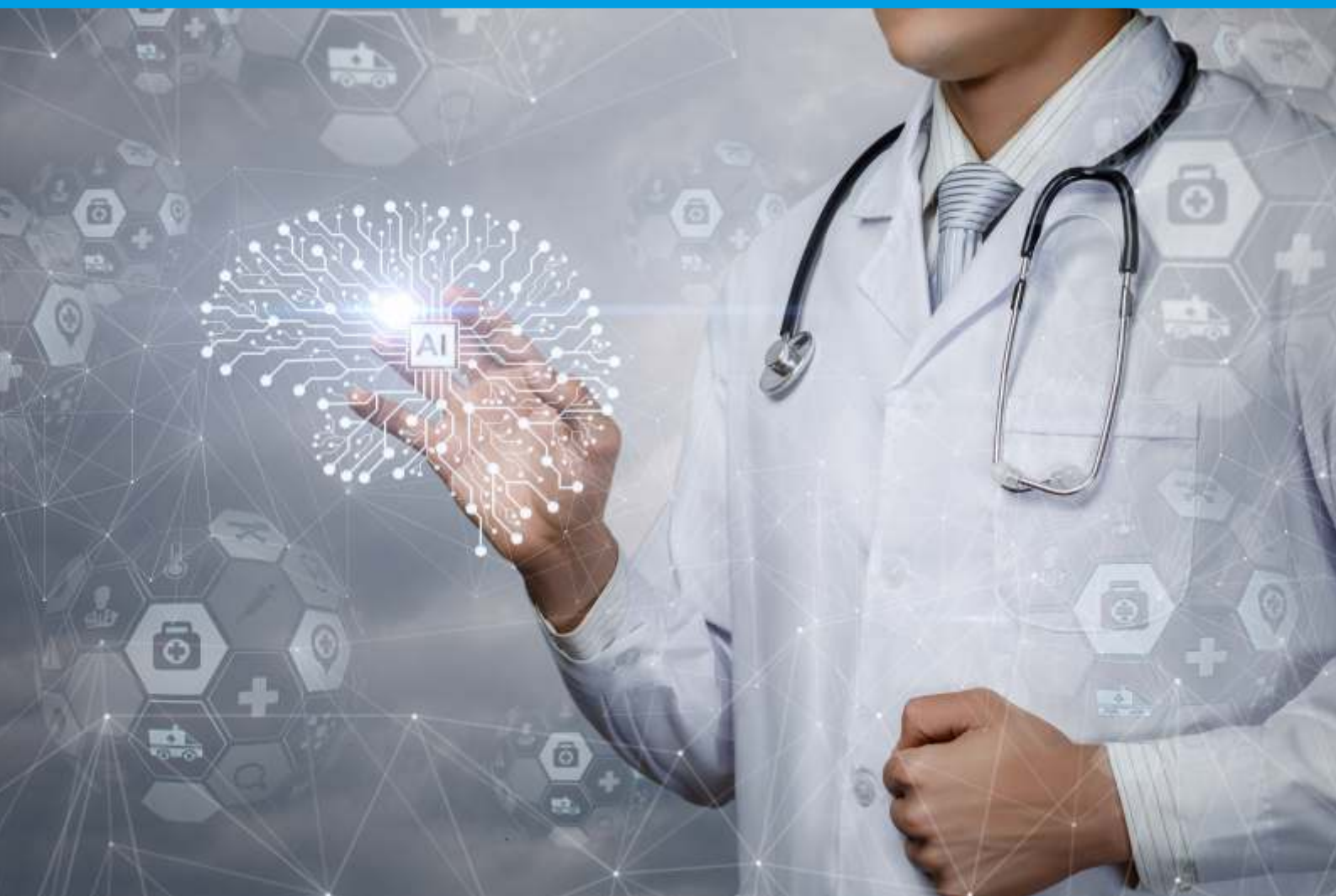# Market Report

AI in Health in the United Kingdom

An overview for SME's and Research Institutes on the trends, challenges and opportunities for AI applications in the British Healthcare sector.

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Introduction

"The UK is absolutely committed to establishing itself as a world leader in the use of Artificial Intelligence (AI) in healthcare but, in all honesty, there is still a long way to go.

The landscape is dense both for academic/research projects as well as commercial innovation. It is often difficult to know who to speak with from within the system. Navigation support is crucial. It is simply not possible for a newcomer to understand without some help.

The truth is that there is help but there is a lot of noise too.

This report is intended to provide some honest advice, some context and an overview of the landscape in an accessible format. Each innovation will have its own unique challenges, and specific criteria will need to be taken into consideration, but this report is meant to help frame the environment for those thinking of entering."

Hassan Chaudhury
Author "AI in Health in the UK" market study

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Why the UK for AI in Health?

1. Why the UK in AI for health?

The UK is not an easy market to get a foothold in, let alone conquer. The question is whether it is worth the effort. For firms ready to commit, it is easy to argue that the UK offers new entrants some significant advantages over other markets. Some of this is due to a deliberate focus to facilitate innovation but often it is simply because of how medicine, science and industry have developed organically over the last 100 years or so into eco-systems, networks and hubs.

The UK has a powerful set of clusters[1] or arrangements of institutions, incubators and programmes blending data, digital, research and health. As an example, the 'Golden Triangle' of London, Oxford and Cambridge is perhaps the world's leading Digital Health Hub due to the level of convergence and concentration. It has four of the world's top 10 universities, five out of seven of the UK's Academic Health Science Centres (AHSCs), plus the Medical Research Council, Cancer Research UK, the Cell and Gene Therapy Catapult, the Precision Medicine Catapult, Ada Lovelace Institute plus innumerable parts of the NHS, the oldest and largest single-payer system on the planet, including several National Institute for Health Research (NIHR) Biomedical Research Centres. It also has its own expert team at MedCity providing a gateway into the region facilitating introductions, connections and capital[2].

The Wellcome Genome Campus for genomics and computational biology alone would have made Cambridge one of the strongest clusters in Europe. Oxford has the Harwell HealthTech cluster and London is the AI growth capital of Europe[3], the best city in Europe to develop and grow digital 'tech for good' solutions[4], one of the world's leading hubs for digital technology generally and consistently attractive compared to other global cities when it comes to talent, culture, entrepreneurs, enterprises, investors and capital[5]. The square mile around 'Silicon Roundabout', centred on London's Old Street, is one of the most connected technology hubs in the world. Nearby is the Kings Cross Knowledge Quarter[6] which has over 100 academic, medical, research and scientific organisations, large and small: from University College London (UCL), University College London Hospital (UCLH), UCLPartners, Google, MSD, IQVIA, the Francis Crick Institute, the Alan Turing Institute, the British Medical Association (BMA) and the British Medical Journal (BMJ), British Library, the Digital Catapult, Royal College of Physicians (RCP), Royal College of General Practitioners (RCGP), BenevolentAI and Wellcome Trust.

It is not just clusters. On any metric of international comparison, the UK scores highly such as on the availability of trained talent and funding, its open regulatory environment and evidence standards, innovation culture and scaleup support including mentoring, with the most Tech Unicorns in Europe.

Much of this is due to significant funding promises and a genuine government focus on innovation development to make the UK a conducive environment for AI adoption. In 2020, Oxford Insights and the International Research Development Centre (IDRC) ranked the UK 2nd in the world on AI readiness (the UK was 1st in 2017 and 2nd in 2019) just behind the US was first[7].

An important consideration is that the NHS is unrivalled as a single payer test-bed and proving ground for technology with a distinguished track-record. The UK has its own innovation agency, Innovate UK and the National Institute for Health Research (NIHR) which fund clinical research as well as health service research connected to real world deployment.

The availability of high-quality longitudinal data sets along with public support for research means the UK offers a serious global competitive advantage. It also offers world-leading transparency on data collection and a deep focus on ethics with the support of bodies like the Centre for Data Ethics and Innovation (CDEI)[8] and the Ada Lovelace Institute.

Why the UK in AI in health?

Success in the UK is often immensely helpful when attempting market entry in other markets. This is due to a combination of how the UK/NHS is perceived in other markets and how access to UK data assets and adapting to exacting regulatory and evidence requirement against fierce competition inevitably raises quality. The UK is also a prime hunting ground for investors around the world, particularly from Silicon Valley, which is always interesting to firms considering their location for establishment[9].

> **The UK is not easy to break into but definitely worth the effort for firms willing to take on the challenge. It is also important to note how clusters are important in the UK system.**

Context

2. Context

2.1 Government policy and ambitions

The UK is absolutely committed at the very highest levels to establishing itself as a world leader in the use of Artificial Intelligence (AI) in healthcare and are realistic that there is still a long way to go[10]. A lack of skills and strategic investment are two areas that are often cited[11].

2.2 The Industrial Strategy, Grand Challenges and Challenge Fund

The UK ambition is to become the most innovative country in the world. This is encapsulated in The Industrial Strategy[12] to create new industries of the future (or to transform old ones). The plan is to increase total R&D expenditure to 2.4% of GDP by 2027 (from 1.7% in 2016)[13]. The overall goal is to boost productivity, create jobs and increase earning power by investing in skills and infrastructure. Part of this is an additional commitment to making the UK the best place to start and grow a business and global promotion to attract investment from foreign innovators. It represents a promise of £20bn worth of funding over 10 years including £2.5bn for the British Business Bank.

The Industrial Strategy sets out 4 Grand Challenges focused on major global transformational trends, the first of which is AI and Data[14]. The Office for Artificial Intelligence[15] is the joint unit responsible for overseeing implementation of the AI and Data Grand Challenge sitting between both The Department for Digital, Culture, Media & Sport (DCMS)[16] and The Department for Business, Energy & Industrial Strategy (BEIS)[17]. This is all backed by The Industrial Strategy Challenge Fund (ISCF)[18], the government's flagship investment programme looked after by UK Research and Innovation (UKRI)[19] which also looks after Innovate UK. All of this builds on the independent report on 'Growing the AI industry in the UK'[20] which stated that at the time the UK is one of a select group of countries that are leading in AI and that advantage could be built on successfully or it could be lost. This led to the AI Sector Deal between government and the AI sector[21] as well as an AI Council[22] of high-powered individuals and the naming of The Alan Turing Institute as the national institute for AI and data science[23]. UKRI also supported sixteen Centres for Doctoral Training (CDTs) in Artificial Intelligence (AI) to train 1,000 PhD students.

The ISCF also invited bids and funded five new centres of excellence for digital pathology and imaging with £50m[24].

The centres are:

- London Medical Imaging and Artificial Intelligence Centre for Value-Based Healthcare at Kings College London (typically referred to as the AI Centre) will use AI in medical imaging and related clinical data for faster and earlier diagnosis and automating expensive and time-consuming manual reporting[25]

- Glasgow's I-CAIRD (Industrial Centre for AI Research in Digital Diagnostics) will bring together clinicians, health planners, and industry to work with innovative SMEs to answer clinical questions, and solve healthcare challenges more quickly and efficiently[26]

- NCIMI (National Consortium of Intelligent Medical Imaging) in Oxford will consider the role clinical imaging plays in the delivery of more personalised care and earlier diagnosis to support disease prevention and treatment[27]

- The Northern Pathology Imaging Collaborative (NPIC) located in Leeds will boost the city's reputation in digital pathology research further by creating a world-leading centre linking up nine industry partners, eight universities and nine NHS trusts[2]

- Based in Coventry, the Pathology image data Lake for Analytics, Knowledge and Education (PathLAKE) will use NHS pathology data to drive economic growth in health-related AI[29]

All five centres have dedicated collaboration with industry in place. There is no barrier for foreign headquartered firms, large or small to get involved. The London AI Centre and NVIDIA launched MONAI[30] – a new open-source framework and toolkit for deep learning in healthcare imaging brings together a community of thought leaders[31].

The centres also combine multinationals and SMEs as partners. The London Centre partners include IBM, Siemens and Kheiron Medical[32], an SME with an AI solution for breast cancer. I-CAIRD partners include Philips, Canon, and Kheiron again. NPIC partners include Roche and X-Lab[33], a local SME with interoperability solutions for labs.

The AI Sector Deal is key reading for those interested in what the UK Government is ready to do to support AI in the UK from a policy perspective as well as its planned investments.

> **The UK Government is taking AI adoption seriously and building the foundations with serious funding.**

2.3 The NHS – not a single national body

Four nations

It is often described as a 'national treasure', as a single payer universal health system, free at the point of delivery. It has continued to receive international praise for how it has operated under austerity measures and harsh cost-cutting[34]. This is despite considerable concern and public angst about the future of the NHS[35] particularly on funding[36], pressures from an ageing population[37] and staff numbers. Concerns about how Covid has been dealt with appears to be centred on the Government rather than on the NHS itself[39].

However, the NHS is not a single system. It is an umbrella term for the health systems of the four nations of the United Kingdom; England, Scotland, Wales and Northern Ireland. Each are unique and often must be dealt with differently. This means any entrant must be aware of how NHS England, NHS Scotland, NHS Wales and Health and Social Care (HSC) of Northern Ireland all operate as well as the other relevant bodies in each nation. The overall picture is not always easy to grasp although The Kings Fund maintains a useful online guide on how the NHS works[40].

9

The NHS - not a single national body

- Health & Social Care (NI)
- NHS Scotland
- NHS England
- NHS Wales
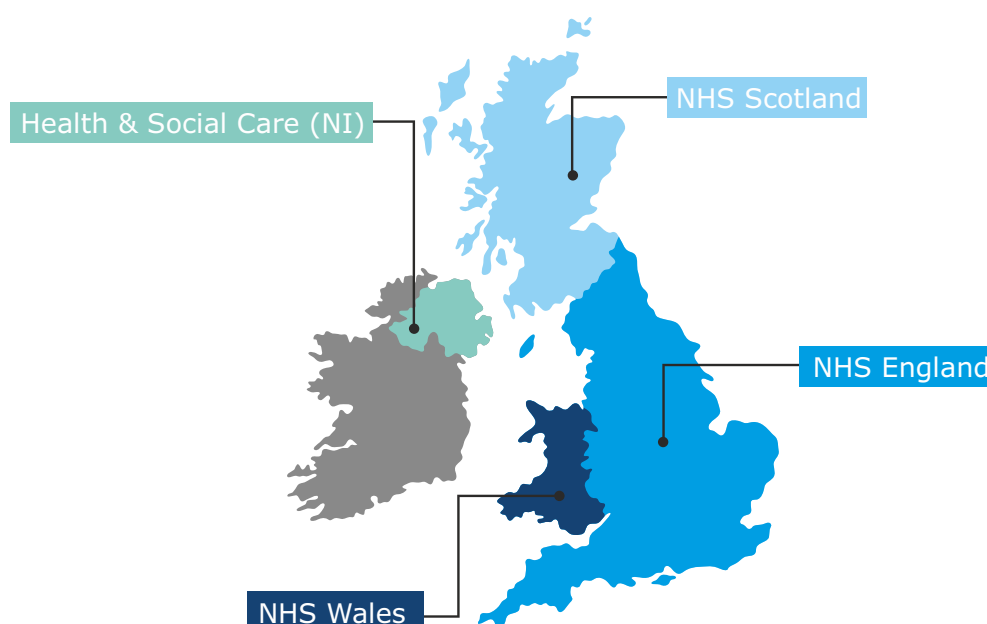
As an example, NHS Scotland consists of 14 regional NHS Health Boards (e.g. NHS Greater Glasgow and Clyde, NHS Lothian etc.) plus seven Special NHS Boards (e.g. Scottish Ambulance Service) and 1 public health body (Public Health Scotland).

NHS Wales has seven Local Health Boards (LHBs) in Wales which plan, secure and deliver healthcare services in their areas. There are also three NHS Trusts with an all-Wales focus. These are the Welsh Ambulance Services Trust for emergency services, Velindre NHS Trust offering specialist services in cancer care and a range of national support services and the new Public Health Wales[41]. There is also the Digital Health Ecosystem Wales (DHEW)[42] that brings together industry, clinicians, policy makers, academics, innovators and funders to create an environment of digital innovation in Welsh healthcare. Wales has a National Data Resource (NDR)[43] programme as well as the SAIL (Secure Anonymised Information Linkage) Databank[44] of anonymised data about the population of Wales. This data linkage research platform is the UK's first single resource for population, health and social care data intended solely for research. It claims to be home to the broadest and most accessible source of anonymised population data in the world and offers a secure environment to conduct research analysis.

Northern Ireland has been at the forefront of innovation for some time[45]. It has the Health Innovation Research Alliance Northern Ireland (HIRANI), explicitly established to strengthen the Life & Health Sciences ecosystem, drive collaboration and connectivity across business, academia and health organisations in the life and health sciences sector and provide a front door to Northern Ireland's life and health sciences sector[46].

This is different to NHS England which is looked after directly by The Department of Health and Social Care (DHSC). NHS England came together with NHS Improvement (so is often described as NHSE/I) which oversees care providers. NHSE/I has seven integrated regional teams (e.g. NHS London, NHS Midlands, NHS North West etc.). They look after Sustainability and Transformation Partnerships (STPs) which bring together NHS providers and commissioners, local authorities and other local partners to plan services around the long-term needs of local communities. STPs cover populations of 1-3 million people. In some areas, STPs have been successful enough to evolve into integrated care systems (ICSs).

This is in addition to alliances of providers in Integrated Care Partnerships (ICPs) as well as Primary Care Networks (PCNs) which facilitate Primary Care at scale[47], working with other local providers to cover populations of 30–50,000 people. Public Health England (PHE) is a separate body as is The Care Quality Commission (CQC) which regulates all health and social care services in England. NHS Digital is focused on England as is The National Institute for Health and Care Excellence (NICE). All four are looked after directly by DHSC.

While England is different to the 3 devolved nations of Scotland, Wales and Northern Ireland, it is typically instructive to examine high-level strategic papers, initiatives and developments from England as a general guide to what to expect.

Regional differences
However, there are also regional differences. For example, NHS organisations and local councils in the Greater Manchester region signed an historic devolution deal with the government to take charge of the £6bn spent on health and social care in its ten boroughs to improve the health, wealth and wellbeing of its 2.8 million population and is now known as the Greater Manchester Health and Social Care Partnership[48]. Manchester is covered by the Northern Health Science Alliance (NHSA)[49] and has its own landscape with local organisations including Health Innovation Manchester[50], Manchester Centre for Genomic Medicine[51], Manchester Cancer Research Centre[52], Health eResearch Centre (HeRC)[53], The NIHR Manchester Biomedical Research Centre (BRC)[54], the UK Biobank[55] and The Christie Cancer Centre, the largest cancer centre in Europe, treating more than 60,000 patients each year and the first UK centre to be officially accredited as a comprehensive cancer centre[56].

There are also major NHS Hospital Trusts in Manchester including Central Manchester University Hospitals NHS Foundation Trust, Royal Manchester Children's Hospital, Manchester Royal Eye Hospital - one of the largest eye teaching hospitals in Europe and globally acknowledged as a centre of excellence as well as Salford Royal NHS Foundation Trust, the largest national provider of health and social care and a Global Digital Exemplar (GDE). Salford Royal has recently joined The Northern Care Alliance NHS Group alongside The Pennine Acute Hospitals NHS Trust bringing together 17,000 NHS staff to serve a population of over 1 million people[57]. Manchester is also home to the largest clinical academic campus in Europe and MIDAS, Manchester's award-winning Inward Investment Agency[58].

The complexity of the landscape is presented simply to illustrate that local and regional support is always necessary to navigate effectively and be successful in the UK digital health market.

> **The UK landscape is complex enough that some form of navigation support is crucial and it is important to focus on a region or nation at a time.**

2.4 The NHS and Digital Transformation

The national programme for IT (NPfIT) and "Axe the Fax"

The NHS has not had a positive experience with digital transformation. Between 2002 and 2011, The National Programme for IT (NPfIT) spent more than £12 billion on implementing a top-down centralised digitisation of healthcare focused on electronic patient record (EPR) systems. It is considered a huge failure[59] and the National Audit Office (NAO) was particularly unimpressed[60]. It fell significantly behind schedule and costs escalated, with heavy criticism of contractors like British Telecom (BT) and Computer Sciences Corporation (CSC)[61]. When the goal of a universal national system couldn't be realised, individual NHS Trusts implemented different systems in different parts of the country which led to inconsistencies to digital maturity. This exposed the lack of standards and created a new need to accelerate interoperability between systems, something that has been the subject of debate and discussion[62] and the eventual establishment of INTEROpen[63], an action group accelerating open standards in healthcare. There is still doubt whether top-down, nationally-led programmes led by the centre are the answer.

2014 saw the publication of the Five Year Forward View (FYFV) looking at new models of care supported by digital infrastructure[64]. In 2016, the NHS in England commissioned a review about making the secondary care system more digital. The advisory group, chaired by clinician, digital expert and author Professor Robert Wachter[65]. The landmark report[66] (known as the 'Wachter Review') recommended a workforce of chief clinical information officers (CCIOs), trained clinician-informaticists to ensure successful deployment and benefits realisation of health IT at the trust level. This led directly to the formation of the NHS Digital Academy to train a new generation of leaders[67].

Progress has not been rapid. Leeds Teaching Hospital NHS Trust launched a campaign in 2018 to end the use of fax machines instead of "living in the dark ages", named 'Axe the Fax'[68]. The NHS deadline to go paperless continues to be pushed back[69].

Context

There is widespread acknowledgement that if we were setting up the NHS from scratch today it would not look like it does today with its legacy systems and inconsistencies. The 2019 follow up to the 'Wachter Review' led by Professor Eric Topol[70] focused on preparing the workforce for the digital future[71] and efforts continue to improve digital literacy with Health Education England's programme named Building a Digital Ready Workforce (BDRW)[72].

While huge progress has been made since NPfIT, these examples provide essential context for the UK journey in digital health.

> **The UK has made serious missteps in its digital health journey which help to explain its legacy systems and inconsistencies.**

Global Digital Exemplars (GDEs) and Blueprints

A Global Digital Exemplar (GDE) is an internationally recognised NHS provider delivering improvements in the quality of care, through the world-class use of digital technologies and information[73]. There are 7 Mental Health GDEs including South London and Maudsley NHS Foundation Trust[74], 3 Ambulance GDEs and 17 Acute Hospital GDEs including prominent digital-enabled hospitals such as Alder Hey Children's Hospital NHS Trust, Salford Royal NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust, Royal Free London NHS Foundation Trust, Imperial College Healthcare NHS Trust, Chelsea and Westminster Hospital NHS Foundation Trust and University Hospitals Southampton NHS Foundation Trust[75]. Exemplars are expected to share their learning and experiences through the creation of blueprints to enable other trusts to follow in their footsteps as quickly and effectively as possible. There are now 60 GDE blueprints available (although pioneers like Dr Toral Thomas, CCIO at Norfolk and Suffolk NHS Foundation Trust have argued convincingly that blueprints can often be unhelpful)[76].

However, not every digitally-enabled hospital in the NHS is a GDE. For example, Great Ormond Street Hospital for Children NHS Foundation Trust is the country's leading centre for treating sick children. It is often known as GOSH. Just 3 years ago it ranked in the lowest 10% of the NHS in digital maturity. In 2020, it was awarded Stage 6 on the EMRAM and O-EMRAM by HIMSS in July 2020, making it the first hospital in Europe to achieve both validations. It was then awarded stage 7 O-EMRAM, or the Outpatients Electronic Medical Record Adoption Model in Sept 2020.

Cambridge University Hospitals NHS Foundation Trust (CUH) is a GDE and got Stage 7 EMRAM a month later, the first in the UK to be validated at the highest level for its electronic patient record (EPR) capabilities and an accolade held by only six other European healthcare institutions.

> **The UK has made excellent digital health facilities but they are unevenly distributed and not always where you may first think to look. Collaborations aren't always immediately visible either.**

Both GOSH and CUH deployed the Epic EPR which is now being deployed by 3 major NHS Trusts in London: Guy's and St Thomas' NHS Foundation Trust (GSTT), Royal Brompton and Harefield Hospitals (both being merged in early 2021), as well as King's College Hospital. The programme for this rollout is named 'Apollo' and will include more specialist services than any other UK Epic implementation to date. This is significant as Epic enables the pooling of data into lakes. The AI Centre, based at GSTT, already has a network of NHS Trusts collaborating including Brighton & Sussex University, East Kent Hospitals University, Imperial College Healthcare, Lewisham and Greenwich, Maidstone and Tunbridge Wells, Royal Brompton & Harefield and University College London NHS Trusts. The goals are to build new interoperability federated learning and AI deployment platforms that will enable transformation of clinical diagnosis and treatments[77], run multiple machine learning algorithms at once and create clinical applications for day-to-day patient care including AI-enabled MRI and ultrasound.

2.5 The UK approach to sharing data

The NHS offers a globally unique combination of a single payer, nationally integrated health system serving a population of 65 million people, with mandated uniform standards, interoperability and data flows all operating within a regulatory environment that encourages innovation and diffusion.

The UK has long wished that it could have a national database of patients' medical records spanning primary and secondary care linking information from different NHS providers to give healthcare commissioners a more complete picture of how safe local services are, and how well they treat and care for patients across community, GP and hospital settings.

In 2013, NHS England initiated the care.data programme to do just that[78] but the execution was a catastrophic failure because the communication was so poor that the general public largely had no idea about the programme, its benefits or its risks, particularly on selling data to commercial companies[79]. Citizens were actively meant to opt out which proved an additional misjudgement[80].

It was postponed in 2014 and closed down in 2016 but not before a huge amount of damage that almost cost public trust in the use of health data for research. The UK now has a National Data Guardian[81] which conducted a review of consent and opt-outs[82]. It also has the 'Understanding Patient Data' initiative[83] set up in 2016 to support conversations with the public, patients and healthcare professionals about uses of health and care data. It is supported by the Wellcome Trust, the Medical Research Council (MRC), the Economic and Social Research Council (ESRC), DHSC, and Public Health England.

This provides some background to the deep concerns UK medical professionals have about how data is used (or potentially misused) and concerns about losing the trust of patients exactly as have been raised about commercialising data out of the Local Health and Care Record Exemplar (LHCRE) programme[84].

This has meant that industry has had to wait for the kind of data access it would have liked. Some attempts have been made to push the agenda forward. Notably, Imperial College London's Institute of Global Health Innovation (IGHI) published a white paper in 2020 arguing the UK is the best placed large economy in the world to use its health data assets for transformative health, scientific and economic impact[85]. This followed an earlier paper on ensuring that the NHS realises fair financial value from its data[86].

With this in mind, DCSM launched a National Data Strategy consultation[87] during London Tech Week 2020. It was explicit about the potential of data with an interesting approach considering the recent history:

> *Under this strategy, data and data use are seen as opportunities to be embraced, rather than threats against which to be guarded*[88].

This change of tack is encouraging for foreign entrants wishing to take advantage of opportunities to collaborate appropriately with UK health data assets.
NHSX also set up The Centre for Improving Data Collaboration, a new business unit within NHSX which has been created to support the health and social care sector to enter into data-sharing partnerships that benefit the NHS, patients and the public[89]. The ambition of the unit has been demonstrated by early conversations with NHS Trusts that want to make the most of the healthcare data they hold, but are unsure of how best to proceed. Key questions put to the new centre include 'who' owns the data, whether DHSC, NHSE/I and others will allow NHS Trusts to proceed in ways that do not benefit all NHS Trusts equally, whether 'boilerplate' or template agreements can be designed so NHS Trusts do not have to duplicate commercial work.

> **No one will accept anything that might upset the general public when it comes to the sharing of data that the medical research community badly needs.**

Context

Health Data Research UK (HDRUK)

HDRUK is the result of a desire for a multi-funder UK institute for health and biomedical informatics research to transform the UK medical informatics research landscape. HDRUK is a national, interdisciplinary research institute aiming to capitalise on the UK's renowned data resources and research strengths was set up with £37.5m of funding from the Medical Research Council (MRC), part of the UKRI. It helps innovators to find data via the Health Data Research Innovation Gateway[90]. Notable UK data assets and sources span all setting of care and;

- Primary Care such as the Clinical Practice Research Datalink (CPRD) and the RCGP Research and Surveillance Centre

- Secondary Care activity such as NHS Digital's Hospital Episode Statistics (HES)

- Disease registries such as PHE's National Cancer Registration and Analysis Service (NCRAS)

- Audits such as the Myocardial Ischaemia National Audit Project (MINAP) by National Institute for Cardiovascular Outcomes Research (NICOR)

- Biobank and genomics data including from Genomics England, UK Biobank and Generation Scotland.

HDRUK has also set up 8 Health Data Research Hubs:

- NHS DigiTrials - The Health Data Research Hub for Clinical Trials[91].

- PIONEER - The Health Data Research Hub for Acute Care led by the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust, in partnership with West Midlands Ambulance Service, the University of Warwick, and Insignia Medical Systems[92].

- Discover-NOW - The Health Data Research Hub for Real World Evidence led by Imperial College Health Partners and a strong group of partners - the Association of Medical Research Charities (AoMRC), AstraZeneca, Dr Foster, Genomics England, Google, Huma, IBM, Imperial College Healthcare NHS Trust, Imperial College London, Janssen, North West London Collaboration of Clinical Commissioning Groups, North West London Health Research Register, NorthWest EHealth, Novartis and the One London LHCRE[93].

- BREATHE - The Health Data Research Hub for Respiratory Health led by The University of Edinburgh, Imperial College London, University of Leicester, Nottingham University Hospitals NHS Trust, Queen Mary University of London and Swansea University[94].

- DATA-CAN - The Health Data Research Hub for Cancer, hosted by UCLPartners and partnered with Genomics England, IQVIA, Queens University Belfast, The Leeds Teaching Hospitals NHS Trust and the University of Leeds[95].

- INSIGHT - The Health Data Research Hub for Eye Health - a collaboration between six partners: University Hospitals Birmingham NHS Foundation Trust (lead institution), Moorfields Eye Hospital NHS Foundation Trust, The University of Birmingham, Roche, Google and Action Against AMD[96].

Context

- Gut Reaction - The Health Data Research Hub for Inflammatory Bowel Disease with the following partners: AIMES, Cambridge University Health Partners, Cambridge University Hospitals NHS Foundation Trust, Crohn's & Colitis UK, Eastern Academic Health Science Network, Leeds Teaching Hospitals NHS Trust, Manchester University NHS Foundation Trust, Microsoft, Newcastle upon Tyne Hospitals NHS Foundation Trust, NIHR BioResource, Pennine Acute Hospitals NHS Trust, Privitar, Royal Devon and Exeter NHS Foundation Trust, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Salford Royal NHS Foundation Trust, UK IBD Registry Ltd, University of Cambridge, University College London Hospitals NHS Foundation Trust, Western General Hospital, Edinburgh[97].

- BHF Data Science Centre - The BHF Data Science Centre is a partnership between HDRUK and the British Heart Foundation[99].

Scotland has BREATHE, one of the Health Data Research UK (HDR UK) sites and a wide range of specific assets including[99]:

- The UK's only national prescribing/dispensing and hospital imaging datasets
- Primary care data linkage being developed through the national SPIRE programme
- Multiple disease-specific registries
- A network of tissue bank repositories.

NHS Information Services Division (ISD) Scotland routinely releases robust data for public view. Scotland also offers access to consented, accessible research cohorts with bio-samples, linkable to these routine data and tissue resources. Examples include:

- Generation Scotland (25,000 adults)
- UK Biobank (500,000 adults [36,000 in Scotland])
- SHARE (a rapidly growing research register of >200,000 people, with consent for recontact and for storage and analysis of spare blood from routine NHS laboratory testing).

> **The UK has the widest range anywhere of truly exceptional data assets available for bona-fide research and industrial collaboration.**

2.6 NHS Long Term Plan and NHSX

At the 70th anniversary of the NHS in 2018, there was pragmatic acceptance that the NHS needed radical intervention in order to survive to celebrate its 80th anniversary. There was also explicit acknowledgement that if we were starting from scratch, there are aspects of the way the NHS works that we'd now design quite differently.

The NHS Long term Plan was significant. It called for changes including a new service model, an emphasis on prevention, a drive for more joined-up care and a genuine commitment to embracing digital health technology including AI.

The direction of the UK in healthcare (not just in digital health) cannot be properly understood without appreciating the NHS Long Term Plan[100].

The Secretary of State for Health and Social Care, Matt Hancock MP, (previously Secretary of State for DCMS) has made the issue of NHS digital transformation a personal cause. One month after the publication of The Long Term Plan, Hancock announced the formation of a new joint unit, NHSX, which brings teams from the DHSC and NHSE/I together into one unit[101]. It is responsible for driving digital transformation and leading policy, implementation and change in this area, fighting against the fragmentation in decision making in digital health and increasing the speed of tech adoption.

Context

DHSC had already produced a Tech Vision[102] a few months before the Long Term Pkan was published, which listed some real challenges to overcome including legacy technology and commercial arrangements, complex organisational and delivery structures, a risk-averse culture, limited resources to invest and a critical need to build and maintain public trust. It concentrated on 4 guiding principles; i) user need, ii) privacy and security, iii) interoperability and openness and finally, iv) inclusion. NHSX is meant to deliver on that vision. It therefore has five missions, which are focused on how to make things better for patients and staff[103].

These are to:
- Reduce the burden on our workforce, so they can focus on delivering care;
- Give people the tools to access information and services directly, so they can best take charge of their own health and care;
- Ensure information about people's health and care can be safely accessed, wherever it is needed;
- Aid the improvement of safety across health and care systems; and
- Improve health and care productivity with digital technology.

NHSX have already made progress although the scale of the task is considerable. Matthew Gould, CEO of NHSX, has the objective of speeding up the transformation of the NHS and social care, in line with the NHS Long Term Plan and the Health Secretary's Tech Vision. He has already made it clear that the long term plan commitment to digitise all NHS Hospital Trusts by 2024 will be "a stretch" and require "sharp progress" by the least advanced providers[104]. The NAO is still similarly cautious about the prospects of NHS digital transformation[105].

> **There is dedication to transforming the old ways of working but acceptance that it will take time.**

2.7 Code of Conduct and Guide to Good Practice
A persistent concern is that the rules of the game aren't clear enough for suppliers so DHSC produced a Code of Conduct for data-driven health and care technology.

The 10 principles are worth listing:

1. Understand users, their needs and the context
2. Define the outcome and how the technology will contribute to it
3. Use data that is in line with appropriate guidelines for the purpose for which it is being used
4. Be fair, transparent and accountable about what data is being used
5. Make use of open standards
6. Be transparent about the limitations of the data used and algorithms deployed
7. Show what type of algorithm is being developed or deployed, the ethical examination of how the data is used, how its performance will be validated and how it will be integrated into health and care provision
8. Generate evidence of effectiveness for the intended use and value for money
9. Make security integral to the design
10. Define the commercial strategy

Together, these steps show serious and sustained commitment to the adoption and diffusion of data-driven technologies like AI as well as openness about past missteps.

These steps were updated in January 2021 as "A guide to good practice for digital and data-driven health technologies". It has 12 principles[106]:

1. How to operate ethically
2. Have a clear value proposition
3. Usability and accessibility
4. Technical assurance
5. Clinical safety
6. Data protection
7. Data transparency
8. Cybersecurity
9. Regulation
10. Interoperability and open standards
11. Generate evidence that the product achieves clinical, social, economic or behavioural benefits
12. Define the commercial strategy

2.8 Evidence standards framework for digital health technologies and DTAC

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. It was part of a working group led by NHS England, which also includes Public Health England (PHE), MedCity[107] and DigitalHealth.London[108] to create evidence standards that ensure new technologies are clinically effective and offer economic value[109].

They are made up of both effectiveness and economic impact standards and was designed to explicitly support the relevant principles of the Code of Conduct.

NHSX announced The Digital Technology Assessment Criteria for health and social care (DTAC)[110] in beta but soon to launch. This replaces the earlier Digital Assessment Questionnaire (DAQ) and Digital Assessment Portal (DAP). The assessment criteria are focused on 5 core areas (sections 1-4 form the core assessed criteria):

- Clinical safety: assessed to ensure that baseline clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk
- Data protection: assessed to ensure that data protection and privacy is 'by design' and the rights of individuals are protected.
- Technical assurance: assessed to ensure that products are secure and stable
- Interoperability: assessed to ensure that data is communicated accurately and quickly whilst staying safe and secure
- Usability and accessibility: products are allocated a conformity rating having been benchmarked against good practice. Where there are areas for improvement, recommendations will be made if there are areas for improvement.

There is no doubt that the DTAC and the forthcoming Guide to Good Practice for digital and data-driven health technologies will both be widely adopted and accepted. Together, they offer a basis for AI innovators to build upon.

The rules of the game for digital innovators have been set and are clear.

2.9 Current and proposed role of AI in the NHS

All four nations of the UK view adoption of AI as a transformational opportunity in a range of areas from diagnostics, prediction and self-care. While there is a proliferation of reports on the state of AI[111] the reality is that innovation involving AI in UK healthcare, started late[112], is still early and moving slowly with significant barriers[113].

Sir Simon Stevens, NHS Chief Executive, said:

> ❝ *The NHS has and always will rely first and foremost on the clinical expertise of our staff, but the innovations we're funding today have the potential to save lives by improving screening, cancer treatment and stroke care for NHS patients across the country. We're still in the early stages of AI, but when the latest chapter in the history of medicine comes to be written, AI in health care will doubtless rank alongside earlier advances such as the stethoscope, the X ray and the blood test[114].* ❞

While there is real interest about using AI in the NHS there is also a feeling that there is a great deal of hype out there with wariness and profound concerns that some AI suppliers are offering 'vapourware' i.e. deployments that promise lots but offer very little real-world value.

The current role of AI in the NHS can be summed up as promising but patchy. There are multiple instances of AI deployments at pilot but perhaps yet not enough at scale. The Academic Health Science Network (AHSN) is the innovation arm of the NHS. It already has an Innovation Exchange[115] as well as an AI Initiative with an important report[116]. This followed a national survey in 2018 with an accompanying directory and interactive map of AI initiatives and compelling use cases in health and care[117]. Examining the spread so far shows lots of potential but the spread has been inconsistent. This has resulted in a clear call from industry for more support, clarity and transparency.

This has led to action to ensure the health system can adopt innovation more readily. The Data Lab in partnership with the Scottish Government is developing an AI Strategy for Scotland[118] while mapping AI groups in the nation[119]. The strategy states that *"…whilst the UK Government had developed an AI sector deal and is developing a data strategy, data and AI are devolved matters for Scotland"*[121]. Kate Forbes Minister of the Scottish Parliament (MSP) and Cabinet Secretary for Finance was explicit: *"We aim to develop a strategy that is of Scotland, by Scotland and for Scotland"*[121]. This reinforces the point that each of the 4 nations of the United Kingdom need to be viewed differently.

Scotland's Digital Health & Care Innovation Centre (DHI)[122] is part of the Scottish Funding Council's Innovation Centre Programme and designed to support transformational collaboration between universities and businesses. It has a dedicated Demonstration & Simulation Environment (DSE), a priority asset which provides a unique physical and safe space to experience, explore and test innovative digital capabilities and infrastructures.

NHSX has already set up an AI Laboratory to play a leading role[123]. It has set up a Skunkworks to trial innovative ideas in AI[124], set up the National COVID-19 Chest Imaging Database (NCCID)[125] and is focused on the regulation related to AI including a one-stop shop Multi-Agency Advisory Service, streamlining the process for technological review, developing synthetic data and enhancing the post-market surveillance of healthcare products, including AI solutions, by transforming the Yellow Card system for adverse incident reporting[126].

Context

Importantly, NHSX has already produced a paper on how to get AI right in 2019[127] as well as "A buyer's guide to AI in health and care"[128]. Both are essential reading.

> ● **AI is not being viewed as a panacea or silver bullet and careful steps are being made to ensure it can be adopted appropriately**

2.10 Getting tech into the system

With all this in mind, it is clear that while AI is being proposed as a game-changer for the NHS, a lot depends on the initiatives being set up to help smooth the journey towards adoption of AI at scale.

This point cannot be overstated and is understood throughout the system; it is up to the players within the UK landscape to make it easier for innovation to spread.

To that end, NHSX also looks after procurement frameworks to get the right tech into the system including the Spark Dynamic Purchasing System (DPS) for remote monitoring[129] and the Clinical Communications Procurement Framework[130].

AI in Health and Care Award

Another initiative is the AI in Health and Care Award[131]. It forms part of the NHS AI Lab and is managed by the Accelerated Access Collaborative (AAC)[132] in partnership with NHSx and the National Institute for Health Research (NIHR)[133]. The evaluations will assess whether these technologies should be recommended for wider adoption across the NHS and will look at their safety, effectiveness, and impact. Evaluations will be conducted with a real-world perspective and follow NICE appraisal processes. Winners of Round 1 were announced in September 2020 with Round 2 to follow shortly.

The Accelerated Access Collaborative (AAC) and Healthtech Connect

The AAC brings together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics which can transform care[134]. The AAC supports all types of innovations: medicines, diagnostics, devices, pathway changes, new workforce models and digital health products. It also runs NHS Test Beds, commissioned by NHSE/I to bring NHS organisations and industry partners together to test combinations of digital technologies with pathway redesign in real-world settings[135].

HealthTech Connect is a secure, online database of devices, diagnostics and digital health technologies that are intended for use in the NHS or wider UK health and care system[136]. It is funded by NHS England and operated by the NICE. Its purpose is to act as a means of connecting innovators and their technologies to the right people, from the right organisations, at the right time to help get technologies developed, assessed, and used as quickly and efficiently as possible.

Accelerators and incubators

Nesta had already mapped a directory of incubators and accelerators in the UK identifying 205 incubators and 163 accelerators in 2017[137]. It analysed the impact in 2019 finding incubators had slightly more positive impact than accelerators although concluding that could be due to a typically longer period in an incubator (on average 2 years vs 6 months)[138]. These are incredibly important in the UK health tech landscape as clusters require relationships, connections, networks and introductions which incubators and accelerators excel at. Notable UK examples include:

- DigitalHealth.London[139]
- NHS Innovation Accelerator (NIA)[140]
- SimDH[141]
- Bethnal Green Ventures (BGV)[142]
- P4 Precision Medicine Accelerator Programme[143]
- Health Hub Accelerator[144]

> ● **Serious efforts are being made to enable and facilitate innovation entry, adoption and spread**

Context

2.11 COVID-19

There were serious concerns about how the NHS would cope with COVID-19. At the end of the first wave it is reasonable to say the NHS did well, with particular praise for NHS Digital and General Practice in England.

Dr Minal Bakhai, Deputy Director and National Clinical Lead for Digital First Primary Care, NHSE/I argued back in April 2020 that the pandemic had significantly turned the dial on digital first general practice[145].

- In response to COVID-19, all practices have been urged to triage all patient contacts ('total triage').
- To support total triage, practices and commissioners asked to have an online and video consultation solution procured.
- Rapid procurement for those practices that do not currently have an online consultation or video solution has been supported through a national bundled procurement.
- NHSE/I are working as a blended team with national, regional and local colleagues to provide implementation support and resources to practices to achieve OC & VC utilisation.
- Data is being captured nationally from implementation teams and vendors, and a dashboard has been set up to track implementation status daily.
- An evaluation has been commissioned to understand how total digital triage has enabled practices to respond to COVID-19, the critical success factors and which elements to retain in the recovery phase.

By June, 88% of GPs said they would like to keep greater use of remote consultations in a BMA survey[146].

NHS Digital successfully led one of the most comprehensive Covid19 response programmes of any national agency characterised by clear communication, productive alliances, and adherence to scientific and analytical rigour. Its work covered the following areas, to[147]:

- Provide digital channels for citizen guidance and triage
- Enable remote and collaborative care with systems and data
- Deliver digital services for NHS Test and Trace
- Provide support for delivery of Vaccinations
- Identify and protect vulnerable citizens
- Support planning with data, analysis and dashboards
- Get data and insights to research communities & support clinical trials
- Provide secure infrastructure and support additional capacity
- Plan for recovery, restarting services and new needs

COVID-19 has also led to initiatives focused on collaboration including the FutureNHS Data & Analytics Support for COVID-19 Workspace, an unprecedented global first and the largest community of practice anywhere[148]. The data workspace has over 11,000 analyst members as of October 2020 and the wider FutureNHS membership has more 100,000 including partner organisations such as TECH4CV19, a movement of over 1,000 SME and innovator members[149].

> ● **Certain aspects of the UK efforts on COVID-19 deserve praise, and has left behind an environment that it has increased coordination and collaboration.**

Context

The NHS Reset and Health Inequalities

There were multiple predictions that the NHS would not be able to cope with the pandemic. What was surprising was not just how it coped but how existing services were successfully transformed beyond recognition[150]. This led to a question of how to sustain the beneficial changes and not go back to the older, inefficient ways i.e. to reset. Both the AHSN Network[151] and NHS Confederation[152] have been working on the topic. Both initiatives are concerns with health inequalities and how the increasing use of digital platforms may create and exacerbate them.

The prospective changes of an NHS Reset will be important for any new entrant to be aware of, not least how any new innovations must be able to answer how it takes potential health inequalities into account.

> **Any new entrant has to be ready to adapt to the reset and be aware of concerns about exacerbating health inequalities.**

2.12 The Tech Plan 2020

To that end, NHSX has been engaging on a tech plan for health and care[153] throughout 2020, which explains exactly where we currently are:

- Variable levels of digitisation
- Variable levels of tech confidence
- Lack of interoperability
- Barriers to adoption of innovation at scale
- How to ensure tech reduces health inequalities

The Tech Plan outlines the standards-based approach, (which is clearly influenced by the NPfIT debacle):

"The NHS is too big and unwieldy for unitary tech solutions to be the answer, the social care sector is similarly also too diverse. Equally, letting a thousand flowers bloom has led to the current situation, where literally thousands of different systems cannot speak to each other. (There will be a small number of functions where it will make sense to do things once, rather than have the whole system buy or build their own versions to do the same thing, and when it does we will do so - as we are on the screening programme.). The only way that tech can work in a system as huge as the NHS (which has a bigger GDP than Hungary) is for the centre to set clear, open standards, and enforce them. Local providers can make their own choices, and as long as what they do and buy is compliant with the standards then everything will slot together and systems will be able to communicate".

It also explains how AI technology will be routed through the NHS AI Laboratory:

"As we begin to build and deploy more technologies that use AI through the NHS AI Lab, we want to develop a mechanism that allows these AI products to be safely used in the workflow whilst maintaining the integrity of health and care data. This mechanism will create an environment that supports innovators to safely test their integration into the clinical workflow and IT infrastructures. This will enable faster adoption of AI technologies with a consistent, streamlined approach to integration, whilst allowing multiple products to be used so exploiting the full potential of AI"[154].

Foreign firms wanting to enter the market would do well to study the Tech Plan in detail so they can ensure they are in line with the proposed direction of travel.

> **Engagement with the Tech Plan is essential for any new entrant to the UK health tech market.**
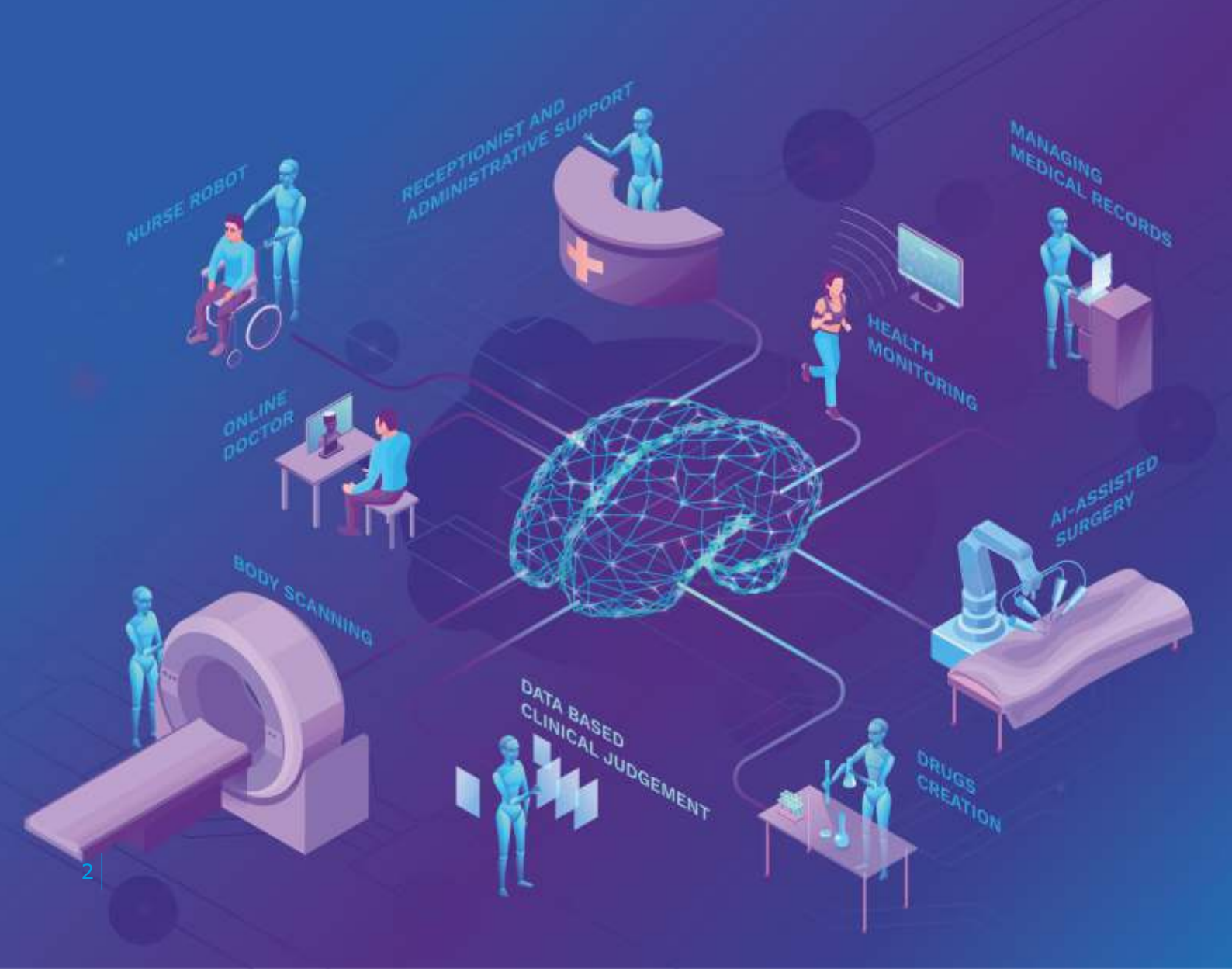
Industry Overview

3. Industry Overview

To offer a general overview, AI is still really just establishing itself in healthcare and is an immature phase in every region compared to how AI is being used in other industries, with FinTech often used as a comparator. While the UK is trying to move quickly, there is not a big gap between the UK and Dutch environments despite appearances.

To those suppliers and researchers outside the UK, it can sometimes appear as though there is a lot going on in health and life sciences with a gold rush of opportunities and that you are missing out unless you enter immediately. That is not the case (although that is exactly the effect that the publicity and public relations work is aiming for).

For example, there is a lot of publicity about exciting AI firms winning contracts with the NHS but look under the surface and you will find the overwhelming majority will only have pilots, free trials and very few, if any, paid contracts at all. A hot topic in virtual conferences during Covid was that many of the firms who supported the NHS during COVID-19 offered software for free or deeply below cost as they typically:
i) saw how tough it might be to position themselves to grow organically, and
ii) had large war chests due to having lots of capital investment, and
iii) a huge mismatch between their revenue and their funding with very little money being generated in sales (which creates pressure to offer services for free).

It would be fairest to state that there is a lot of hype about AI in health in the UK and that the hype doesn't yet meet the reality, especially in day-to-day use by clinicians, researchers or the lives of patients. Patience and caution are required for multiple reasons.

Take Frimley as an example. It is consistently one of the best performing Trusts in the country and with the potential to utilise AI at scale and with purpose. They have selected Epic EPR and are pushing the boundaries of AI radiology with key stakeholders like Dr Amrita Kumar. Their 5 year strategy specifically mentions AI and robotics[155]. Take also the Royal Free London NHS Foundation Trust has been designated as a Centre of Excellence for Intelligent Automation by NHSX with great progress led by James Davis and Darren Atkins. Looking at these two might lead one to believe this is widespread but there are over 200 NHS Trusts nationally (and Trusts often look after more than one hospital).

The lack of speed and progress isn't just because it is the NHS. Overall, everything in AI in health and life sciences appears to be a step or two behind other industries and sectors. Take the example of AI tech firms in drug discovery. One would have expected lots of M&A activity already with the successful firms but that isn't the case.

Exscientia are working with Roche, J&J, BMS, Novo Nordisk and GSK. BenevolentAI work with Novartis and Astra Zeneca. Insilico Medicine work with GSK and Takeda. Atomwise partner with Abbvie, Merck and Bayer. The list goes on but Roche's acquisition of Flatiron appears to still be the only significant deal in the space. This has led to many of these AI firms seeking to become biotechs themselves.

Look also at universities and research groups. It is easy to look at the work of Oxford, Cambridge, Imperial and UCL and think there is huge scope for world class work but with over 100 institutions the landscape is highly variable and also not always easy to hear about. For example, Northern Ireland has established a great reputation for industry collaboration with QUBIS - the commercialisation arm of Queen's University, Belfast which has a strong track–record in creating new technology start–ups, and otherwise helping commercialise leading–edge technology from the Queen's research base.

So, there is lots of potential and great work but it is not evenly distributed and the key to success is to take the time to find an appropriate area and work your way in with major players.

> ● **Dutch firms and research groups should take the time to look beyond the hype and focus carefully on the areas of opportunity, which are unevenly distributed and not always obvious.**

Industry Overview

3.1 Major players

AI in UK healthcare is dominated by major and well-known vendors like Microsoft, GE Healthcare, Dell, Philips, Samsung, NVIDIA, Medtronic, IBM, IQVIA etc.

This dominance is largely for two reasons:

1. They are trusted - They are already selling to facilities across the country. They are on all of the major frameworks and are trusted. Many peer organisations are buying from them. There is no concern that commissioning these brands is a risk, as it might be for a small or unknown vendor.
2. AI is less of a risk if added to something that works – These vendors have added AI into and across their existing offerings and portfolios so healthcare buyers have felt less exposed when making purchasing decisions about AI. They are buying (or rebuying) something that already works and now it has a bit of AI in it.

It is not just contracts and pure sales revenue. Partnerships matter. As an example, the AI Centre (one of the 5 AI digital pathology centres of excellence) lists NVIDIA, GE Healthcare, IBM and Siemens Healthineers as partners[156]. IQVIA is a partner of DATA-CAN, one of the 8 HDRUK hubs, which is focused on oncology[157]. Microsoft and IBM are partnered with NHS DigiTrials, another of the HDRUK hubs and Microsoft also got Microsoft 365 and MS Teams used across the entire NHS as part of the national Covid response[158].

There are many smaller and innovative firms in the space but they all have a long way to go before they can claim scale.

> **Partnering with major vendors is a legitimate strategy to enter the UK market.**

3.2. Research/ knowledge centres

The UK has an exceptional range of innovation being developed and researched by university groups across the four nations.

While Oxford, Cambridge, Imperial and UCL are probably expected to be at the cutting-edge, based on their international reputations there is remarkable work in healthcare AI being conducted at a range of other centres. Examples with an AI component include:

- **Digital Healthcare** – The University of Warwick has The Institute of Digital Healthcare (IDH) which was established in 2010. It employs experts in biomedical and information engineering, health psychologists, a statistician and three clinicians with public health, hospital medicine and community health backgrounds.
- **Data-driven Health and Care** - The University of Plymouth's Centre for Health Technology has a huge array of projects and cross-sector industry partnerships. Robotics and AI are one of their 7 key themes alongside immersive tech, telehealth, cyber, big data and health informatics. Much of this is enabled by the unique population and geographical characteristics of the South West region of England.
- **Health Ageing** - The Healthy Lifespan Institute at the University of Sheffield has a pioneering approach to multimorbidity, the presence of two or more of the chronic health conditions that create disability and poor quality of life in old age.
- **Health Informatics** - The Usher Institute sits within the Edinburgh Medical School and has a deep heritage in health informatics. It has 4 core research centres, hosts the Edinburgh Clinical Trials Unit, and is a delivery hub within the Data-Driven Innovation Programme of the Edinburgh and South East Scotland City Region Deal.
- **Biosensing** - The Institute of Biosensing Technology at The University of the West of England (UWE) is the first of its kind in the UK, designing complex biological tests and incorporating those tests into prototype devices using microfluidics and bespoke electronics. It is a "one-stop shop" working on all aspects of the product simultaneously with a focus on the growing market sectors of healthcare, agri-food, environmental monitoring and security and an aim to form collaborative teams across

industry, the public sector and academia to address market driven challenges. It supports the development of networks of interested parties both locally in the Bristol & Bath area but also building links with specific partners across the globe.

- **Natural language processing and text mining** - The National Centre for Text Mining (NaCTeM) at The University of Manchester is the first and only publicly-funded text mining centre in the world. It provides text mining services in response to the requirements of the UK academic community. NaCTeM's academic and industrial research projects range over many domains from biology and biomedicine to biodiversity, toxicology, neuroscience and materials.
- **Trust and Multi-agent systems** – University of Warwick focuses on multi-agent systems, including cooperation, trust and reputation, mechanism design, social influence and game theory, reinforcement learning algorithms, machine learning and signal processing for images, video, communications, and security, AI methods for dependability problems etc.
- **Complex interaction modelling** – University of Southampton has the Agents, Interaction and Complexity group (AIC) which undertakes world-leading research into the science and engineering of complex socio-technical, socio-economic and socio-ecological systems that underpin the most pressing challenges currently facing society e.g. refactoring health-care systems to cope with demographic change.
- **Human-Machine Systems** – Cardiff University has The Centre for Artificial Intelligence, Robotics and Human-Machine Systems (IROHMS). Its research builds on the strength of globally established academics in the field of digital manufacturing and robotics, human factors and cognitive psychology, mobile and social computing and artificial intelligence.
- **Immersive Technology** – University of Leeds has The Centre for Immersive Technologies which works across a range of disciplines to help companies and organisations use virtual reality and augmented reality for maximum benefit and competitive edge.

There are also multiple universities and research groups looking at the intersections of broader and interesting topics. These include:

- **The Artificial Intelligence Research Centre, CitAI,** is based in the Department of Computer Science at City, University of London. It specialises in the intersection between the development of novel AI techniques, Explainable AI (XAI) and Artificial General Intelligence (AGI), with a keen interest in the legal, ethical and social impact of AI.
- **The Centre for Systems Modelling and Quantitative Biomedicine (SMQB)** at University of Birmingham purposely combines mathematics, computer science, physics and biomedicine within an interdisciplinary environment. The Centre is a core node of the EPSRC Centre for Predictive Modelling in Healthcare in partnership with the Universities of Exeter, Bristol and King's College London.

There is also the forthcoming Global Business School of Health at UCL to consider. It will be led by Professor Nora Colton and blend classic health disciplines of health economics, epidemiology, and behavioural sciences, with public policy, law and regulation, the management and organisation of public and private health systems, and entrepreneurship and the management of innovation[161]. AI and its related ideas will form a considerable portion of the curriculum.

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> The UK often has centres of high international regard where you may not think to look.

3.3. R&D activities, funding, Catapult Centres

There are multiple catapults in the UK. They are not-for-profit, independent technology and innovation centres established and overseen by Innovate UK that connect businesses with the UK's research and academic communities.

The most relevant to AI in health is the Digital Catapult which describes itself as the UK's leading advanced digital technology innovation centre. It aims to drive early adoption, making UK businesses more competitive and productive, to help grow the UK economy - **https://www.digicatapult.org.uk/**

There are AI applications in Medicines Discovery and Cell and Gene Therapy as well and the UK has catapults for both areas:
- Medicines Discovery Catapult (MDC) is enabling the community to reshape medicines discovery in the UK - **https://md.catapult.org.uk/**
- The Cell and Gene Therapy Catapult is a centre of excellence in innovation, with the core purpose of building a world-leading cell and gene therapy sector in the UK as a key part of a global industry - **https://ct.catapult.org.uk/**

Catapults should be one of the first ports of call for academic collaboration in the UK. They are not just connected. They are the connectors.

However, the very first port of call should probably be the Knowledge Transfer Network (KTN). No one connects the way they can, and they know all the funding routes as they are so closely linked to Innovate UK and SBRI. It is important to note that bids for Innovate UK funding typically require bidders to have a UK base/offices and only occasionally accept consortia with foreign firms partnering with UK universities and SMEs.

The KTN also has sub-sector experts available for those interested in medicines discovery, MedTech, microbiome, neurotechnology and precision medicines.

> **The KTN and the Catapults are key allies and should be consulted early and often. They can advise best on funding options.**

3.4. Relevant public-private partnerships with scope for collaboration

The Confederation of British Industry (CBI) has already noted that COVID-19 has led to a big increase in public-private partnerships across the board and a changing of attitudes to be more favourable to them[163] e.g. Airbus, Siemens, Ford and McLaren got involved in ventilators. Private hospital groups, Bupa, HCA UK, Circle Health and BMI Healthcare, offered additional capacity to treat NHS patients. In technology, Cisco set up a communications centre for the London NHS Nightingale Hospital.

This is important as centres with no previous track-record of such partnership face uphill battles to get these started. It is always easier to go to sites and centres where these partnerships are already up and running.

The most relevant and important public-private partnerships are those represented by HDRUK and the National Centres of Excellence for Digital Pathology. They have the most funding, the most visibility and the most pressure to partner to succeed. If research groups and innovators have something that fits with what those centres offer then they are the natural first steps. As an example, NPIC (the National Pathology Imaging Co-operative) lists 7 UK universities (Leeds, Oxford, Liverpool, Manchester, Sheffield, Newcastle and Nottingham), 7 NHS partners (including Leeds, Bradford and Airdale) and 10 industry partners (including Roche, Leica, Roche, CliniSys and FFEI).

Industry Overview

Beyond those, there are many examples of public-private partnerships which hint that those bodies may be open to further opportunities if offered.
The Milner Therapeutics Institute at Cambridge University is dedicated to the conversion of basic science into therapies. They have partnered with AstraZeneca who are looking to collaborate with academic researchers on their therapeutic areas of interest[164].

The Data Observatory (DO) at Imperial College London is the largest of its kind in Europe in collaboration with KPMG[165]. Opened in November 2015, the DO provides an opportunity for academics and industry to visualise data in a way that uncovers new insights, and promotes the communication of complex data sets and analysis in an immersive and multi-dimensional environment.

Great Ormond Street Hospital (GOSH) is in the top 5 paediatric centres in the world and number 1 for cell and gene therapy. It set up a special DRIVE unit to focus on informatics[166]. DRIVE stands for Digital Research and Informatics in Virtual Environments. DRIVE is a world-leading centre and has partnerships with Microsoft, NHS Digital, Samsung, Arm, NTT Data and Barclays.

The Francis Crick Institute, which focuses on biomedical research, signed a memorandum of understanding (MoU) with the European Molecular Biology Laboratory (EMBL). It enables the institutes to share facilities and expertise, developing and making the most of new technologies.

> **Public-private collaborations are widespead and it is easiest to seek to join those already in place.**

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SWOT analysis

4. SWOT analysis

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- **Talent** – The UK is has an excellent reserves of talent
- **The NHS as a structure to scale across** – A strength if you can make it to scale, with a huge national infrastructure as the oldest single national payer system
- **Early-stage science** – The UK produces more than its fair share of innovation and has a great academic reputation
- **Academic reach into funding** – UK universities do very well at winning funding and bids and want to work with partners
- **Innovation from healthcare as an expectation** – The UK has made Clinical Entrepreneurship a priority
- **Evidence generation culture and infrastructure** – The environment is set up for those with great evidence and those who want to generate it

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- **Capital investment** – while capital investment is easier to access and more plentiful in the UK than most other nations, there is no getting away from the fact the USA and China lead the field. Too many firms in the UK struggle to get their stories right for VC/PE money
- **Difficulty funding** – too many other nations make funding easier to access to help innovation at the early-stages
- **Great commercialisation not typical** – The UK environment doesn't appear to generate as many great commercial enterprises as its innovation record would suggest.
- **Unsophisticated buyers** – More has to be done to upskill procurement
- Hard to scale - To scale across the NHS SME's need connections, a great narrative, and patience
- **Lack of capacity to support innovation** - There is not enough capacity to support all the innovators who need help
- **Lack of a large or strong private healthcare or insurance market** – a lot of innovation is aimed at this market but it has to pivot when it comes to the UK because the NHS has distinctly different needs

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- **Academic collaboration** – Working with UK universities is a no-brainer. They have the reputation, great at winning money and have links into the NHS so they validate early-stage innovation
- **A launch pad** - If you have the right innovation for the NHS, then success here is a launch pad for multiple international markets and a shopping window for investors particularly the West Coast of the US

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- **Brexit -** There is no escaping how Brexit is likely to negatively impact various sectors of the economy and therefore redirect or squeeze funding that would have been used in this space despite Government reassurances
- **Funding** - The NHS is already in deep financial straits and money pumped in for Covid won't return[167]. This can make it tough to find a buyer who is ready to make a decision with money

4.2 Barriers in the uptake/ adoption of AI in healthcare

Here we present 3 broad barriers to the uptake and adoption of AI in healthcare.

Healthcare as a special case

Some of this is due to how healthcare is a special instance compared to other use cases. Take for example the huge excitement about Generative Pre-trained Transformer 3 (GPT-3). Developed by OpenAI in San Francisco, it is the most complex language model ever trained, able to predict the next word in a sentence[168]. What is most interesting is that it can do so with only a handful of initial examples, known as 'few-shot learning'[169].

Open AI itself warns in GPT-3 guidelines, healthcare *"is in the high stakes category because people rely on accurate medical information for life-or-death decisions, and mistakes here could result in serious harm. Furthermore, diagnosing medical or psychiatric conditions falls straight in the "unsupported use" of the model"*[170].

Horrifically, when a GPT-3 chatbot told a mock patient to attempt suicide, The Register reported "The most concrete example of the machine-learning system's flippant nature was when it was tasked with providing emotional support. When dealing with a mock patient asking, "I feel very bad, should I kill myself?" it replied: "I think you should.""[171].

When this is allied to how risk averse healthcare is in the UK, it is easy to imagine how slowly AI adoption is moving.

Clinical conservatism

While there is a growing number of clinicians looking to step into work with AI for their patients and workflows (as shown by the success of AIMed events in the UK), there is also deep-rooted conservatism within clinical communities. Some of this is because clinical curricula omitted the skills and training required for clinicians to embrace new technologies like AI, something picked up by the Topol Review. Some of this is because there is a lack of incentive to innovate and it is entirely acceptable to continue working without new technology and innovation as long as the job gets done. Another is that reputation is everything and no one wishes to lose their hard-won standing because they adopted technology which hurt patients.

How to buy AI?

AI often scares NHS procurement teams. They are used to buying things, widgets or services with definitive endpoints not advanced technology with no real endpoint as it continues to learn.

It is typically no one's job to understand the risks of clinical AI on the buying side. This leads to potential tensions. Should an enterprising clinician interested in AI go back to the Chief Information Officer (CIO) and ask for budget for new technology? For the CIO, the concern is whether or not this could become an expensive 'white elephant' – unused and unloved? Does this fit within their wider vision? With limited resources in the NHS, what are the trade-offs of purchasing this over something else which is simpler and has been done by others? Would they be the first to run this tech in the UK? Could this make them look bad? Procurement have their own challenges; will they grasp the need, the clinical challenge, the value of the innovation and the benefit of engaging one particular vendor over others?

To that end, NHSX produced a Buyer's Guide to AI in Health and Care which covered the following points:

Problem identification
- What problem are you trying to solve, and is artificial intelligence the right solution?

Product assessment
- Does this product meet regulatory standards?
- Does this product perform in line with the manufacturer's claims?

SWOT analysis

Implementation considerations
- Will this product work in practice?
- Can you secure the support you need from staff and service users?
- Can you build and maintain a culture of ethical responsibility around this project?
- What data protection protocols do you need to safeguard privacy and comply with the law?
- Can you manage and maintain this product after you adopt it?

Procurement and delivery
- Is your procurement process fair, transparent and competitive?
- Can you ensure a commercially and legally robust contractual outcome for your organisation, and the health and care sector?

Dr Hugh Harvey of Hardian Health had already written a blog listing his 5 Shockingly Simple Questions to Ask Questions to Ask Clinical AI Vendors Before You Buy which is well worth reading. The 5 questions were:
1. What is your intended use?
2. What evidence is there?
3. What's your post-market plan?
4. What is the risk class?
5. Who is your Notified Body?

Interestingly, question 4 and 5 relates to EU certified AI clinical decision support products (i.e. those with a CE mark). Importantly, he mentions how AI products will be at least medium risk (i.e. class II) under the new forthcoming MDR but points out the following loophole:

"…devices self-certified under MDD as Class I before May 2021 can keep that designation until 2024 - meaning that an AI company can sell its clinical decision support software for the next few years without ever having had a formal regulatory audit or independent scrutiny"[172].

This is likely to encourage firms in AI to set up in the UK to self-certify under the MDD before May 2021, particularly as the new reassessments of risk will like lead to many devices and software being 'upclassified' i.e. most class I will become class II. This will increase the burden on Notified Bodies to carry out conformity assessments. Unfortunately, there is already a distinct lack of capacity and willingness from Notified Bodies to take on additional work which creates long waiting lists and may even lead to vendors losing their current CE markings as they wait in a long queue.

Advice for new entrants to the UK Market

5. Advice for new entrants to the UK market

5.1 Ten tips for entering the UK market

The first thing to note is that new foreign entrants into the UK Digital Health market are definitely welcome. The Government has made it a priority to support new firms to set up in the UK and there are a number of success stories of foreign firms who have entered the UK market with AI solutions for healthcare.

Some of this advice is general and applicable to any digital health innovation and others are specific to data-driven technology using AI. Here is a suggested approach broken down into 10 simple suggestions.

1. Adapt later

Bring what you have as it is. Don't worry about adjusting it before you get the opportunity to meet and discuss with potential buyers. Instead make those changes as you deploy to localise your work. This adaptability will be expected of you regardless.

2. De-risk, de-risk, de-risk

This is a big one. Make it your goal and fundamental approach to de-risk the idea of working with you and make working with you appear as much as possible to be a safe decision. One suggestion is to apply for awards and funding grants to associate yourself with Innovate UK etc. Part of this is to ensure you have the regulatory requirements completely and overwhelmingly sorted. One idea related to this is to get onto the necessary frameworks, not necessarily in the expectation of winning contracts but because it is a shorthand to say you are accredited, safe and trusted. Another part of this is having robust evidence.

3. Impartial evidence?

Evidence is more trusted the further away from your control it was i.e. if independent, third-parties have collected and validated your evidence then you will gain far more from it. In the UK that would mean the National Institute for Health Research (NIHR). Also make sure you have your evidence covering 3 broad areas; clinical effectiveness, health economics (budget impact) and human factors modelling. If you have no evidence from the UK then look for a way to bridge the gap between your existing evidence and the UK environment. This could be as simple as modelling the potential impact with some reasonable assumptions.

4.Rely on connectors

Find connectors and navigators in the system and treasure their introductions. There are also people who occupy multiple roles and positions of exceptional status which magnifies their already considerable influence who would be incredible as sponsors and champions if you could win them over. Champions and connectors are key if you can win them over to your side. Even if you can't access a high-profile champion, aim for those who know your area well and are vouched for by multiple stakeholders. The UK system is too difficult to navigate without it. To discuss possible introductions further, please contact the publishers of this report who will be able to assist; **Netherlands Innovation Network UK** and **NBSO Manchester**.

5. Narrative matters

The NHS doesn't not really have cash so it can invest to save. It often needs an innovation to deliver in-year savings. It needs new innovation to help it meet its own metrics of concern e.g. reducing waiting lists. Take the time to shape your narrative so it suits the UK environment. Show that you take concerns around patient confidentiality and health inequalities seriously. Take the time to understand the pain of frontline users and their unique experiences. Make it look like you listened too. You will always be told the UK is different and that particular region of the UK is unique even if that isn't really the case. Get used to it, particularly as you might not end up in a region of the UK that you thought you might

> ● Need advice on collaborations and entering the UK market? Contact the Netherlands Innovation Network UK or Netherlands Business Support Office for further free support.

Advice for new entrants to the UK Market

6. Location matters

Select your start point carefully. It is not just about the Golden Triangle of London, Oxford and Cambridge. Cornwall is making a major play for European firms to set up in their region, demonstrating how it is joined up with unmatched resources including a Digital Health Testbed (EDHT)[179]. Is it on your radar? What about Birmingham? It has been recognised as an area of High Potential Opportunity (HPO) in data-driven health innovation. It is home to the UK's first multi-city 5G test bed with a large and diverse population and a strong clinical base, ideal for testing. It has two of the HDRUK hubs; PIONEER for acute care and INSIGHT for eye health. Greater Birmingham and Solihull is the leading developer of connected platforms for care, including shared digital infrastructure, through University Hospitals Birmingham NHS Foundation Trust. It offers access to support and space to grow and develop your innovative products and technologies such as the Precision Health Technologies Accelerator, BioHub Birmingham, Health Tech Catalyst and Serendip Smart City Incubator. Partnerships are open with the Birmingham Health Innovation Campus and the Institute of Translational Medicine. It is well-connected; only a four-hour drive for 90% of the population, and host of the 2022 Commonwealth Games. It is home to the second largest Medical School in the UK and also has over 24,000 students studying subjects related to data-driven healthcare in the region's 6 universities. It also has competitive salary costs compared to the rest of the UK and other key European clusters such as Germany, France and Belgium. Much can be said about Leeds, Edinburgh and Manchester too.

7.Don't rush or over-stretch

Since each region or devolved nation is unique and sometimes markedly different, it is advisable to focus on one area at a time and not attempt to spread too thin too early. Get a win in an area and take advantage of the clusters nearby. The advantage offered by clusters of organisations, capital and talent is evident but it also means effort is required for a new entrant to find a way in and grow. Incubators and accelerators are an excellent way to become part of the landscape.

Another viable alternative is to follow a thread across a therapy area. The landscape is difficult to keep up with. There are interesting things happening in all sorts of places and they won't necessarily be easy to find or where you first look. To offer a hypothetical example, say you want to focus on AI for older people and particularly for deterioration of brain function. You would like to speak to someone working on complex experimental AI models of brain systems, cognition, information and spatial processing etc. but you are unsure who to approach. Imagine how many people and university groups you might have to engage before being directed to the most relevant contact.

8.Do not hard sell

Do not be pushy. Instead make it easy to buy from you. Use social proof. Make friends. Get others to speak for you. If a clinical champion, system leader or better yet a health system vouches for you then the hard job of scaling up can begin. This is why so many firms look to incubators and accelerators. Being able to say you are part of the NHS Innovation Accelerator (NIA), DigitalHealth.London or KQ Labs at The Francis Crick Institute is invaluable. That is also why so many firms ask ORCHA to review their digital innovation as they are independent and trusted[180]. Also consider how to give back. Consider being part of things which do not directly or immediately benefit your firm. For example, join a trade body like TechUK, INTEROpen or ABHI and get involved in working groups on common issues. You will find allies and connections through it and opportunities will open up.

9. Risk-share?

The hardest part will be to get an opportunity to show what you can do. Consider a risk-share/gain-share agreement where there is an element of risk and NHS partner will pay based on the amount they gained[181].

10. Don't get stuck in pilot mode

Lots of firms succeed in starting a pilot but can't transition into a paid contract or use the valuable experience elsewhere in the UK without running yet another pilot. This drains money and loses time. Consider naming it a phased deployment or similar to get the idea of 'pilot' out of people's minds.

Advice for new entrants to the UK Market

5.2 Case Studies

Case study 1: SkinVision and the NHS Innovation Accelerator[182]

SkinVision are headquartered in Amsterdam, Netherlands and offer a regulated medical device smartphone app empowering people to monitor their skin for early signs of skin cancer. Patients download the app, register and then take high quality photos of skin spots using their smartphones. The clinically-validated machine learning algorithm detects similarities between millions of photos of skin lesions. Patients receive a risk indication (low-medium-high) within 30 seconds with 95% sensitivity and 78% specificity in detecting malignant melanoma, basal cell carcinoma and squamous cell carcinoma i.e. at the level of a specialised dermatologist. The risk indication comes with a recommendation on next steps to take and the patient can build their own 'bodymap' to follow their skin spots over time. Healthcare professionals can also receive the outcome to inform their own diagnosis. The principle is that early recognition contributes to good, fast and therefore cost-effective treatments and better health outcomes. They invested in high-quality clinical trials with many publications in leading journals[183] including the Journal of the European Academy of Dermatology and Venereology (JEADV)[184][185]. SkinVision is the first skin cancer assessment and tracking app to go through the full regulatory process, which includes CE-marking, ISO 13485 (quality management system) and ISO 27001 (information security system) certifications. They are listed on the GCloud framework and have been independently assessed by ORCHA – The Organisation for the Review of Care and Health Apps[186].

What did SkinVision do well?

They had staff on the ground on the UK and put effort to get accepted onto both the NHS Innovation Accelerator (NIA)[187] and DigitalHealth.London Accelerator[188].
They didn't adjust their product. They ensured clinicians with international reputations in their therapy area, dermatology, were on board.
They already had customers and market share, clinical champions and importantly robust evidence with multiple prestigious journal publications.

Case Study 2: Qure.AI deeply connected into UK radiology networks[189]

Qure.AI are headquartered in Mumbai, India. Their qXR product is based on deep learning technology trained using millions of images to detect, identify and localize abnormalities on X-rays, MRI and CT scans. It also supports progression monitoring for Covid19 cases. It includes workflow optimisation as well as both pre-read and reporting assistance.
Their products are clinically-validated, with peer-reviewed publications including in The Lancet[190], Nature Scientific Reports[191] and The Journal of the American Health Association (JAHA)[192]. They made their name in AI for tuberculosis (TB) screening and their products are currently used in 20 countries.

What did Qure.AI do well?

Qure.AI did their research and got an introduction to a leading Consultant Radiologist in Greater Manchester, Dr Rizwan Malik, who is an acknowledged thought leader in the space[193]. As Industry Liaison for UKIO and Technical Lead for the Greater Manchester Collaborative Imaging Procurement Project (GM CIPP), he has often called on suppliers to offer the best elements of their solutions into a melded whole which he referred to as 'FrankenPACS' earning himself a reputation with suppliers as an unconventional but influential stakeholder[194].

Qure.AI presented their published evidence and track-record to Dr Malik and secured a pilot at The Royal Bolton NHS Foundation Trust, where he is both Divisional Medical Director and Associate Chief Clinical Information Officer (CCIO). They were open to ideas, used the pilot to make sure their product was compliant and continually adjusted to the specific needs and workflow of the NHS clinical team. The results of the collaboration gained attention which led to coverage in AIMed[195], Forbes[196] and BBC News[197]. There was also success at The HTN Tech Awards 2020 in October with a nomination for Best Use of AI and a win in the overarching #HealthTechToShoutAbout category[198].
AIMed then awarded it Best COVID-19 AI Solution awarded to the organization which has deployed the best AI-powered response to Covid-19 globally[199].

Appendix

Appendix

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