10 Year Health Plan Supporting Documentation - Digital Sector Plan

BACKGROUND

The digital health sector in the UK has experienced significant growth and transformation over the past decade, driven by advances in technology, changing healthcare demands, and strategic government initiatives. It has been the segment with the highest employment within the medical technology sector since 2009/10.

The UK, like many countries, faces increasing healthcare demands due to an aging population, rising chronic disease rates, and resource constraints within the health system. Successive governments have identified digital health as a priority to improve efficiency, reduce costs, and enhance patient outcomes. This has been translated into policy, such as the NHS Long Term Plan, Digital Health and Care Plan, as well as initiatives such as Global Digital Exemplars and the NHS AI Lab, to name just a few.

Industry has responded to the digitisation challenge through a thriving health tech startup ecosystem and a substantial increase in venture capital investment in digital health, supporting areas such as telemedicine, AI diagnostics, remote monitoring, and wellness apps. The UK has seen HealthTech investment levels rise from just $420m (£345.48m) in 2016 to $3.8bn in 2021following close behind China's $4.1bn (28.24bn yuan), and leading the way in Europe.[1] Previous Industrial strategies have also incorporated public-private partnerships to support developments in key areas such as AI in imaging Diagnostics. The COVID-19 pandemic further accelerated these collaborations, with digital solutions like remote consultations, vaccine tracking apps, and COVID-19 testing systems rapidly deployed.

OPPORTUNITY

The digital health sector in the UK presents substantial opportunities from both economic and NHS perspectives. The sector has attracted significant venture capital, is creating high-skilled jobs and has strong export potential. Innovative solutions, particularly in AI-driven diagnostics, telemedicine, and data analytics, are being sought after worldwide.

Continued partnership between industry, Government and NHS can provide a strong home market and provide a base for exporting these technologies. This will strengthen the UK economic position in the global HealthTech market, where we are currently a net importer.

Digital tools can address NHS resource constraints, including workforce shortages and increased demand from an aging population. Digital health solutions, such as AI for diagnostics, remote monitoring, and telehealth, can help the NHS improve efficiency, free up capacity, and reduce patient backlogs by enabling remote care and self-management. These also contribute to better patient outcomes by enabling early intervention, personalised care plans, and continuous monitoring of chronic conditions. Improved outcomes reduce the burden on NHS facilities by preventing complications, reducing hospital admissions and minimising the need for in-person consultations, leading to lower operational costs.

[1] https://www.investmentmonitor.ai/comment/uk-healthtech-sector-2023-investors-pharmacy/?cf-view

Digital tools and pathways also have potential to support a healthy workforce reducing sickness levels and facilitating return to work pathways.

RECOMMENDATIONS

Digital Health is a collective term encompassing a range of technologies, processes and applications, for the UK it offers an economically attractive and strategically valuable path for growth while also aligning with the NHS's goals of efficiency, patient-centred care, and sustainable cost management. These opportunities need to be supported by sustained investment and innovation. There are several key area that need to be addressed to support the development and deployment of digital tools generally and some that relate to specific areas or use cases, such as AI or remote monitoring

1. **Enhancing Digital Health Infrastructure**

   Re-prioritise NHS spend devoted to developing a digital enabled system to 5% to meet recommendations made in the Wade Gery review, supporting the development of infrastructure that allows for access to the full depth and diversity of UK health data with a streamlined governance system that preserves privacy and data security, and with commercial terms that are globally competitive

   - **High-Speed Connectivity**: Ensure that healthcare providers, including those in remote or underserved areas, have access to high-speed internet and digital infrastructure. This connectivity is crucial for telemedicine, remote monitoring, and data sharing.
   - **Invest in Platforms**: Build robust digital health platforms that allow healthcare providers, patients, and researchers to access, share, and analyse health data. This includes electronic health records (EHRs), imaging data, genomic sequencing, telemedicine platforms, and mobile health (mHealth) applications.
   - **Cloud Computing and Data Centres**: Invest in cloud computing and secure data centres to support the storage and processing of large volumes of health data, ensuring scalability, security, and accessibility.

2. **Surfacing the NHS and UK data asset**

   The NHS holds vast amounts of health data that, if effectively leveraged, can support predictive analytics, identify trends, and inform healthcare policy. From an industry perspective it could potentially offer a unique resource for research and development. However, at present, data is stored in disparate systems and quality is variable. To maximise the attractiveness of the NHS data asset industry would be looking for multi-modal, cradle to grave data linked across primary and secondary care at a population level. Current initiatives, such as the Data for R&D programme, are moving towards this with the SDE network and alignment with HDRUK, but do not currently have sufficient scale or scope. We highly recommend continued funding of the programme and integration into proposals for a national data library. There are however additional activities that can further support the development and access to NHS data

   - **Enhance the SDE Network:**
     - Clarity on the role and interplay of national, regional and local SDEs
     - Provide a unified, integrated service, with a single point of entry to the SDE Network, to streamline user experience and reduce duplication of effort.

    - Adopt consistent and harmonised processes for data access to the SDE Network, including information governance, contracting and pricing within commercially competitive frameworks.
    - Put in place appropriate external advisory structures that ensure that users are placed at the heart of strategic and operational decision-making
    - Standardised technical infrastructure across sub-national SDEs to improve researcher usability

- **Pro-innovation policy and processes**: That support public-private partnerships to enhance data quality and insights. These could, for example, include ensuring Trusts are allowed the flexibility to continue to take a local approach that support their specific needs and the needs of the local population.
- **Data quality challenge**: Utilise private sector capabilities, with necessary governance and ethics oversight, to support NHS resource to tackle the significant resources and expertise required to curate research-ready datasets of sufficient quality to generate revenue.
- **Interoperability Standards:** Define and enforce interoperability standards that allow different health systems, devices, and platforms to communicate seamlessly, ensuring that patient data flows smoothly across providers.

3. **Development of AI**

There is limited access to diverse data for training AI models which require access to extensive and diverse patient data. However, as NHS data is often siloed across different institutions, it can be labour intensive to gather sufficient datasets for training. The SDE Network could be a resource of enormous value, capable of providing rich linked multimodal data at scale to train and validate AI solutions of international importance. An AI development platform should be layered onto the SDE network to facilitate the development of world-changing AI solutions. There are some further steps that need to be taken to help realise this potential.

- A focus on imaging data across radiology and pathology, bringing together national image dataset specifically with a large-scale machine learning use case in mind.
- The necessary technical infrastructure including high performance GPUs closely coupled to SSD storage together with a development environment where AI researchers can deploy their annotation tools and containerised training toolchains.
- Use should be made of national resources (such as Cambridge -1, Isambard-AI) in a joined-up approach.

Such an approach would not only provide access to deidentified data at scale but also couple these datasets to the enormous compute resource needed to train models capable of human-level performance in healthcare diagnostics and treatment decisions.

To demonstrate the unique potential of such a resource, a headline project involving the triple helix of industry, academia and the NHS should be commissioned to create AI solutions of international importance. This should include all aspects of a typical engagement, including PPIE, cohort identification, data governance, PPIE, system co-design, annotation and training, validation, deployment and post market surveillance of the resulting technology.

4. **Deployment of AI**

AI is being increasingly integrated into healthcare. It is used for early diagnosis through medical imaging, predictive analytics for patient outcomes, and personalised treatment plans. AI-driven platforms assist in managing healthcare resources and improving. Currently the use of AI as a medical device is restricted to 'narrow' algorithms but increasing tools are being development based on LLMs. There remain many challenges to deployment of AI technology such as, but not limited to:

- Integration and interoperability with Existing Healthcare Systems.
- Workflow Disruption.
- Ethical and Privacy Concerns including data security and bias.
- Regulatory, compliance and liability concerns.
- Trust and acceptance among Healthcare Professionals due to lack of transparency and explainability.
- Cost and resource constraints including infrastructure, training and maintenance.

The MHRA should be fully funded to deliver its Software and AI roadmap and provide future focused guidance on its stance regarding Generative AI and LLMs, which needs further detail. We fully support the international stance that MHRA is taking in working with other regulatory authorities, such as the FDA, both through bilaterials and the International Medical Device Regulators Forum. This approach should be supported. Existing guidance that has been issued jointly with Health Canada and the FDA should be codified into regulatory processes.

There are specific issues for AI and Software as a medical device (SaMD) with current. Proposals from MHRA for International reliance. We believe that the proposals are too onerous, effectively providing no route for SaMD approved in the US, given that 90% follow the 510(k) process. While we understand the MHRA concerns, the proposed remedy is disproportionate and we believe that safety can be maintained by accepting FDA 510(k) approval with additional safeguards, similar to those proposed for SaMD with CE certification.

More generally there is a lack of clarity on how UK government will approach cross-sectoral regulation of AI.

The NHS AI Lab has provided significant resource through grant funding to pilot AI tools, however this approach creates 'cliff edges' when grants cease and makes long term investment in equipment and staff challenging for NHS organisations. Given the strategic and tactical importance of AI a more sustainable approach to AI funding needs to be taken. A central resource for support and expertise is a welcome, but the local organisation need to have long term oversight of funding flows to enable the move between trial/pilot to business-as-usual, which remains the crucial step to realising the potential of AI.

The work of the Incubator for AI and Digital Healthcare [2] should be continued and expanded to provide a wider resource for AI innovation, providing a focal point for the

[2] https://www.regulatoryscience.ai/

multiple initiatives in the sector and a key facilitator of collaborations across industry, regulators, academia and NHS.

5. **Cybersecurity**

Cybersecurity is critical for the NHS, as it plays a direct role in safeguarding patient care, data, and operational stability. With the increasing use of connected medical devices (e.g., monitors, pacemakers), Health technology suppliers have an important role in bolstering cybersecurity in healthcare, and embed security into these devices to protect them against cyber threats. This ensures that these devices meet security standards for both data protection and operational continuity. Suppliers conduct regular security assessments and penetration testing for medical devices and IoT solutions to identify and address potential weaknesses, reducing the risk of exploitation. As threat levels and sophistication of attacks increase it is vital that a coordinated approach is taken between regulators, suppliers and NHS national and local.

- We recommend that the previous Connected Medical Device Working Group is re-established to coordinate policy and, most importantly ensure consistent practice, in the delivery of a secure digital NHS infrastructure.
- Streamlined requirements for certification based on international standards and removal of duplication with medical device regulation.
- Stronger guidance and oversight of local trusts implementation of national policy to support easier integration of connected medical devices.

6. **Supporting Innovation and Research**

- **Removing Operational Obstacles:** We want the 10-Year Health Plan to prioritise the development by NHSE of an operational toolkit to support Trusts with the implementation of public-private data partnerships. Tools could include downloadable templates and checklists for key areas such as Information Governance, risk assessments, internal and external communication.
    - **Compliance and Governance**: it is recognised that NHS locally and nationally has legal obligations it needs to comply with. Rather than develop new processes we recommend that alignment with international standards is utilised wherever possible. These processes (eg DTAC, DCB, DPIA) should be run centrally to remove duplication, for industry and NHS, and provide a standard approach. Information should be held centrally and securely, but easily accessed by local organisations to undertake assurance.
- **Public-Private Partnerships:** Encourage partnerships between healthcare providers, universities, and tech companies to foster innovation. These partnerships can help accelerate the development and testing of new digital health solutions.
- **Innovation Hubs and Incubators:** Establish digital health incubators and innovation hubs where startups can collaborate with industry experts, gain access to funding, and test their products within healthcare environments. This aligns with recommendations in "A sector strategy to transform the economic and societal benefits of UK HealthTech" [3] from ABHI and Imperial College London.
- **Incentivising Adoption in the Healthcare System:** Offer financial incentives for healthcare providers to adopt and integrate digital health solutions into their practices, accelerating digital transformation across the sector.

[3] https://www.abhi.org.uk/media/ymcfex5q/final-helthtech_report.pdf

- **Clarity on evidence:** Transparency of the scope, quality and depth of evidence require for digital and AI solutions is required to enable industry to develop the necessary information required of the system. Current frameworks are too generalist and need sub categorisation, based on levels of risk.
- **Business planning:** a standardised approach to business planning using HFMA templates would provide transparency to industry on approach.

7. **Workforce Development and Training**
   - **Digital Skills Training:** Develop programmes to train healthcare professionals in digital skills, including data analysis, AI, cybersecurity, IG and the use of digital tools. This training can help them leverage technology effectively in their roles and address the skills gap / lack of specialised data expertise that hinders effective data stewardship
   - **Create a Skilled Talent Pool:** Work with educational institutions to create digital health programmes, ensuring a steady pipeline of data scientists, digital health specialists, and healthcare IT professionals.
   - **Establishing Digital Health Specialist Roles**: New roles focused on digital health — such as digital health project managers, data analysts, and cybersecurity specialists — can ensure smooth implementation and management. Funding to develop these roles helps build in-house expertise within the NHS.

8. **Building Public Trust and Engagement**
   - **Data Opt Out** When it comes to deciding how their confidential patient information is used beyond direct care, we believe the public could be better supported to make choices that are more specific and more informed. This can be done by considering how to move to a more nuanced NHS national data opt-out model and improving communications surrounding the NHS national data opt-out for greater awareness and transparency.
   - **Build on public dialogue**: the Government, in collaboration with NHS England, should develop a health data communications strategy as well as robust data governance standards and protocols pertaining to public communication. This could sit within a wider programme concerning the national data library. However given the sensitivity and history of heath data we believe it needs a specific approach.
     - **Transparency and Communication:** Be transparent about how health data is used, stored, and shared, and address public concerns about data privacy. Engaging the public in the conversation can build trust and encourage adoption.
     - **Educational Campaigns:** Run public education campaigns on the benefits of digital health tools, such as telemedicine and remote monitoring, to drive adoption and help people feel comfortable with new technologies.

9. **Funding**

In line with our recommendations on digital infrastructure above the NHS should re-prioritise spend devoted to developing a digital enabled system to 5% to meet recommendations made in the Wade Gery review. Digital health includes everything from electronic health records (EHRs) and telemedicine to mobile health apps, artificial intelligence, and wearable health technology, as well as the infrastructure, such as cloud storage, data sharing platforms, network enhancements, and secure servers, needed to ensure that digital health tools can operate efficiently and securely.

Funding digital health in the NHS requires a strategic, comprehensive, multi-layered approach, considering the diversity and vast potential of digital health to transform care delivery, improve patient outcomes, and streamline operations. It is critical that organisations have sustainable funding to enable investment decisions and resource allocation to have maximum impact.

- **National Digital Health Initiatives**: Direct government funding should be utilised to drive large-scale, transformative digital health programmes. These should provide dedicated, multi-year budget for digital health transformation to ensure continuity and allow NHS trusts to plan long-term implementations. Such funds would support core infrastructure improvements, digital health pilots, and workforce training.
- **Grant Funding**: Organisations such, the National Institute for Health Research (NIHR), and Innovate UK often provide grants focused on digital health technology. This should be continued with a broad focus with an emphasis on supporting routine clinical adoption of new technologies. Grant funding runs a risk of "cliff-edges" once funding stops, this should be addressed through joint working between grant organisations, industry and NHS to ensure each grant has potential mechanism to continue the work, if KPIs are achieved.
- **ICS Funding for Shared Projects**: Digital health initiatives often benefit from economies of scale and can run across organisational boundaries. Funding pools shared among organisations can support projects like regional health information exchanges, digital diagnostic platforms, and shared data analytics infrastructure.
- **Trust-Level Digital Health Budgets**: Aligned to the recommendation on re-prioritising spend to digital transformation and infrastructure, NHS trusts should have dedicated digital health budgets to allow for investments in local needs. This enables each trust to address unique challenges through tailored digital health solutions, from telehealth expansions to patient engagement platforms.
- **Scaling Pilot Programmes:** Pilot programmes should include a budget for outcome evaluation, with a business plan to expand successful initiatives. Pilots demonstrating clear benefits should receive additional funding to roll out across multiple trusts, maximising impact.
- **Strategy for Patient-Facing Tools**: Digital health must include solutions that empower patients, such as mobile apps for health monitoring and treatment, remote consultation platforms, and online appointment systems. Funding for patient-facing tools can improve access, convenience, and engagement, but needs to be part of a coherent strategy to optimise the benefits. Specifically for mobile Health Apps, a national implementation and evaluation process to deliver a formulary of assessed, cost-effective and nationally reimbursed digital treatments should be developed. A pathway for prescribing should be introduced, this can be modelled on successful initiatives such as DiGA in Germany, but learn from their experiences to offer an improved system. Key elements of a system would be:
    - **Regulation and Compliance:** Classified as low-risk medical devices (Class I or IIa) and compliant with UK legislation and international standards on data protection, cybersecurity, clinical risk, interoperability and usability.
    - **Assessment**: Proven health benefits with evidence-backed outcomes, assessed by NICE through a specific 'app appropriate' methodology that is structured, stable, and transparent and considers the holistic benefit: impact on access, quality of life, socio-economic benefit, efficiency of care, and health system costs.
    - **Funding:** via Drug Tariff Part IX explicitly linked with reimbursement and coverage recommendation for provider and payers.

- **Ongoing Quality Assurance**: Continuous monitoring, updates, and quality control to maintain app reliability.
- **System support:** Inclusion on prescribing systems and in guidance and guidelines.