by industry, with academic-industry collaborations doubling between 2012 and 2016, growing from 12,672 to 25,962 and almost half of those collaborations in 2016 were in life sciences.⁷ Pre-competitive collaborations facilitate the sharing of knowledge, expertise and resources, without the burden of commercial sensitivities. Under such partnerships, results and data are shared with the understanding that improving the knowledge base will benefit the entire research community.

Pre-competitive projects are an exciting opportunity for the early stage development of new therapies, by creating a "front end" for drug development that provides academics with access to new resources, such as proprietary design tools, and can help industry de-risk projects by providing better understanding of a disease, pharmacology and disease target discovery. While intellectual property (IP) rights may still remain a concern for some researchers, these protections can be agreed up-front, and successful collaborations can often transition into successful commercial partnerships.

Pre-competitive collaborations can significantly improve our understanding of a disease, opening up new avenues for the discovery and early stage development of innovative therapies in areas of high unmet need. In addition, pre-competitive collaborations can be scaled to respond to major societal challenges, such as dementia, diabetes, or other chronic and multi-morbid conditions, in which talent and resources are targeted towards developing therapies for disease areas that impose the most significant burdens on society.

The effective sharing of knowledge, skills and expertise reduces drug development attrition (i.e. unsuccessful drug development projects) and de-risks translational research to increase the chances of finding a successful treatment. In oncology, decades of sustained

investment in clinical research has transformed our understanding of cancer, which is now known to comprise numerous different disorders. The recent US Cancer Moonshot Initiative pooled resources across pharmaceutical and biotechnology companies, academic centres and other experts, and targeted funding to incentivise cross-sector working and accelerate the development of innovative new treatments.⁸

While the societal cost and burden of cancer is comparable to Alzheimer's disease, life sciences companies are studying 20 times more potential treatments for cancer than Alzheimer's.⁹ With the number of people living with dementia set to grow exponentially, and no disease modifying treatment yet available, the search for a dementia cure will hinge on our ability to fund, resource, and organise research activity at a much greater intensity.

Initiatives such as the UK's Dementia Discovery Fund (DDF) represent a significant step in the right direction. Pooling resources and expertise against a shared goal has been a driving force in promoting cross-sector collaboration and enhancing funding opportunities in the field of dementia research. Dementia is by no means the only complex health challenge we face as a society, and a similar approach may be just as valuable in other areas of high unmet need. We believe further opportunities to mobilise the

ingenuity and expertise of our life sciences sector in a co-ordinated, ambitious and collaborative way should be explored to accelerate the delivery of transformational therapies in areas deemed to be key national strategic priorities. Major health challenges such as diabetes are estimated to cost the NHS upwards of £10 billion each year and warrant particular attention in terms of improving cross-sector collaboration and allocating necessary funding to address this significant societal burden.¹⁰

£10b

Diabetes is estimated to cost the NHS upwards of £10 billion each year



CASE STUDY

Dementia Discovery Fund (DDF)

The DDF is the world's largest venture fund focused entirely on discovering and developing novel therapies for dementia, including Alzheimer's disease. This is a unique approach to medicines development, supported by the UK Government's Department of Health and Social Care, Alzheimer's Research UK, Lilly, and a number of other global pharmaceutical companies. For Lilly, participating in the DDF builds on the company's own 30-plus year commitment to research in Alzheimer's disease.

The DDF has raised a total of £250 million to develop novel disease-modifying therapeutics for all forms of dementia. It has a mandate to validate novel hypotheses and expand the breadth of targets and mechanisms in development for dementia over the 15-year life of the fund. This enables the DDF to invest in truly novel, early-stage projects starting from target identification, and explore novel biological insights for translation into disease-modifying drugs.

Consortium (SGC), a not-for-profit partnership formed in 2004 to determine the three-dimensional structures of proteins of medical relevance, provides an excellent example of how this model can support research through partnerships across sectors.

CASE STUDY

Structural Genomics Consortium (SGC)

The SGC is an international, not-for-profit public-private partnership, consisting of members from academia, industry, and charitable organisations. These organisations work collaboratively to study target proteins of biomedical importance. Any data generated on these targets is made public via an open source approach, which enables widespread dissemination of the science and advances the drug discovery process.

To date, the SGC's findings have included determining the functional characteristics of TNIK protein, a schizophrenia target, and the characterisation of a range of potential drug targets of relevance to cell programming and regenerative medicines.

Recommendation: The Government should explore opportunities for establishing new pre-competitive consortia (such as the DDF and US Cancer Moonshot Initiative) in which resources of pharmaceutical, biotechnology companies, academic centres, and experts are pooled, with funding targeted to incentivise cross-sector working and accelerate the development of innovative new treatments. This targeted approach should be implemented in areas of high unmet need and where the societal burden is acute and set to grow exponentially.

Public-Private Partnerships

Public-private partnerships are increasingly used to distribute the risk involved in research across multiple partners and sectors. These long-term collaborative arrangements offer a significant opportunity in underfunded disease areas, and can help to bring together early stage, not-for-profit, and industry research to drive new drug discoveries. The Structural Genomics

The Innovative Medicines Initiative (IMI), is the world's largest medical research public-private partnership and flagship of health research under Horizon 2020. Funded jointly by the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA), the IMI provides a key mechanism for cross-sectoral collaboration in Europe. From the total budget of €5bn, more than a quarter of funding has gone to the UK, making it the largest single recipient among EU states. Around one quarter of the 3,000 academic articles produced by IMI research projects involved UK scientists.

CASE STUDY

Lilly and the Innovative Medicines Initiative (IMI)

The EU's IMI is the largest biomedical public-private partnership in the world. Lilly is currently participating in 33 projects, including leading or co-leading eight projects, covering neurodegeneration and pain, diabetes, oncology, immunology, translational safety, and digital health. The total spend on these projects will be €665 million; including a €32 million contribution from Lilly in funding and benefits.

A significant part of Lilly's contribution is made by our UK-based scientists. As only 15 per cent of IMI project contributions can come from outside the EU, the UK's status as part of the EU is vital to enabling UK-based pharmaceutical companies to effectively participate in these projects. Post-Brexit, the UK's participation would be limited by the 15 per cent "non-EU" limit.

It remains to be seen how the UK will be involved in future EU research collaboratives after Brexit. The Government's guarantee of funding for UK Horizon 2020 bids submitted before Brexit, and all successful UK bids where the UK is able to participate as a third-country between Brexit and the end of 2020, is welcome and provides some certainty in the event of a no-deal exit from the EU. However, access and participation in successor programmes, where collaboration across Europe is possible and UK is able to continue to attract talent is vital.

The EU's recent legislative proposal on Horizon Europe (the successor of Horizon 2020) set out a clear route for the UK to participate as an 'associated country'¹¹. While this would be a positive step to retaining some level of participation, it is important to note that the UK is the second largest recipient of Horizon 2020 funding.¹² Under this new arrangement, the UK would no longer be able to receive funds greater than it has paid in, and as an 'associate country' would be prevented from leading any research projects that receive IMI funding. To maintain the UK's leading science base, the Government should seek to secure commitment that the UK will be able to participate in Horizon Europe as an associate country, at minimum. While the UK will no longer benefit from the full opportunities for research and collaboration provided by membership of the EU and Horizon Europe, associated

membership will ensure UK researchers and industry have some level of certainty in terms of access to networks, collaborations and funding pools.

Recommendation: The UK's domestic science base has benefited from IMI and Horizon 2020 funding, both financially, through access to collaborative consortia, and in terms of attracting talented researchers. The UK must remain at the heart of the EU's integrated research ecosystem, including continued participation in Horizon Europe.

Maintaining the attractiveness of the UK as a place to conduct clinical research

Today, the UK is considered a leader in clinical research. Our country is home to one of the largest development pipelines in the world, including 500 new biotechnology-based drugs and 600 innovative pharmaceutical product candidates¹³. The UK is also a key partner in the EU research landscape, contributing to almost 20% of the total research work carried out within EU health programmes between 2006 and 2017.¹³

The uncertainty caused by Brexit is of significant concern for the future of the UK's clinical research environment. If the UK wishes to maintain its position as a global leader in medicines discovery, the Government must act to ensure the UK continues to provide a policy environment that supports R&D activities, and the development of partnership models that can unlock medical innovations.

Long term funding initiatives for the research environment

The Life Sciences Industrial Strategy (LSIS) recommended increased funding for basic science in order that the UK is in line with the upper quartile of OECD countries. To that end, the Prime Minister's announcement on increasing investment in research and development is welcome, especially given central Government research funding is already lower than comparable countries.¹⁴ While the Government has set an ambition to increase overall R&D investment across all sectors to 2.4 per cent of GDP by 2027, (encompassing public and private investment), this commitment remains a modest one when compared to the 3 per cent EU-wide target.¹⁵

The Government's commitment to increase investment in UK R&D is welcomed but being a world-leader means setting targets that are more ambitious. To create a supportive environment for future life sciences R&D investment, Government should outline a long-term road map, demonstrating how the 2.4 per cent target can be achieved by 2027, with clear outcome measures and accountability clearly owned by the relevant Government departments at Cabinet level. It is well-established that public investment drives increased private investment. Government analysis previously demonstrated that an extra £1 of public spending gives rise to an increase in private funding of £1.36 over a ten-year period, therefore increases in public investment will be in vital in enabling Government to achieve their own target.¹⁶ Long-term R&D investment from Government will provide the industry with the certainty it needs to make long-term investment decisions, enhancing the UK's attractiveness and providing further opportunity for public-private partnerships. In addition, implementation of the Life Sciences Industrial Strategy should be committed to in full to support the ambitious goals for clinical trials set out in the strategy, linking R&D to job creation and economic growth.¹⁷

Recommendation: The Government should outline a long-term budget for public investment that demonstrates how the 2.4 per cent target can be achieved, with clear outcome measures and accountability for delivery owned by the relevant Government departments at Cabinet level. Long term R&D investment from Government will provide the industry with the certainty it needs to make long-term investment decisions, enhancing the opportunity for public-private partnerships.

Regulation of clinical trials at an EU level

UK clinical trials are currently regulated by the EU Clinical Trials Directive, which was transposed into law by the Medicines for Human Use Regulations (2004). The EU has subsequently legislated to change the Clinical Trials Directive to the EU Clinical Trials Regulation (CTR). While this came into force in 2014, it does not yet apply to member states.

The UK participated in developing the new regulation, which has been widely welcomed by Europe's research sector, including academia, medical research charities and industry. Once adopted, it will allow for a streamlined application process, harmonised assessment procedure, a single portal for all EU clinical trials, and simplified reporting procedures, including for multi-Member State trials.

If there are delays in the implementation of the CTR, so that it happens after 2020, it will impact on the UK's ability to participate post-Brexit, particularly affecting the UK's access to the shared central data portal and single assessment model, both of which would require a negotiated agreement on UK involvement. To continue to participate in EU collaborations, it is vital that the UK remains aligned with the EU CTR. This is particularly important for research into rarer conditions, where the required patient pool cannot be found in the UK alone. While there are potential partners across the world, our closest partners in so many ongoing collaborations are EU member states¹³.

Recommendation: It is vital that the UK remains aligned with the EU CTR, in order to ensure a streamlined and efficient regulation process, and support partnerships with EU member-states.

Regulation of clinical trials at a UK level

To maintain the attractiveness of the UK as a global hub for medicines research, the development of agile clinical trial regulations and processes must remain a key area of focus.

The Health Research Authority (HRA) should be commended on the advances made in reducing trial approval times.

In October 2018 a new standardised, national approach to NHS clinical trials was launched, to improve consistency and reduce unnecessary delays to study set-up. However, multi-site trials remain a challenge in the NHS, as this not consistently adhered to.

Recommendation: As of October 2018, all NHS Trusts and life sciences companies are mandated to use an unmodified model site agreement to establish clinical trials. This needs to be adhered to in full to reduce unnecessary delays to study launches and support efficient multi-site trials.

Role of phase 0 studies in medicines research

One of the biggest hurdles in the drug development process continues to be the difficulty of demonstrating efficacy of novel therapeutics, which require effective translation from the pre-clinical to clinical research. To enhance the UK's offering as a centre for R&D, greater support could be established to facilitate the use of phase 0 studies. While not used widely, phase 0 studies are an important tool for medical researchers, as they can help evaluate how a drug will respond in a very small

sample of patients. This process may help avoid the delay and expense of finding out years later, in phase II or even phase III clinical trials, that the drug does not act as expected to.

The ability to conduct phase 0 trials would create an attractive platform for industry to partner with academia and the NHS. All parties involved in the research development process from academia, the NHS, industry and research bodies such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR) should work together to consider how phase 0 trials could be implemented in the UK.

Recommendation: All parties involved in the research development process from academia, the NHS, industry and research bodies such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR) should work together to consider how phase 0 trials could be implemented in the UK.

NHS-data research collaboration

Innovators are increasingly turning to real-world evidence (RWE) to understand how medicines perform after the clinical trials have ended; building a broader and deeper data set that in turn represents a significant opportunity to improve patient outcomes and the sustainability of health systems. Definitions of RWE vary, but a commonly held view is that RWE is data obtained outside the context of randomised controlled trials (RCTs) generated during routine clinical practice.¹⁸

Healthcare professionals (HCPs) can leverage anonymised data to review the real-world clinical value of drugs and patient outcomes in order to prescribe the most appropriate treatment for individual patients, based on their individual characteristics and treatment responses. The life sciences industry can use RWE to better direct drug discovery efforts and reduce both R&D failure rates and attrition of developmental molecules by enabling stratification of patients and disease, identification and verification of targets, development of biomarkers to identify appropriate treatments for patients, and the development of proof of concept mechanisms.

Beyond the drug discovery process, around the world RWE is also being used to explore the potential for outcomes-based payment models, sharing the cost of new medical innovations based on the outcomes they achieve. In addition, regulators are increasingly accepting RWE as a means of documenting a product's safety or supporting effectiveness data. With the development of accelerated access and adaptive pathways, the use

CASE STUDY

Research Collaboration between Lilly and the University of Surrey

In 2014, Lilly and the University of Surrey began a long-term research partnership to analyse the management of type 2 diabetes; aiming to provide insight into how optimum glycaemic control can be achieved and other health outcomes improved.

The study uses RWE to seek answers to the role and timing of injectable therapy, the factors that impact adherence to prescribed medicines, and the pattern and rationale of therapy following diagnosis. Using a mixed methods approach of targeted focus groups, simulations, and a larger scale consensus survey, the study explored the patient and clinician perceptions regarding the initiation of injectable therapies, and the context within which these decisions are made.

The study identified several barriers to the initiation of injectable therapy, alongside potential facilitators, including greater support and education for people with type 2 diabetes and the need for more effective communication between clinicians and patients. Overall, the study gathered real-world insight into the experiences of patients and the approaches of clinicians in managing patients with type 2 diabetes to inform future clinical practice.

of RWE as a way of determining the value of a new treatment is likely to increase, as will the need for high quality RWE sources.

As a single, centralised healthcare system with longitudinal data on a population representing 65 million people, the NHS represents a unique ecosystem for undertaking real-world studies. Providing researchers with access to a rich repository of anonymised patient data could facilitate research that ranges from supporting clinical target identification and validation to assessing the effectiveness and safety of medical interventions. Such an offering could prove to be a significant attraction to global R&D investors the world over.

CASE STUDY

RWE Collaboration between the Karolinska Institutet and industry

The Karolinska Institutet (KI) in Sweden is leading the way in collaborating with the life sciences industry to improve patient outcomes by utilising RWE. Over the last five years, KI has signed a number of agreements with major life sciences companies to leverage Sweden's National Quality Registries and use patient data more effectively for clinical trials across a range of therapy areas.

One collaboration brings together data across broad population segments, to help inform future medical and clinical research, product development and economic models. Another partnership seeks to explore the discrepancy in outcomes achieved by medicines in clinical trials versus those achieved in the real world. The ultimate aim is to improve understanding of medicines in clinical practice, providing clinicians with certainty and predictability over how a medicine will perform in real-world settings when compared to their Phase III trial.

The financial support for these projects is provided by the partner company, with KI providing the data and research capacity. Sweden is a pioneer in the collection of patient experiences via digital tools and strengthening healthcare outcomes using research. These partnership agreements are an example of how industry and academia can work together to improve patient outcomes.

While the opportunity is palpable, the NHS is comprised of many fragmented components, with data held in both activity (radiology, laboratory, etc.) and organisational silos (Trusts, GP surgeries, etc.).¹⁹ Realising the potential of this data for research requires radical improvements in the digital architecture of the NHS, enhanced interoperability across the technology landscape, and more work to earn the confidence of patients and build trust that their information will be stored and used responsibly. It is vital that academia, the NHS, and industry recognise the significant opportunity provided by this rich data source and establish collaborative ways of working, built on trust and the shared ambition of improving patient outcomes.

In line with the Government's ambition to join up health and care data at local levels, delivered through programmes such as the Local Health and Care Record Exemplars (LHCREs) and Digital Innovation Hubs (DIHs), Government should look to ensure data is collected consistently and joined up at a local level. This will improve the quality and accessibility of anonymised NHS data, and support the system in the delivery of integrated care.

Lessons can be drawn from examples such as the Haematological Malignancy Research Network (HMRN), which combines Hospital Episode Statistics (HES), cancer registry and national administration datasets across Yorkshire to provide a detailed picture of all people living with blood cancer. Insights from the HMRN are used to evaluate patient's responses to different treatment types, determine which treatment paths are likely to deliver the best outcomes, and identify links between socio-economic background and survival rates.²⁰ Government can also draw on learnings from the Nordic countries, who have had national datasets since the 1970s, and France and Belgium, who began developing national Electronic Health Records (EHRs) in the mid-2000s.²¹

CASE STUDY

The Haematological Malignancy Research Network (HMRN)

The HMRN was established in 2004 to provide real-world, robust, generalisable data on haematological malignancies, in order to inform appropriate clinical practice and research. The HMRN's region operates across 14 hospitals, organised into five multi-disciplinary teams, and a network wide paediatric oncology service. Importantly, with a population of approximately 3.8 million, the sociodemographic structure of the HMRN's study area is generalisable to the UK population as a whole.

The network represents a unique collaboration between the NHS, University researchers, clinicians and patients. Since its inception the HMRN has collected anonymised data on approximately 26,000 patients.²⁰ Insights from the HMRN have led to increased understanding of the patient pathway and referral process, explored treatment response in a real-world setting, and highlighted areas where there is a need for more research into better outcomes and improved diagnostic tests.²²

At minimum, the way data is collected should be standardised across all healthcare settings, increasing comparability so that datasets can be linked to generate optimal and deeper insights. The use of the Observational Medical Outcomes Partnership (OMOP) model, a common data model enabling the comparison of data collected in different formats, should be promoted across the NHS, to ensure alignment with the standard data model being rolled out across Europe by the IMI.

CASE STUDY

The European Health Data and Evidence Network (EHDEN)

The IMI EHDEN is a five-year consortium of 11 public and 12 EFPIA member companies, launched in 2018. Its focus is on rolling out a 'build fuel and drive' strategy that will develop an EU ecosystem for real world health research, supported by technology, engagement and outreach with data sources and data users. Using the OMOP model, the Network will seek to harmonise approximately 100 million EU records to support outcomes-based research across the wider IMI 'Big Data for Better Outcomes' programme and support the use of RWE in clinical care and decision-making, using outcome standards.²³

Recommendation: Building on the Local Health and Care Record Exemplars (LHCRES) and Digital Innovation Hubs (DIHs), the Government should look to ensure that data is collected consistently, and is joined up at a local level. This will improve the quality and accessibility of anonymised NHS data, and support the system in the delivery of integrated care.

Recommendation: At minimum, the way that data is collected should be standardised. The OMOP model, a common data model enabling the comparison of data collected in different formats, should be promoted across the NHS to ensure alignment with the standard data model being rolled out across Europe by the IMI. This will enhance the ability to compare clinical outcomes across multi-country cohorts, supporting the UK's ability to participate in global research collaborations.

CHAPTER 2

PARTNERING FOR CAPABILITY DEVELOPMENT

In order to maintain the UK's position as an internationally competitive centre for R&D, it is vital that we continue to attract, maintain and develop a talented R&D workforce. The UK's focus on research cannot remain the concern of academia and industry alone. The growing pressures on the NHS of an ageing, multi-morbid population, rising costs, and tightening budgets makes the need to develop innovative new treatments and efficient solutions more pressing than ever.

Research by the Royal College of Physicians (RCPs)²⁴ has shown that the majority of doctors wish to be more actively involved in research, but this resource remains untapped, due to a lack of time, funding, and access to research training. Greater involvement of clinicians in the R&D process, will encourage greater integration of the NHS into the drug discovery process and facilitate target validation through clinical collaborations.

While research skills are essential for addressing the immediate demands facing the healthcare system, we also need to play close attention to the skills needed to generate new innovations and respond to emerging technologies. The UK must ensure these skills are developed to stay globally competitive, attract international talent, and maintain a thriving and productive R&D skills base, now and in the future.



Enhancing partnerships with the NHS

Better integrating the NHS into broader research discovery work will enable doctors to participate in the R&D process and enhance their understanding of the role R&D plays in improving patient outcomes.

Research undertaken by the NIHR has demonstrated that patients cared for in research-active acute Trusts have lower rates of mortality and improved outcomes.²⁵

The Care Quality Commission (CQC) has subsequently included clinical research activity within its remit for Trust inspections²⁶.

Clinicians are uniquely well placed to ensure medical innovations are patient-centred. Their day-to-day roles treating people allows them to observe and identify the research needs that will deliver the greatest benefits. Practicing clinicians are also best able to advise on how to translate innovation from the lab to the bedside and share best practices to ensure their use across the NHS.

The majority of doctors would like to do more research if it was possible.²⁴ However, clinicians are challenged, due to a lack of protected time and resource for patient-facing research. More action is needed to support this section of the workforce. NHS Trusts should ensure that career planning provides clinicians interested in research with protected supported professional activities (SPA) time to undertake research projects wherever possible. All available funding (from charitable funds to NIHR research capability funding) should be pursued by local Trusts to provide clinical staff with the opportunity to undertake a wide range of research projects.

Recommendation: NHS Trusts should ensure that all clinicians interested in undertaking research are provided with SPA time to participate in research projects. All available funding should be pursued to provide clinical staff with the opportunity to undertake a wide range of research activities.

Cross-sector working across the UK life sciences industry

As the life sciences industry seeks increased collaboration and moves away from the traditional in-house R&D model to a more externally-focused, collaborative approach, partnership working is becoming increasingly important to enable the mutual exchange of expertise between industry, academia, and the NHS, creating a range of benefits for all parties.

Despite the opportunities of collaborating to tackle unmet health needs, anecdotal evidence suggests that there is still an underlying mistrust of industry among some academic researchers and members of the NHS, driven by cultural differences across the sectors²⁷. To be effective, partnerships require a mutual recognition of the different and complementary expertise held across the sectors, and a tacit understanding of how best to work together in practice. To facilitate this, more needs to be done to encourage the movement of researchers and other staff between sectors.

CASE STUDY

The Royal Society Pairing Scheme

Each year the Royal Society pairs 30 research scientists with parliamentarians and civil servants in order to provide policymakers and research scientists with the opportunity to experience each other's worlds. The scheme lasts a week and provides participants with a greater level of understanding of how research findings can be used to inform policy making.

The creation of a new reciprocal exchange programme, similar to the Royal Society's pairing scheme, would provide enhanced opportunities for research organisation staff to gain insight and experience across academia, industry and the NHS.

A new scheme, following the Royal Society model, should seek to foster flexible working with industry by providing the opportunity for interested staff to move between sectors and spend a limited period in a new institution. Such a scheme would facilitate the exchange of knowledge and skills between sectors, break down cultural barriers and misconceptions, and forge direct links between individuals that could spawn future successful partnerships.

Additionally, industry, NHS trusts, and Higher Education Institutions should collaborate further to support flexible career paths, enabling individuals to move between sectors to develop broader expertise and experience. Together, tangible barriers preventing individuals taking up opportunities to broaden their experience across sectors should be addressed.

The RCP specifically identified the need to protect people's employment benefits when considering such a move.²⁴ This is a particular concern for parental leave, and there have been reports that a loss of maternity benefits is a deterrent for women moving into research roles. University College London provides an example of best practice in this area, where all employment rights are maintained when academic trainees move between the NHS and academia.

Recommendation: Industry, NHS Trusts, and Higher Education Institutions need to partner to support flexible career paths, where individuals can move between sectors to develop broader expertise and experience.

Supporting cross-industry movement of early career scientists

It's often assumed that on completion of their PhDs, early career scientists are "fully trained". However, due to the complexity and breadth of modern science, the first one or two post-doctorate positions should ideally be considered to be training posts, as they are in much of Europe and North America, allowing researchers and clinicians to gain a broad understanding of the R&D process to complement their own research.

Structuring the career development of post-doctoral scientists in this manner could provide a huge benefit. For example, new programmes could be established to provide individuals with the opportunity to gain experience across both academia and industry. This would allow individuals to improve their understanding of the research process in both an academic and an industry environment, benefiting their ability to undertake collaborative research activities between the sectors. Equally, this would make further resources available in collaborative projects as early career scientists require additional resource compared to advanced post-doctorate scientists. Lilly has supported the movement of early-career scientists into industry, by funding its Lilly Research Award Programme to support early career scientists.

Additionally, an early career equivalent (for example post-doctorate level) to the Collaborative Awards in Science and Engineering (CASE) award programme could be developed to broaden the number of opportunities available.

Recommendation: Building on models such as the post-graduate Collaborative Awards in Science and Engineering (CASE) award programme, academia and industry should collaborate to develop 'training posts' for early career scientists to gain experience in both

CASE STUDY

Lilly Research Award Programme (LRAP)

The Lilly Research Award Program (LRAP), has been running for approximately 14 years and provides scientists who are working on basic and applied research projects with an avenue to partner with global external researchers to collaboratively advance research projects.

LRAP provides a two-way, pre-competitive collaborative environment in which an external partner can gain invaluable access to Lilly expertise and resources. The pre-competitive nature of the program enables Lilly and external researchers the opportunity to jointly publish their results.

LRAP projects have often proved pivotal in providing key pre-competitive validation of pharmacological mechanisms, chemical process, statistical approach, and now increasingly the application of digital technology.

industry and academia. This would substantially improve the ability to undertake pre-competitive collaborative research.

Continued researcher mobility between the UK and the European Economic Area (EEA)

The development of new medical innovation is an increasingly international endeavour, with research teams and trial sites spanning multiple countries. UK-EU partnerships are critical to maintaining the UK's leadership role in R&D; and have helped establish Europe as a world leading location for science. With only seven percent of the global population, the EU28 produces a third of the world's scientific publications.²⁸

The importance of mobility between countries as a driver for collaboration and innovation cannot be understated. In addition, ease of movement for workers and their families has helped the UK to attract talented researchers, greatly contributing to the country's economic growth and development. From 2007-2016,

more than one in five European Research Council (ERC) grant holders chose to work in the UK.²⁸

Ease of movement for UK researchers within the EU, and vice-versa, is likely to be impacted by all possible Brexit scenarios. The Government's announcement to work with the scientific community to develop a fast-track immigration route designed to attract elite researchers and specialists in science, engineering, and technology is welcome.²⁹ However, clear proposals need to be put in place immediately. Recent evidence from Cancer Research UK suggests the UK is already struggling to recruit skilled research staff to deliver UK clinical trials and support the healthcare system more broadly.³⁰ This new visa system should be streamlined, easy to use and competitively priced compared to other leading research and development countries as UK visas are significantly more expensive than those of other countries.³¹ Moreover, medical research and development is a collaborative process involving researchers, technicians, and other highly skilled workers. Any new visa system must support unhindered movement for all involved in the discovery process, not just those categorised as "exceptional" or "elite".

A loss of freedom of movement could limit UK researchers' ability to participate in cross-country collaborations. If we wish to participate in European research collaboratives after Brexit, this new visa scheme needs to remain as close to the EEA as possible, to maintain the benefits that free movement has afforded. However, agreeing a broader reciprocal arrangement between the UK and EU that facilitates the ease of movement of all involved in the discovery process, would provide certainty to researchers and facilitate greater collaboration. If we do not address this, there is a real concern that other countries will become more attractive destinations for researchers, and the UK workforce will become less diverse, less competitive, and less innovative.

Recommendation: The Government's new visa scheme for elite scientists should be streamlined, easy to use and competitively priced compared to other leading research and development countries, and expanded to include all parties involved in the research process. To ensure the UK can participate in European research collaborations, agreeing a reciprocal arrangement between the UK and EU would facilitate greater ease of movement of scientists, researchers, and highly skilled workers.

Ensuring a research workforce fit for the future

As approaches to medicine innovation evolve, so too do the skills required from the clinical and research workforce. Identifying future skills gaps across the industry is essential to maintain the UK's position as a global leader in R&D. According to the ABPI³², skills gaps have already begun to emerge in the biological sciences, particularly in immunology and genomics, for specialist drug development, and for skills in bioinformatics and statistics, which have seen an increase in demand across the board.

As part of the Life Sciences Industrial Strategy¹⁷ and subsequent Sector Deal³³ the Science Industry Partnership (SIP) has been commissioned to develop a skills strategy. This will provide an assessment of the new skills demands in life sciences between now and 2030. The strategy will be developed as a collaborative initiative, working with SIP employers, the Office for Life Sciences (OLS), the ABPI, and the Bio-Industry Association (BIA).

The skills strategy will be a key vehicle for identifying future skills gaps, which if mitigated will lead to the development of new medical innovations, drive economic productivity and promote confidence in the UK as a global hub for R&D. The ABPI, BIA, Health Education England (HEE), Royal Colleges, the General Medical Council (GMC), and relevant specialty societies all need to review and respond to the finalised recommendations.

The findings and recommendations also need to be considered by the Home Office's Migration Advisory Committee (MAC), to ensure we establish an immigration policy that facilitates seamless movement of students and researchers with new skills both in and out of the UK.

Recommendation: The skills strategy report provides a key vehicle for identifying future skills gaps. The ABPI, BIA, HEE, Royal Colleges, the GMC, and relevant specialty societies need to review and respond to the finalised recommendations. The recommendations also need to be considered by the MAC, to ensure we establish an immigration policy that facilitates the easy movement of students and researchers with new skills.



CHAPTER 3

PARTNERING FOR SYSTEM CHANGE

The UK has all the capabilities required to conduct world-class research in medical science at this time of unprecedented scientific opportunity. Previous chapters have demonstrated that partnership working and embracing cross-sector collaboration, where academia, industry, and the NHS combine their expertise, resources and talent in a streamlined manner, can deliver transformative innovation in medical research.

Harnessing new medical innovation for the benefit of patients, the NHS and society is the next step. In this next stage, continued partnership and collaboration is required to ensure our healthcare system embraces innovation at every stage of the patient journey. A system-wide approach is needed, in which all stakeholders involved in medicine creation, development, and delivery, work together to ensure that medical innovation can be embedded across the system. This approach should be implemented across national and local structures, facilitated by an open platform wherein all stakeholders can constructively engage on what action needs to be taken to build a system that is receptive of new innovations that improve patient care.

At a national level, platforms, institutions and processes need to be established to facilitate the sharing of expertise, allow for collaborative working, and create a system that is fit to deliver modern medical innovation. This should

include governance structures that support enhanced cross-sector dialogue, a fit-for-purpose appraisal and reimbursement system, and processes to monitor progress.

Locally, the delivery system for bringing innovative therapies to patients needs to be enhanced to ensure the NHS is equipped with the skills, tools and expertise to embrace innovation. This should include all stakeholders from system leaders, managers, clinicians and involve a structured approach that allows for pathway redesign, training and upskilling of the workforce, embraces new technology, and maximises joint working to realise this opportunity.

National approach

Governance

At a national level, the development of the Life Sciences Industrial Strategy (LSIS) established a number of governance structures and institutions such as the Life Sciences Council (LSC), Life Sciences Industrial Strategy Implementation Board (LSISIB), Sector Deal Implementation Board (SDIN), and the Patient Access to Medicines Partnership (PAMP). These new forums bring together Government, NHS, patient, academic and industry stakeholders, providing an open platform that facilitates a shared approach to ensuring the UK can continue to progress research and enable UK patients to access medical innovations.

Additionally, they have provided an excellent forum for constructive dialogue and have helped establish new areas for partnership working between senior policymakers and those involved in developing and bringing innovation to UK patients. Maintaining open dialogue between these stakeholders is a vital ingredient in the effective functioning of a vibrant life sciences ecosystem and we encourage the new Government to maintain the existing governance structures, which are particularly valuable at this turbulent time.

Recommendation: The Government should maintain existing governance structures, such as the Life Sciences Council (LSC), and Patient Access to Medicines Partnership (PAMP), which have become important forums for collaboration between academia, industry, the NHS, and Government.

Life Sciences Industrial Strategy (LSIS)

The Life Sciences Industrial Strategy (LSIS) has set the national agenda for putting the UK in a world-leading position to take advantage of future health technology trends. The Strategy, along with two Sector Deals, contains an ambitious framework of recommendations, including increasing funding for basic science, enhancing clinical trial capabilities, embracing data and digital technology, and supporting faster adoption and uptake of innovation in the NHS.

While this Strategy is welcome, its full ambition has not yet been realised and not all recommendations have been implemented. Given the uncertainty of Brexit and the UK's position outside of the EU, full implementation of the LSIS is now more important than ever. Critically, a House of Lords Science and Technology Committee inquiry uncovered complicated arrangements for implementation, a lack of clear authority and accountability and a failure to engage the NHS effectively.³⁴ Using the above forums which

allow for constructive dialogue, all stakeholders should work together to ensure all recommendations are implemented in full.

The Lords Science and Technology Committee also questioned the NHS' commitment to implementation of the Strategy and called for a more co-ordinated approach. The NHS has acknowledged its willingness to play its part in the Life Sciences Sector Deal in the NHS Long Term Plan, which is welcomed.³⁵ However, to realise the full ambition of the Strategy, there needs to be a structured process for engagement and collaboration between industry and the NHS to support partnership working. A formal NHS-Industry Council, alongside existing governance structures, would facilitate constructive dialogue and a shared approach to not only support the full implementation of the LSIS but also realise the ambitions of the NHS Long Term Plan.

In addition, the Government, the NHS and industry agreed a new scheme (the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)), to place a 2 per cent cap on the growth in sales of branded medicines to the NHS, with companies repaying the NHS for any spending above that limit. The scheme will also support innovation in the sector, ensure the most cost-effective medicines get to patients as quickly as possible, and provide predictability on spending for the NHS. The VPAS recognises the shared ambition across Government, the NHS, and industry of ensuring UK patients can access the most effective new medicines as fast as possible, however to realise this goal, commitments outlined in the scheme must be implemented in full to ensure patients, the NHS, and the UK economy benefits.

Specifically, the VPAS committed to the development of a Commercial Framework that aims to provide greater detail on how more complex commercial arrangements between industry and the NHS can be developed to facilitate the uptake of new medicines. Given the role of the NHS in supporting the adoption and spread of innovation in the system, a formal NHS-Industry Council would facilitate discussion and support cross-sector partnership working to ensure the next wave of innovation is embedded across the system.³⁴

Recommendation: The Life Sciences Industrial Strategy and Sector Deal recommendations should be delivered in full and all stakeholders should work constructively to realise the ambitions of the Strategy.

Recommendation: A formal NHS-Industry Council should be established to support implementation of the LSIS, the NHS Long Term Plan, the development of the Commercial Framework, and the embrace of innovation across the healthcare system.

Collaborative working to ensure access to the next wave of innovation

The LSIS set out an ambition for the UK to be in the top quartile of comparator countries for speed of adoption and overall uptake of innovative, cost effective products by the end of 2023. This sent an extremely positive signal that, within the next five years, UK patients will have the same access to innovations as their counterparts in comparable countries.

EU regulatory alignment

However, Brexit will challenge the UK's ability to provide access to new treatments and meet this target, should the UK no longer work closely with the European Medicines Agency (EMA). UK patients and industry have benefitted from decades of medicines regulatory alignment. The single regulatory system provides the scale and certainty required to bring innovative, effective, and safe medical technologies to UK patients quickly. Divergence from EMA regulation has the potential to delay or disincentivise marketing authorisation applications to the UK, impacting the speed at which UK patients have access to new treatments, and resulting in a less conducive market for innovation and research.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) should seek a relationship with the EMA that is as close as possible; either via associated membership or a co-operation agreement.

The EMA cooperates with other regulatory bodies such as Australia, Canada, and Switzerland, however these countries experience delays in receiving new treatments.³⁶ For example, research shows that 45% of marketing authorisation applications submitted to the EMA in 2013-15 had not been submitted to countries outside of the EMA like Australia, Canada, and Switzerland by the end of 2016, making the prospect of a separate UK regulatory system a very real concern for industry and patients.³⁷ Given the countries covered by the EMA represent 25% of the world's overall pharmaceutical sales and the UK accounts for only 3% of the market, international pharmaceutical headquarters will focus efforts and investment on the largest markets. It is an imperative that UK agrees as close as possible relationship with the EMA that seeks commonality with the EU regulatory system, alignment of current and future regulations, and participation in European processes.

Recommendation: The Medicines and Healthcare products Regulatory Agency (MHRA) should seek as close as possible relationship with the European Medicines Agency (EMA) via associated membership or

a co-operation agreement to avoid delays in access and protect patient safety.

Improving access to medical innovation

Building on the vision of the LSIS to improve access and uptake to innovative medicines, Government has established new models for adopting innovation, including the Accelerated Access Collaborative (AAC), Academic Health and Science Networks (AHSNs), and the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS). These models are welcome as patient access to innovative medicines has remained historically low compared to comparator countries in Europe.⁴

Given this is a time of unprecedented opportunity in biomedical research, with the development of truly innovative and breakthrough therapies, personalised therapies, and new approaches to healthcare involving digital health and wearable sensors, there is a need to work together across sectors to ensure patients are able to benefit from new treatment interventions and innovative solutions to full effect. Partnership working will be necessary to support the development of a healthcare system that can adopt innovation at every stage of the patient journey. As a first step, the appraisal and reimbursement system must be "fit-for-the-future" and capable of assessing the innovations launching now and in the near future.

The current appraisal system, which employs the Quality Adjusted Life Year (QALY) to measure incremental health benefit of a new treatment against the standard of care, has remained fundamentally unchanged for two decades. We recognise the need for a system that ensures value for money and a sustainable healthcare system. However, the appraisal method for new medicines must also keep pace with emerging trends in biopharmaceutical innovation; the current methodology can fail to account for the full value of a medicine to a patient.

We are fully committed to working in partnership with all stakeholders to enhance patient access to new medicines. The upcoming NICE Methods Review represents a valuable opportunity to ensure NICE's methodology is fit-for-purpose and capable of assessing the medicines being launched today and in the future. Every stakeholder from Government, the NHS, patients, and industry, has a role to play in working together to ensure NICE methodologies are able to effectively evaluate emerging innovations. To ensure these innovations can move into the system and reach patients, NICE should consider the following:

1. Introduce greater flexibility in Health Technology Assessment (HTA) to accommodate new treatments:

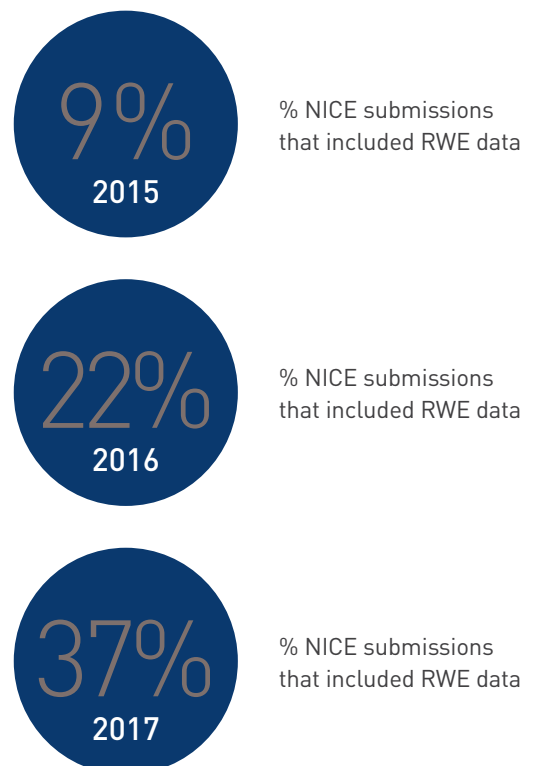
Currently, England's HTA body, the National Institute for Health and Care Excellence (NICE), employs a limited measure of health benefit, known as a Quality Adjusted Life Year (QALY), to determine the clinical and economic value of a treatment. Upgrades to NICE's methods are required to deliver the necessary flexibility to ensure NHS patients can access the latest innovations in a timely manner. This should include updating the Incremental Cost Effectiveness Ratio (ICER) to keep pace with inflation. Additionally, wider definitions of value with appropriate modifiers should be considered, enabling Appraisal Committees to consider a more holistic view of a treatment's value. For example, society may be willing to pay more for new treatments in areas of unmet need, high burden, and severity or they may wish to put a greater weight on outcomes for specific patient groups, such as children. The QALY only considers health benefits and does not account for benefits to wider society such as reducing costs on social care, or the education or justice systems.

- 2. Better manage evidence uncertainty:** With more innovative therapies such as personalised and targeted treatments being launched, and a desire to speed approval processes, companies are often required to submit appraisal dossiers with less conclusive evidence packages and results from earlier stages in the medicines development process. The NICE system has to date had limited experience of assessing this level of data, especially for personalised medicines, and even less experience with cell-based therapies. For many assessments, there is limited evidence of long-term effect and insufficient follow-up data to make a robust assessment. Uncertainty can result in very broad QALY ranges, and either a decision not to reimburse, or a decision that reimbursement is only

permitted when the manufacturer offers a non-disclosed discount. A clear, more balanced approach is required to prevent delays and enable patients to access new types of technology such as cell and gene therapies which can provide long-term (and sometimes potentially curative) benefits that cannot always be demonstrated with absolute certainty at the time of appraisal.

- 3. Expand the use of Real-World Evidence:** RWE has the potential to offer significant benefits, but it is a rapidly evolving arena, which some stakeholders are struggling to fully understand and adopt. In the UK, the share of NICE submissions that included RWE has steadily increased from 9 per cent in 2015 to 22 per cent in 2016 and 37 per cent in 2017.³⁸ Although the share of appraisals that include RWE is growing, there is an opportunity to make even better use of RWE data collection in appraisal methods to manage evidence uncertainty and demonstrate the true value of a medicine, especially in the context of the Cancer Drugs Fund, Managed Access Agreements, the Early Access to Medicines Scheme, and the Accelerated Access Collaborative (AAC).

Recommendation: All parties should work together to enhance the HTA system to ensure it can effectively appraise innovative treatments, specifically considering wider definitions of value, balancing uncertainty in data and embracing the use of Real World Evidence.



Collaborative working to improve uptake of the next wave of innovation

Recognising the UK's historically low uptake of innovation, the LSIS included commitments on uptake, while the five-year Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) set out targets for reaching the upper quartile uptake target for the five highest health gain categories. The Scheme included NHS England implementation support for these health gain categories, and continued development of uptake measurement tools. This has been complemented by the NHS Long Term Plan, which includes a desire for proven innovations to be provided to patients at a faster pace. To realise these ambitions and ensure these targets are achieved, appropriate forums such as the Patient Access to Medicines Partnership (PAMP) and the proposed NHS-Industry Council should be used to develop collective solutions to improving the uptake of new innovations.

Additionally, the NHS Long Term Plan recognised the importance of AHSNs for spreading innovation across the NHS, which is becoming increasingly important due to the formation of Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICS) which create an increased opportunity for cross-sector collaborations between NHS and industry at a local population level.

This collaborative working has previously been hampered by the time taken to agree collaborations, concerns about governance and the challenge of aligning system needs with industry offers. The AHSNs can provide a streamlined, structured approach to support NHS organisations in embracing cross-sector collaborations to improve the adoption of innovation.³⁹ The Memorandum of Understanding between the ABPI and the AHSN network recognises this opportunity and has established a governance process between both parties to support this endeavour. More broadly, to ensure AHSNs can provide this structured approach, extra resource and further funding should be allocated to allow for the increased spread of innovation across the NHS.⁴⁰

Recommendation: Appropriate forums (Patient Access to Medicines Partnership (PAMP) and the proposed NHS-Industry Council) should be used to develop collective solutions to improving uptake of new innovations.

Recommendation: NHS system leaders should promote and leverage the role of the AHSNs to facilitate cross-sector collaborations between academia, the NHS, and industry, while additional resource and further funding should be allocated to ensure AHSNs are equipped to support the adoption of innovation in the NHS.

CASE STUDY

Lilly Digital Health Applications and Connected Care

Lilly has developed a mobile application to help diabetes caregivers and healthcare providers be more prepared to deal with people experiencing a severe hypoglycaemic event. The app is designed to train individuals in the person's support network, such as family members, teachers, and colleagues, when and how to treat severe hypoglycaemia safely and effectively.

Lilly also launched a mobile application to support patients suffering from depression. The interactive tool allows the patient to keep a mood diary, which can be used to track changes over time. The app can also be used to help facilitate conversations with healthcare professionals by encouraging the patient to ask appropriate questions. Both these examples highlight the potential of mobile applications to empower patients to co-manage their own healthcare needs.

Lilly is now developing its Connected Care programme, a personalised diabetes management system designed to make diabetes management easier by enabling patients to use insulin more effectively. The delivery system comprises an insulin pump with a dedicated controller, dosing algorithm and continuous glucose monitor to automate insulin dosing. These components are designed to work together to automatically adjust insulin infusion rates and maintain blood sugar levels within a specified target range. In addition to the delivery system, Lilly is also developing an integrated insulin management system, which combines a connected insulin pen with glucose-sensing technologies and software applications to deliver personalised insulin dose recommendations. Although both of these systems are currently under development, they are indicative of a future where digital technology provides a platform from which to deliver effective patient care (often in a community setting), enabling both patients and healthcare professionals to achieve improved outcomes together.

Local approach

Cross-sector partnerships and collaborative working at a national level are key to ensuring the correct platforms, institutions, and processes are in place to allow the healthcare system to embrace the next wave of innovation but local delivery systems must be appropriately set up too. Equipping local systems with the skills, tools, and expertise required to allow patients to fully benefit from this medical innovation will require partnership working between all stakeholders, including system leaders, managers, clinicians, and industry.

The next wave of innovation will present challenges in how healthcare can and will be delivered, and how patients interact with the delivery system, but it will also provide significant opportunities to fundamentally improve patient outcomes. Even today, many industry treatments are now combined with a 'beyond the pill' service, delivering improved outcomes along entire care pathways and optimising the use of medications rather than simply focusing on the treatment itself. This new 'product plus service' approach aligns with the strategy of the NHS, towards increasing care in the community, reducing the burden on acute care, and facilitating a more population health approach in which all stakeholders and organisations are involved in care delivery.

All stakeholders will have to engage in effective partnership working to ensure the system is optimised to deliver new innovations across the NHS. This will include pathway redesign, training and upskilling of staff, and the use of new digital and data technology:

1. **Pathway redesign:** Some current clinical pathways are outdated and have not been updated to reflect NICE decisions or medical innovation. This inhibits the consistent uptake of innovation and can delay the uptake of new therapies, as clinic and staffing structures are not set up to embrace this innovation and deliver it to patients.
2. **Training and upskilling of staff:** In addition to filling current vacancies in the NHS to reduce pressure on existing staff, there needs to be investment in staff training in order to develop skills and understanding of how the next wave of innovations will impact how they work. The extended value proposition of this innovation means that new treatments will include services and technology to optimise patient experience and outcomes. The Topol Review concluded that *"within 20 years, 90 percent of all jobs in the NHS will require some element of digital skills. Staff will need to be able to navigate a data-rich healthcare environment. All staff will need digital and genomics literacy."*⁴¹

3. **Use of new digital and data technology:** The NHS Long Term Plan outlines that digital and wearable technology is a growing element of healthcare monitoring and that has the potential to change the NHS. This embrace of technology will see more care being delivered at home, while increasing monitoring of patients' adherence to treatment and the eventual outcome.

Joint Working

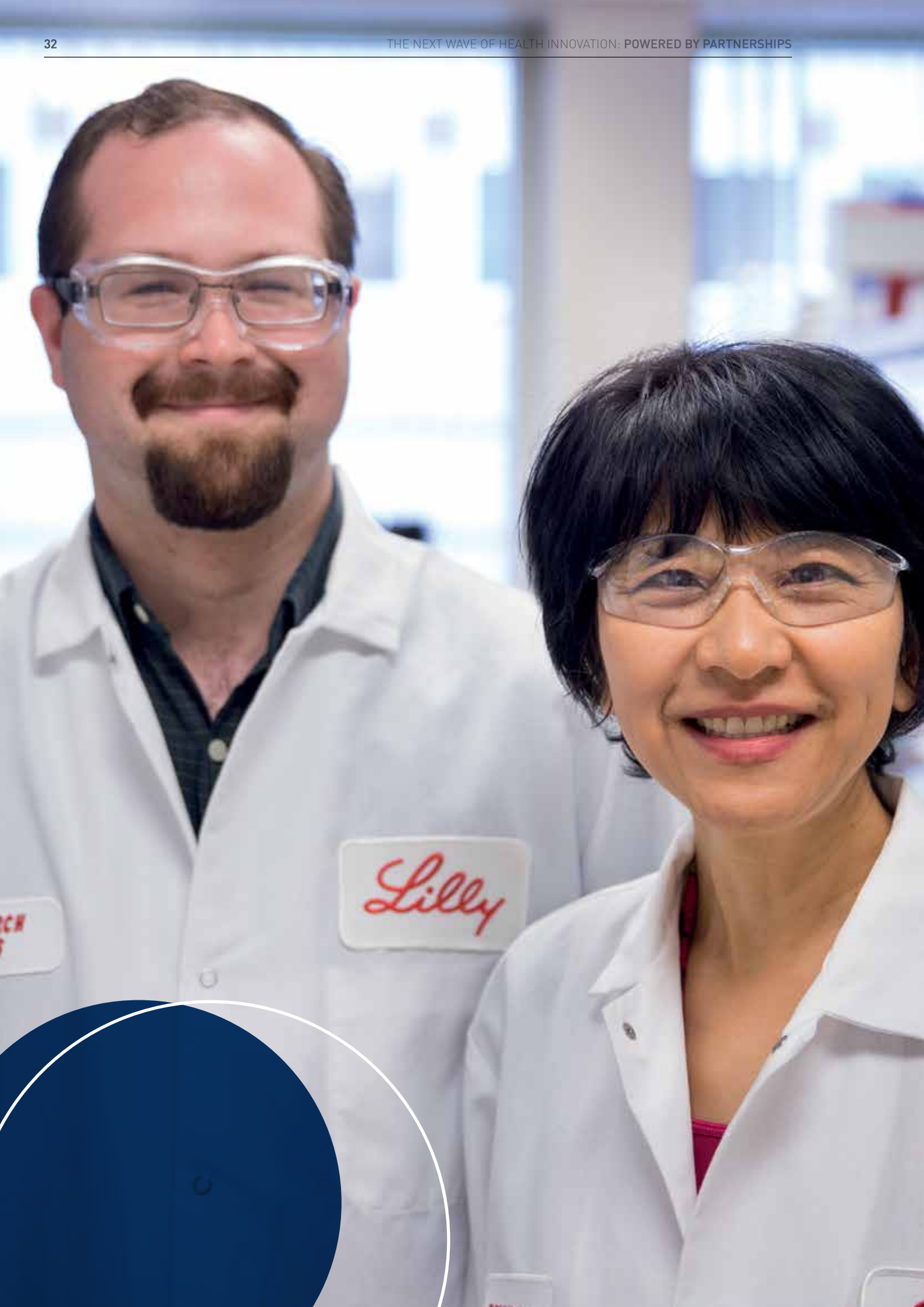
Enhancing patient outcomes through the best use of innovation requires a collaborative approach in which industry and NHS work together to optimise care. Joint Working has the potential to support optimisation of the system at a local level, delivering the triple win of enhanced patient care, more efficient use of NHS resources, and improved uptake of industry innovation.

The benefits of Joint Working have been recognised by many NHS trusts, who now actively encourage collaboration that benefits patient care. Joint Working between the NHS and industry is a vital tool for breaking down barriers and encouraging collaboration, and this is a growing area of partnership.

CASE STUDY

Lilly and NHS Greater Glasgow and Clyde Health Board - Reducing glycaemic episodes for diabetic inpatients

Approximately 23 per cent of patients with diabetes in NHS Greater Glasgow and Clyde Health Board will suffer a glycaemic episode at some point after being admitted to hospital. In Scotland, Lilly worked with NHS Greater Glasgow and Clyde to understand the extent of this problem and its root causes. The project implemented a routine medication review for patients at risk of a hypoglycaemic episode, funding a specialist nurse to support and work with patients. More than 220 patients have been seen to date, and more than 200 of them have received a change in their medication to improve their blood glucose control, leading to decreased length of hospital stays and re-admission rates while improving patient satisfaction.



A recent report by the NHS Confederation highlights the challenges and opportunities of partnership; “... the potential for co-operation has never been fully realised – relations between the two have not always been as productive as they might have been. There is now wide agreement that for a variety of reasons, the potential of a genuinely collaborative future is enormous and perhaps just as important. Failure to embrace this opportunity risks severe damage to both.”⁴²

CASE STUDY

Lilly and Leeds Teaching Hospital NHS Trust - Dermatology service redesign

In March 2019, Lilly and Leeds Teaching Hospital NHS Trust entered into a Joint Working agreement to test a holistic approach to psoriasis care. Through the dermatology clinic in Leeds, psoriasis patients are identified to facilitate appropriate signposting or interventions for those at risk of psychological difficulties and cardiovascular disease (CVD).

By working in partnership with the local NHS Trust, Lilly are supporting the implementation of the NICE Primary Prevention Strategy and meeting NICE guidance on improving the dermatology care pathway for psoriasis. The project will improve outcomes for patients by creating a more holistic service and grow revenue for the trust by increasing the number of referrals to its services. The funding for this project has been provided by Lilly, who will work collaboratively with the Trust to introduce the service redesign.

The ABPI, Department of Health and NHS Confederation set out a robust framework for Joint Working⁴³, which has been helpful in setting out expectations and responsibilities for each party. However, ABPI/NHS Confederation research shows that projects are not being replicated or scaled, and there is still significant distrust of industry partnering in some parts of the NHS. In 2016-17, companies spent £7.5 million on Joint Working, yet one in five Trusts felt they needed to

keep their partnership secret.⁴⁴ This needs to change and exemplars of successful joint working should be promoted to showcase how such projects can benefit patient care and outcomes.

Recommendation: Joint Working between the NHS and industry is a valuable way to share skills and expand NHS capacity. The NHS Confederation and ABPI report ‘A new ambition for cross-sector collaboration with the life sciences industry to support NHS sustainability and transformation’ developed excellent recommendations to improve partnership working between industry and the NHS, and these should be reviewed and implemented.

Recommendation: The ABPI, industry, NHS, and other Joint Working partners should do more to share successful joint working practices and outcomes, to encourage replication and scalability of projects.

CASE STUDY

Lilly and Cambridge University Hospital Foundation Trust – Improving identification of patients with psoriatic arthritis (PsA)

In June 2018, Lilly and Cambridge University Hospital Foundation Trust began a joint project to improve the identification of patients with psoriatic arthritis (PsA) within the dermatology clinic. PsA sits between dermatology and rheumatology so the project will support a more efficient referral pathway between the two departments and ensure there is capacity available to deal with any increase in demand.

The funding for the project has been provided by Lilly and they will work with the Trust to improve shared decision-making for patients regarding their treatment options and their escalation. The aim of the project is to demonstrate the need for this additional resource to be applied permanently and the practices piloted in the project adopted into standard clinical practice.



PARTNERING FOR RESEARCH RECOMMENDATIONS

1. The Government should explore opportunities for establishing new pre-competitive consortia (such as the DDF and US Cancer Moonshot Initiative) in which resources of pharmaceutical, biotechnology companies, academic centres, and experts are pooled, with funding targeted to incentivise cross-sector working and accelerate the development of innovative new treatments. This targeted approach should be implemented in areas of high unmet need and where the societal burden is acute and set to grow exponentially.
2. The UK's domestic science base has benefited from IMI and Horizon 2020 funding, both financially, through access to collaborative consortia, and in terms of attracting talented researchers. The UK must remain at the heart of the EU's integrated research ecosystem, including continued participation in Horizon Europe.
3. The Government should outline a long-term budget for public investment that demonstrates how the 2.4 per cent target can be achieved, with clear outcome measures and accountability for delivery owned by the relevant Government departments at Cabinet level. Long term R&D investment from Government will provide the industry with the certainty it needs to make long-term investment decisions, enhancing the opportunity for public-private partnerships.
4. It is vital that the UK remains aligned with the EU CTR, in order to ensure a streamlined and efficient regulation process, and support partnerships with EU member-states.
5. As of October 2018, all NHS Trusts and life sciences companies are mandated to use an unmodified model site agreement to establish clinical trials. This needs to be adhered to in full to reduce unnecessary delays to study launches and support efficient multi-site trials.
6. All parties involved in the research development process from academia, the NHS, industry and research bodies such as the Medical Research Council (MRC) and the National Institute for Health Research (NIHR) should work together to consider how phase 0 trials could be implemented in the UK.
7. Building on the Local Health and Care Record Exemplars (LHCREs) and Digital Innovation Hubs (DIHs), the Government should look to ensure that data is collected consistently, and joined up at a local level. This will improve the quality and accessibility of anonymised NHS data, and support the system in the delivery of integrated care.
8. At minimum, the way that data is collected should be standardised. The OMOP model, a common data model enabling the comparison of data collected in different formats, should be promoted across the NHS to ensure alignment with the standard data model being rolled out across Europe by the IMI. This will enhance the ability to compare clinical outcomes across multi-country cohorts, supporting the UK's ability to participate in global research collaborations.

PARTNERING FOR CAPABILITY DEVELOPMENT

1. NHS Trusts should ensure that all clinicians interested in undertaking research are provided with SPA time to participate in research projects. All available funding should be pursued to provide clinical staff with the opportunity to undertake a wide range of research activities.

2. Industry, NHS Trusts, and Higher Education Institutions need to partner to support flexible career paths, where individuals can move between sectors to develop broader expertise and experience.

3. Building on models such as the post-graduate Collaborative Awards in Science and Engineering (CASE) award programme, academia and industry should collaborate to develop 'training posts' for early career scientists to gain experience in both industry and academia. This would substantially improve the ability to undertake pre-competitive collaborative research.

4. The Government's new visa scheme for elite scientists should be streamlined, easy to use and competitively priced compared to other leading research and development countries, and expanded to include all parties involved in the research process. To ensure the UK can participate in European research collaborations, agreeing a reciprocal arrangement between the UK and EU would facilitate greater ease of movement of scientists, researchers and highly skilled workers.

5. The skills strategy report provides a key vehicle for identifying future skills gaps. The ABPI, BIA, HEE, Royal Colleges, the GMC, and relevant specialty societies need to review and respond to the finalised recommendations. The recommendations also need to be considered by the MAC, to ensure we establish an immigration policy that facilitates the easy movement of students and researchers with new skills.

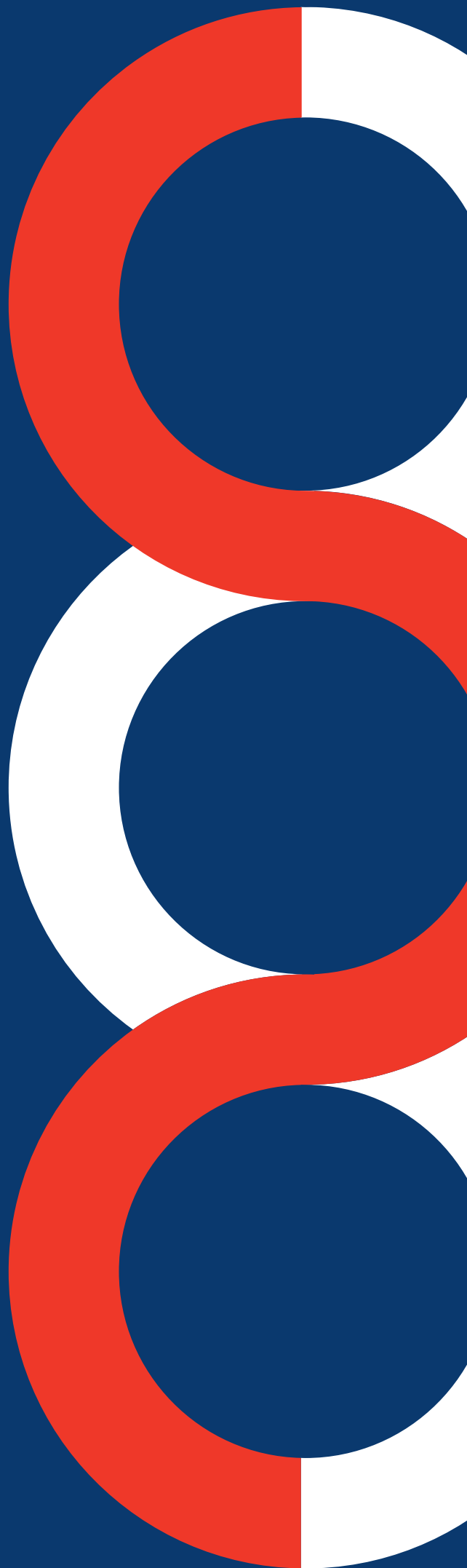
PARTNERING FOR SYSTEM CHANGE

1. The Government should maintain existing governance structures, such as the Life Sciences Council (LSC) and Patient Access to Medicines Partnership (PAMP), which have become important forums for collaboration between academia, industry, the NHS, and Government.
2. The Life Sciences Industrial Strategy and Sector Deal recommendations should be delivered in full and all stakeholders should work constructively to realise the ambitions of the Strategy.
3. A formal NHS-Industry Council should be established to support implementation of the LSIS, the NHS Long Term Plan, the development of the Commercial Framework, and the embrace of innovation across the healthcare system.
4. The Medicines and Healthcare products Regulatory Agency (MHRA) should seek as close as possible relationship with the European Medicines Agency (EMA) via associated membership or a co-operation agreement to avoid delays in access and protect patient safety.
5. All parties should work together to enhance the HTA system to ensure it can effectively appraise innovative treatments, specifically considering wider definitions of value, balancing uncertainty in data and embracing the use of Real-World Evidence.
6. Appropriate forums (Patient Access to Medicines Partnership (PAMP) and the proposed NHS-Industry Council) should be used to develop collective solutions to improving uptake of new innovations.
7. NHS system leaders should promote and leverage the role of the AHSNs to facilitate cross-sector collaborations between academia, the NHS and industry, while additional resource and further funding should be allocated to ensure AHSNs are equipped to support the adoption of innovation in the NHS.
8. Joint Working between the NHS and industry is a valuable way to share skills and expand NHS capacity. The NHS Confederation and ABPI report 'A new ambition for cross-sector collaboration with the life sciences industry to support NHS sustainability and transformation' developed excellent recommendations to improve partnership working between industry and the NHS, and these should be reviewed and implemented.
9. The ABPI, industry, NHS, and other Joint Working partners should do more to share successful joint working practices and outcomes, to encourage replication and scalability of projects.

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