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Navigating the Landscape of Digital Health

United Kingdom

OHE
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MINISTRY OF PUBLIC HEALTH
HITAP
Health Intervention and Technology Assessment Program

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Any errors are the sole responsibility of the authors.

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Executive summary

Digital health technologies (DHTs) represent various products used in the healthcare system, including software, applications (apps) and online platforms benefiting individuals and the wider health and social care system. It is a field characterised by complexity and dynamism.

The English digital health ecosystem centres around patients as the ultimate beneficiaries but comprises a vibrant network of stakeholders from all the private, public and third sectors (e.g., non-profits), engaging with each other at various steps along the technology lifecycle.

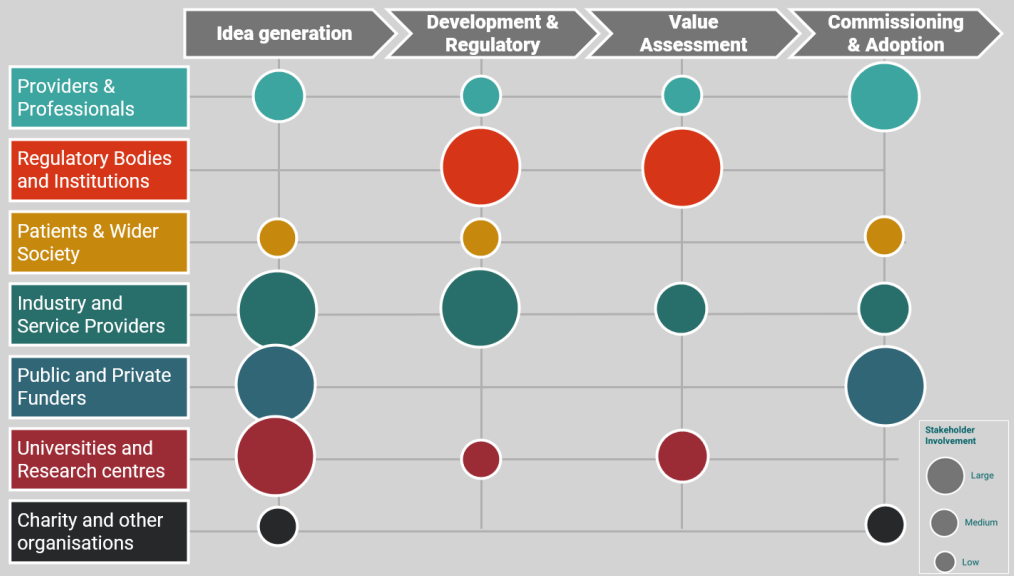


FIGURE 1: STAKEHOLDER MAP OF DIFFERENT ACTORS IN THE DHT ECOSYSTEM ALONG A TECHNOLOGIES LIFECYCLE

EMBRACING COMPLEXITY

The English digital health landscape embraces these complex characteristics. Rather than a single national strategy for DHTs, the UK government's Department of Health and Social Care (DHSC) and National Health Service (NHS) have conducted and commissioned a set of key reviews which attempt to learn from past endeavours to build a strategic outline for the future. This complexity is further enhanced by overlapping regulatory regimes, such as in the case of data protection which is overseen by multiple, distinct bodies. As a result, in many areas, England is not bound to provide a regular strategic update cycle or to publish legislation and regulation at a high pace.

The regulation of DHTs in England acknowledges the product variety in the field, as it is adaptive to the associated risk of a product. Following its withdrawal from the EU in January 2020, the UK's regulatory framework is currently in transition and attempts to re-redesign existing legislation to strike a better balance between enabling fast pace innovation and ensuring the safety and efficacy of products through a mix of hard and *soft regulation*.

CLOSING GAPS IN DIGITAL LITERACY

England is one of the most digitalised countries globally, offering its citizens broad physical access to digital technologies and the internet. However, the wider population and the health care workforce

often do not have sufficient digital capabilities to make best use of DHTs and approximately a fifth of the population does not possess basic digital skills. Therefore, various actors from all three sectors take target actions to measure and improve digital literacy to fully reap the benefits of this digital infrastructure.

FLEXIBILITY AND GUIDANCE FOR HEALTH TECHNOLOGY ASSESSMENTS OF DHTS AND THEIR REIMBURSEMENT

There are currently no standardised reimbursement pathways specific to DHTs, and innovators usually navigate a complex jungle of different options, often having to negotiate with multiple local budget holders.

Efforts to formalise the HTA of DHTs in line with arrangements for traditional medical devices and diagnostics are currently being piloted with the goal of streamlining and clarifying the process for value assessment and reimbursement. The approach taken by the National Institute for Health and Care Excellence (NICE) embraces the wide spectrum of DHTs and attempts to avoid a one-size-fits-all approach for their value assessment. This lowers the evidence requirements for clinical and economic evidence for low-risk technologies while adopting established evidence requirements and assessment methodologies for higher-risk technologies.

LESSONS TO LEARN

The English expertise offers countries the opportunity to learn from its vast experience embracing digitalisation in health and social care. While not comprehensive, we see four high-level key learnings as specifically relevant:

Digital Literacy	Harvesting the benefits of DHTs requires digital skills within the general public and the health workforce beyond physical-digital access. England demonstrates how different actors, frameworks, and actions tackle the digital skills gap.
Regulation	Due to the broad DHT product spectrum, a one-size-fits-all regulatory solution risks suffocating digital's innovative potential in health care. England shows how pragmatic regulatory frameworks may separate between hard and soft regulation to address the variety of regulated medical devices and unregulated products and services while maintaining standards for safety and efficacy.
Value assessment	Similar to the regulation of DHTs, value assessment should be flexible to require different standards depending on the risk posed by the DHT. Several actors in England demonstrate how dedicated guidance for innovators and buyers, openness for exchange and adaptive value assessment frameworks can help fit the right methodology to the right product.
Futureproofing	Adjacent fields to Digital Health, such as AI & Machine Learning, put unpreceded challenges in front of policymakers, regulators and value assessors. England proactively embraces interdisciplinary efforts in regulation, value assessment, and ethics and offers learnings to ensure that the opportunities of related future innovation are maximised and the risks minimised.

1 The English digital health ecosystem and its regulations

1.1 Overview of the digital health ecosystem in England

Digital Health is "the field of knowledge and practice associated with the development and use of digital technologies to improve health" (World Health Organization, 2021). Digital health technologies (DHTs) represent various products used in the healthcare system, including software, apps and online platforms for the benefit of individuals and the wider health and social care system. They can be standalone or used in combination with other products such as medical devices (NICE, 2021) and are generally seen as complex interventions within complex systems (McNamee et al., 2016).

Due to this variety in DHTs, the ecosystem of DHTs in England[1] is also complex (Figure 2). Similar to other health technologies, it centres around patients as the ultimate beneficiaries - although it should be acknowledged that many DHTs focus on boosting system efficiency and are not clinically orientated. Relevant stakeholders include the NHS workforce, regulatory bodies, an extensive array of organisations within the NHS or the broader policy system, charities, funders, and institutions within the academic and industry sectors. They all contribute to a vibrant innovation and research system which develops dynamically to progress in line with the advancements of the technology itself. As a result, the digital health ecosystem in England is best described as a wide-ranging web bringing together stakeholders from various backgrounds on national, regional and local levels.

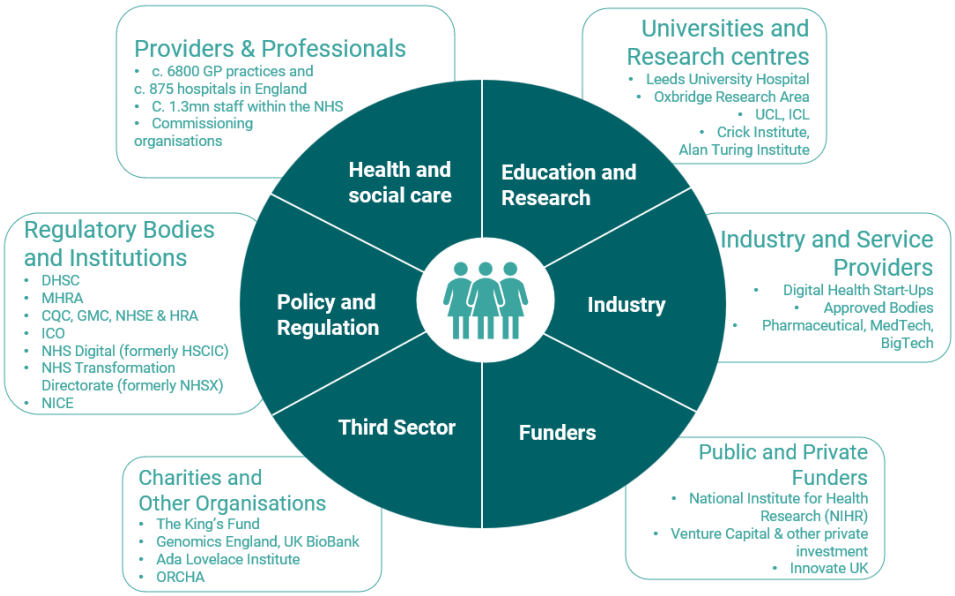


FIGURE 2: THE DIGITAL HEALTH ECOSYSTEM.
Adapted from ECHAlliance (2022).

[1] *Please note that major parts of this analysis focus on England as the largest of the devolved nations in the United Kingdom. However, some parts, (e.g. regulation) apply across the whole the UK.*

1.2 The national digital health strategy

The complexity of the digital health ecosystem is reflected in the lack of a single, dedicated national digital health strategy in England. The way forward is, therefore, rather determined by past ambitions and reviews that developed over the years.

Notable policy milestones include the Five Year Forward View (2014) by NHS England, setting out ambitions focusing on interoperability, digital literacy within the workforce and an increase in the use of digital apps. The Wachter review (2016), an independent review into NHS technology commissioned by the Secretary of State for Health and published two years later, has shaped vast amounts of the digital agenda to date. Amongst other factors, it sheds light on the importance of cultural change, the value of 'doing digitalisation right' rather than quickly, and the balance between national incentives, centralisation and local control.

In more recent years, the government set out its vision for the use of technology, digital and data within the Future of Healthcare report (2018b), while the Topol review (2019), also commissioned by the Secretary of State for Health, advised on the technology-induced change to roles and functions of clinical staff, related implications and consequences for training the health workforce of the future. Finally, the NHS long term plan (2019b) makes digitalisation a top priority for the NHS and commits to better use of data and digital technology (NHS, 2019a).

The Department of Health and Social Care (DHSC) is in the process of finalising its national data strategy framework, *Data Saves Lives* (DHSC, 2022b), which aims to elaborate on the role of data in the digital transformation of the NHS. The key priorities underpinning the strategy include building an understanding of how data is used and its potential for innovation while improving individuals' ownership of their data; normalising appropriate data sharing for the benefit of patients and healthcare staff; and building the suitable foundations to support these changes from a regulatory, technical and legal perspective.

1.3 Regulatory framework of relevance for DHTs

1.3.1 Overview

Following its withdrawal from the EU in January 2020, the UK's regulatory framework is currently in a state of transition, where large parts of the regulatory framework of relevance to EU regulations have been adopted and adapted. The transition period is currently scheduled to end on 1 July 2023, and a new UK regulation will apply after the deadline; hence there is uncertainty regarding any near-term future outlook.

As depicted in Figure 3, the current main regulatory requirements for DHTs depend on whether these are considered to be *medical devices* or not. Thus, depending on the products' intended purpose, DHTs may be regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and must comply with dedicated legislation to obtain a UKCA mark (equivalent to the CE mark pre-Brexit).

The underlying legislation for medical devices post-Brexit is the 2002 UK Medical Device Regulation (SI 2002 No 618, as amended) (UK MDR 2002), which originates from the three European Union (EU) Devices Directives that have been amended for the transition period:

- Directive 93/42/EEC for Medical Devices (EU MDD)
- Directive 90/385/EEC for Active Implantable Medical Devices (EU AMIDD) and
- Directive 98/79/EC In-vitro Diagnostic Device (IVDD).

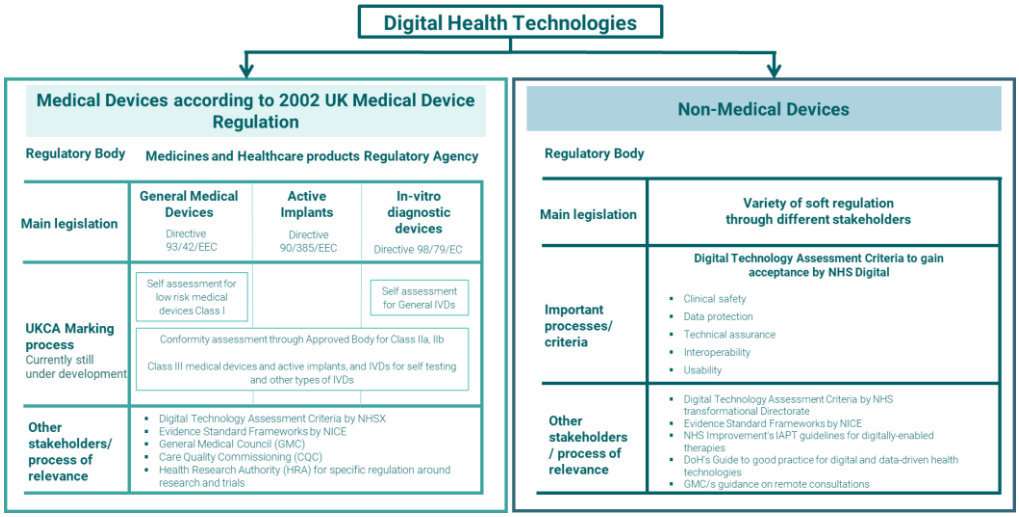


FIGURE 3: OVERVIEW OF REGULATORY SYSTEM FOR DIGITAL HEALTH TECHNOLOGIES IN ENGLAND

If a DHT does not fall under the legislation outlined above, it will not have to comply with any of the outlined directives. However, there may still be "soft-regulations" such as guidelines or frameworks that should be considered, further discussed in chapter 1.3.4.

DHTs which have been tried and tested by clinical teams are showcased in *Digital Playbooks,* which cater to various clinical specialities, including cardiology, gastroenterology and oncology. These digital playbooks are developed to support clinicians in choosing which technologies to use for solving real-world problems by learning from the experience of others. They provide scenarios and case studies displaying best-practice to encourage the digitalisation of healthcare through the use of digital solutions for the improvement of patient care. All the apps recommended in the case studies have either passed or are currently undergoing the DTAC assessment (described in section 1.3.4) (NHSX, 2022).

DETERMINING WHICH REGULATION APPLIES

Before the DHT can undergo the correct regulatory route, the first step for manufacturers is to determine whether the product in question is a *medical device* and which directive applies.

The UK MDR 2002 describes a medical device as "an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which —

- is intended by the manufacturer to be used for human beings for the purpose of:
  - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
  - (iv) control of conception; and
- does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device."

Multiple stakeholders, such as the MHRA itself and other third-party organisations, provide guidance and support to manufacturers as the device determination is a crucial step with highly relevant consequences for the remaining development process. An example is the classification flow chart provided by MHRA, which is given in Figure 4.

A large number of DHTs are classified as medical devices (according to the UK MDR 2002 definition) and must meet the requirements outlined in the UK MRD 2002 before they can be introduced in the market.

MHRA-regulated DHTs are divided into general medical devices, active implantable medical devices and in-vitro diagnostic medical devices (IVDs). A summary of the specific requirements for each category is outlined in section 1.3.2 and section 1.3.3.

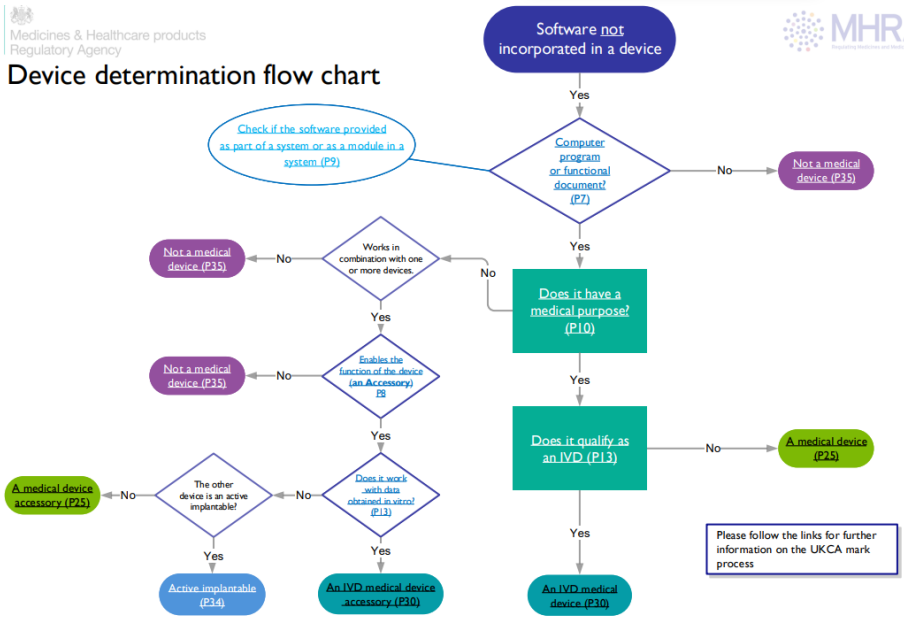


FIGURE 4: EXAMPLE OF THE MHRA GUIDANCE ON DETERMINING THE DEVICE CLASSIFICATION. SOURCE: MHRA

THE ROLE OF MHRA IN REGULATING MEDICAL DEVICES

For medical devices that fall under the UK MDR 2002, the MHRA is responsible for ensuring products' competency and safety (MHRA, 2022). The MHRA oversees market surveillance and compliance of medical devices, and all medical devices need to be registered with the MHRA to be placed on the UK market.

The MHRA is also responsible for ensuring conformity with the correct product marking, the UKCA Mark, which confirms the safety and efficacy in accordance with the intended use of the product in question. The UKCA Mark has been introduced as the new route to the UK market to replace the former (pre-Brexit) European CE Mark. It can be used voluntarily and will become compulsory for devices placed on the UK market from 1 July 2023. The CE Mark will continue to be accepted in the meantime to ensure a smooth transition and a continued safe supply of medical devices to the UK.

To obtain the UKCA Mark, a third-party organisation called an Approved Body is generally required to help assist the conformity assessment procedure for higher-risk medical devices. The MHRA designates and monitors UK conformity assessment bodies, such as the Approved Bodies. The EU no longer recognises UK Approved Bodies, and thus the UKCA marking is not recognised on the EU market, where a CE Mark is required. Devices can have both UKCA and CE Markings if they are placed on EU and UK markets.

Figure 3 provides an overview of the different regulations outlined below and the role of the Approved Body.

1.3.2 DHTs considered being general medical devices or active implant devices

If the DHT is classified as a medical device regulated under UK MDR 2002, four categories based on the perceived risk with the application of the devices will determine the regulatory pathway to obtain UKCA marking and the associated efforts in doing so. (MHRA, 2020)

Class I devices (such as stethoscopes and bandages) are generally perceived as low risk. Hence, a manufacturer can undergo the self-assessment route, outlined in Part II of the UK MDR 2002, Annex I (as modified by Part II of Schedule 2A to the UK MDR 2002) to draw up a declaration of conformity, register the product with the MHRA and place the UKCA mark on it. An exemption is Class I medical devices with sterile or measuring functions as those would need an approved body to perform a conformity assessment.

The risk classification increases subsequently for class IIa, IIb and III, with class III devices posing the highest perceived risk. These devices always require the involvement of a UK Approved Body to carry out a conformity assessment for their specific classification. The UK Approved Body ensures manufacturers comply with the regulations, including reviewing clinical and scientific data, manufacturing processes and the quality management system. This confers confidence and security that the products used are kept to a high standard.

For all risk classes, manufacturers need to carry out post-market surveillance to minimise the risk of incidents occurring once they are available on the market.

1.3.3 DHTs considered being In-vitro diagnostic medical devices

In-vitro diagnostic medical devices (IVDDs) are medical devices that perform a diagnostic test. These include, for example, reagents or systems used for the examination of specimens, including blood or tissue obtained from humans for general information on pathology, safety and compatibility, for example, in the case of donations or to monitor therapeutic measures.

IVDDs are also categorised based on risk in four main groups, namely general IVDDs, IVDs for self-testing, and IVDDs stated in Part IV of the UK MDR 2002, Annex II, in either List A or B.

- Given the lower risk of general IVDDs, a UK Approved Body is not required, and the manufacturer can perform a self-assessment to ensure conformity.
- IVDs for self-testing require the manufacturer, in addition to complying with the requirements for general IVDs, to seek the guidance of a UK Approved Body for the examination of the design of the device based on (Part IV of the Medical Devices MHRA Guidance on legislation Guidance on the regulation of IVDs January 2021 9/15 Regulations 2002, Annex III [as modified by Part III of Schedule 2A to the UK MDR 2002][2]). This step will ensure compliance with aspects affecting IVDD's suitability for non-professional users.
- The remaining two types, IVDDs stated in List A or B, require the intervention of a UK Approved Body to assess conformity with regulations. The manufacturer must ensure that Annexes to Part IV are followed, taking into account any amendments within Part III of Schedule 2A to the UK MDR 2002.

As with medical devices, manufacturers are required to carry out post-market surveillance to minimise the risk of incidents occurring once IVDDs are placed on the market.

[2] *Alternatively, the manufacturer may follow the conformity assessment routes for higher risk products as detailed below.*

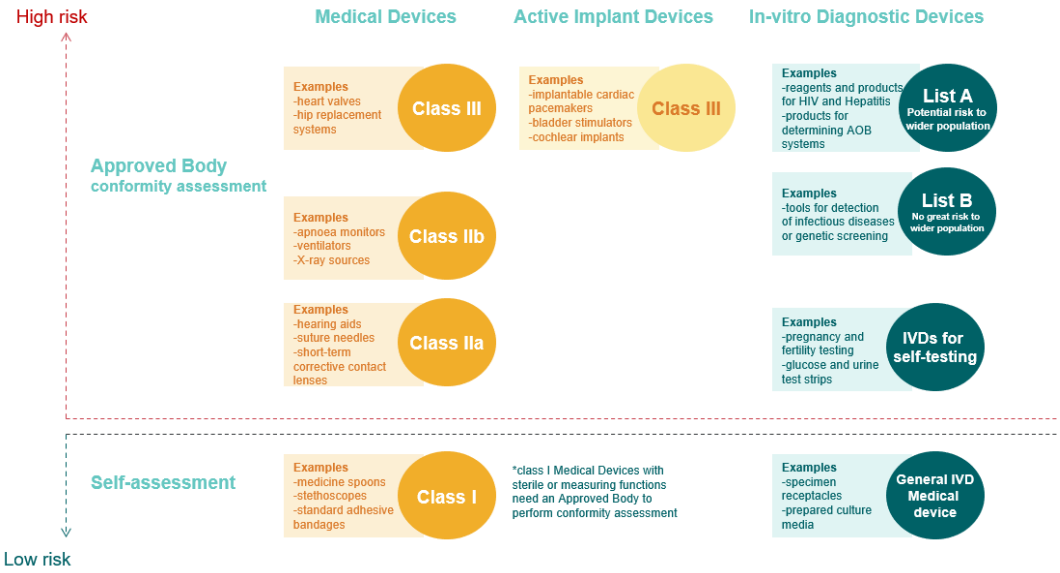


FIGURE 5: RELATIONSHIP BETWEEN MEDICAL DEVICE DIRECTIVES AND THE ROLE OF THE APPROVED BODY

1.3.4 DHTs that do not fall under the medical device regulations

DHTs that do not fall under the medical device umbrella do not have to follow the regulatory requirements set out in the UK MDR 2002. However, non-mandatory "soft regulations" can guide manufacturers to comply with general requirements. Soft regulation refers to the guidance which can help inform manufacturers of the expectations of various DHTs buyers and users, such as standards for quality and safety. While these are not mandatory, following them increases the DHTs prospects of adoption within the NHS.

We draw attention to DHTs, which have the potential to fall into either category, highlighting the importance of establishing the intended purpose. DHTs acting as monitoring or decision support devices can often create confusion for manufacturers. Additionally, the MHRA provides guidance on *borderline products* to aid manufacturers in deciding the nature of the product if this is not clear (MHRA, 2021).

SPECIAL CONSIDERATION FOR DHTS THAT PROVIDE SIMPLE MONITORING

Monitoring of general fitness, well-being and health is not usually considered to be a medical purpose. Apps and software that simply replace a written diary of symptoms would most likely also fall into this category. Additionally, apps and software for monitoring sports and fitness (e.g., heart rate) are also not likely to be considered medical devices unless they are used to investigate the physiological process, in which case they may be.

Alternatively, apps and software that monitor a patient and collect information entered by the user, measured automatically or collected via a point of care device, could qualify as a medical device if they influence an individual's treatment. For example, apps that monitor blood glucose intend to affect an individual's decision to act upon this by adjusting their sugar levels in response to the app readings.

SPECIAL CONSIDERATION FOR DHTS THAT PROVIDE DECISION SUPPORT

Software is unlikely to be considered a device if it provides a digital format of a paper document or the path for a procedure or treatment, given that a health care professional is the one ultimately deciding which treatment path to follow.

On the other hand, if the software has a role in drug dose calculation, symptom monitoring and data interpretation or analysis, it could be seen as a medical device. Additionally, the software may also be considered a medical device if it intends to influence any aspect of the treatment or suggest diagnostic or prognostic information following input from an individual or clinician.

THE REGULATION OF DATA

The MHRA does not generally regulate data, databases or analytical services, but if the product in question is used for analysing or processing data for a medical purpose, then the software used may be covered by the regulations (e.g. analysing genomic data to inform treatment). (NHS Digital, 2021)

Governance of NHS data is aligned with the UK General Data Protection Regulation (GDPR), the Data Protection Act 2018 and the Common Law Duty of Confidentiality. The UK GDPR provides extra protection for personal *data concerning Health,* including biometric and genetic data, due to its higher sensitivity. The Health Research Authority (HRA) is the body responsible for the publication of guidance on the implementation of the GDPR and Data Protection Act for health and social care research. It is also responsible for granting section 251 support for temporary lifting the common law duty of confidentiality, enabling confidential patient information to be disclosed for medical purposes. Information Commissioner's Office (ICO) also provides guidance on data protection and is the organisation responsible for investigations into breaches or unlawful processing of data.

Anonymised health data falls outside of the UK data protection regulation as it does not constitute *personal data.* However, controllers of anonymised data must keep in mind that the act of anonymising data could be considered an act of data processing under GDPR laws. Notably, anonymised data retains a risk of reidentification.

REQUIREMENTS FOR CYBERSECURITY

The DHSC is responsible for overseeing the operation of the Network and Information Systems (NIS) Regulations within the healthcare sector. It guides data security standards on the NHS Digital platform. These requirements include taking appropriate measures to ensure the network's security, considering developments and potential risks, minimising the impact of security incidents, and notifying authorities of any serious incident (DHSC, 2018a).

NHS Digital also provides a toolkit for organisations to measure their performance against the National Data Guardian's 10 data security standards (NHS Digital, 2022b). Standards bodies which work with NHS Digital provide standards and accreditations on a wide range of topics such as interoperability and cybersecurity (ISO, 2021).

OTHER USEFUL SOFT-GUIDANCE

- The NHS has published a guide bringing together legislation and good practice to help manufacturers understand what the NHS considers when purchasing digital health devices. The Digital Technology Assessment Criteria (DTAC) assesses clinical safety, data protection, technical security, interoperability, usability and accessibility (NHSX, 2022).

- The DHSC also put together a guide to good practice for digital and data-driven health technologies, which looks at similar topics as the DTAC but includes ethics, transparency, cybersecurity and market strategy (DHSC, 2021b).

- The NICE Evidence Standard Framework for Digital Health Technologies (NICE, 2021) defines different evidence requirement levels for DHTs that become relevant during their value assessment. While not directly aligned, the evidence levels correspond broadly with the risk classes within the UK MDR 2002. For example, DHTs that fall into Tier C are likely to be considered "Software as Medical Device (SaMD)" from a regulatory perspective. However, DHTs within Tier A or Tier B are generally less like to be considered a medical device from a regulatory point of view. In general, the framework may help better interpret the regulatory framework for medical devices in the context of DHTs.

- The General Medical Council (GMC) provides guidance on when remote consultations and prescribing are appropriate and standards of good practice. In addition, it provides a confidentiality navigation tool for healthcare staff (GMC, 2022a). The GMC also touches on telemedicine to implement a more binding regulatory approach to the process, where there currently is none(GMC, 2022b).

1.3.5 Outlook

Several areas within Digital Health, such as telehealth or the utilisation of artificial intelligence within health care products, lack a dedicated regulatory framework when they are not considered a SaMD and are only covered by guidance and *soft regulation.* The fast-moving pace of technology development means that the regulatory framework can lag behind digital progress. However, regulations are under constant review, and updates ensure compliance with safety measures while providing innovative research and development flexibility.

As a result, in 2022, a new service is planned to go live to provide the world's first cross-regulatory advisory service for developers and adopters of Artificial Intelligence (AI) and other data-driven technologies in healthcare[3]. This Multi-Agency Advisory Service (MAAS) is a collaboration between the HTA agency NICE, the main regulator MHRA, the HRA and the Care Quality Commission (CQC). The vision of MAAS is to provide advice and sign-posting to enable access to a more robust and streamlined regulatory pathway that will lead to safer and more effective development and adoption of data-driven technologies (NHS, 2021c).

[3] Since the completion of this report, the MAAS developed and tested the pathway for its informational platform for developers and launched an early version of its website in August 2022. The group is expecting to launch an informational platform for adopters in Spring 2023 (NHS England - Transformation Directorate, 2022).

2 Market Overview

2.1 Digital Health Trends

The Digital Health market in the UK is dynamic, with involvement from both private and public sectors and significant research input from academic institutions. While private investors play a crucial role in the initial stages of development, the NHS remains the largest buyer of health technologies in the UK. Thus, it is no surprise that manufacturers strive to adhere to NHS guidelines and regulations and commit to NICE frameworks to benefit from wide adoption within the healthcare system. The UK digital health market is mainly focused on a few key areas, highlighted in Figure 6. While the figure is not fully exhaustive, it does capture the sub-sectors where the UK features most predominantly in terms of investment and innovation from the life sciences sector.

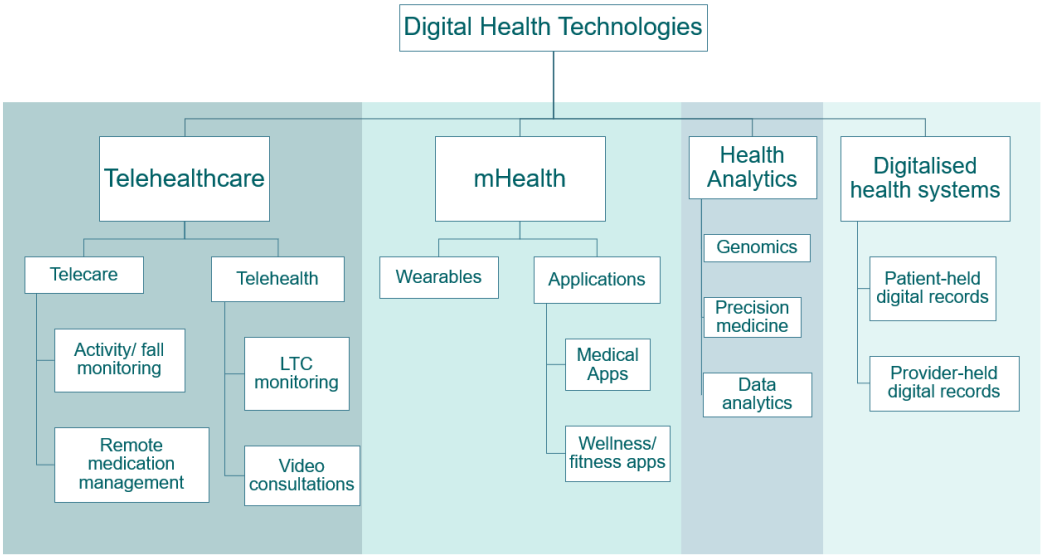


FIGURE 6: OVERVIEW OF DHTS.
Adapted from OLS, 2020

According to the Office of Life Sciences (2020), the UK life sciences industry employs around 256,100 people in over 6,000 businesses and generates a turnover of more than £80B. It is made up of the core Biopharma sector, the largest by turnover, and the core MedTech sector, which is the largest by employment. 82% of the businesses in the industry are small and medium-sized enterprises (SMEs), employing 24% of the workforce and generating 10% of the turnover.

Digital Health is the largest segment of the core MedTech sector by workforce, employing 12,900 people over 640 businesses and generating a total turnover of £1.7B. The segment has increased employment by 3,300 and turnover by £490M between 2010 and 2019, and it is estimated that 63% (400) of digital health businesses were formed in that time period.

2.2 Market Opportunities

The UK is a leader in several fields, driven by prestigious academic research and expertise spanning the life sciences and technology sectors. Here we explore three areas that we consider to hold the most significant potential in the digital health space.

GENOMICS

The UK is at the forefront of genetics and genomics research. It benefits from the most extensive collection of genome sequences globally, comprising the exomes and whole genomes of 500,000 participants, sequenced by the UK Biobank and whole-genome sequences from 100,000 patients with cancer or rare diseases held by Genomics England. These are all linked to participants' detailed NHS records, enabling in-depth analysis of rich data sets while protecting patients' data and ensuring that no identifiable information is accessed by researchers (DHSC, 2022c).

The research initiatives are primarily driven by the government, which outlined its vision to create the most advanced healthcare system in the world by setting out a 10-year strategy (DHSC, 2020). The *Genome UK: the future of healthcare* is built on three pillars: diagnosis and personalised medicine, prevention and research. NHS England plans to roll out the world's first whole-genome sequencing service for individuals with certain cancers or undiagnosed rare diseases. This step would have serious implications in precision medicine, guiding personalised treatments to significantly improve patients' lives. The commitment to prevention and early detection is closely linked to diagnosis. The government is determined to support screening programmes nationwide and encourage a transformation in the healthcare system from treatment to prevention. This would lead to great savings, relieving pressures on the healthcare system and generally better prospects for individuals (DHSC, 2022c).

DATA

As already mentioned, data plays a crucial role in the process of digitalisation of the healthcare system. The NHS has one of the richest health data sets in the world, largely due to the centralised nature of the system. These data sets are ethnically diverse and have been collected over decades in the case of GP records. This provides a wealth of raw data with specific information from patient contacts with health services, including blood tests and diagnoses as well as prescriptions and treatments. The NHS analytic community contains a wide range of experts and specialists who are well suited to analyse this data (Goldacre, 2022).

The government encourages improvements in data access and management. It recently commissioned a review of the current use of data and retrieved recommendations for relevant optimisation and streamlining opportunities (Goldacre, 2022). In addition, the government has recently committed £200M to be invested in research for improved access to NHS data through Trusted Research Environments – safe platforms for data analysis by trusted researchers – and digital clinical trial services (DHSC, 2022a). Harnessing the unparalleled power of the UK health data has significant potential to improve patients' lives, specifically in the fields of diagnostics.

ARTIFICIAL INTELLIGENCE

The UK is a global trailblazer in this field, having adopted and incorporated AI and machine learning techniques in the healthcare sector. The UK has a National Strategy for AI guiding its fair and effective use and is currently adapting it to the use within Health and social care. In 2019, the government committed £250M for the development of a national AI lab with the aim to improve diagnostics, specifically for cancers and mental Health (DHSC, 2019). More recently, the government has pledged another £36M to test innovative AI-driven technologies to accelerate diagnosis and improve patients' lives (DHSC, 2021a).

Most notably, NHS England is working on a pilot aiming to reduce health inequality by addressing potential risks such as algorithm biases before they can access NHS data. The project is the first of its kind worldwide and highlights efforts to eradicate discrimination in the systems underpinning the future of data analytics and research (DHSC, 2022d).

3 Digital Health Literacy

3.1 General Digital literacy in the UK

Health Education England (HEE) defines digital literacy as "those capabilities that fit someone for living, learning, working, participating and thriving in a digital society" (2017). Health literacy is described by the NHS as a person's ability to understand and use information to make decisions about their Health (2021b). Combining these two terms results in digital health literacy, which is described by the World Health Organisation (WHO) as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem (WHO, 2016).

The UK is a highly digitalised country. The Lloyds Bank Consumer Digital Index (2021), a report outlining digital literacy across the UK based on a country-wide survey, provides annual insights into the nation's digital state. Over 95% of households benefit from internet access, and 81% of the population (c.42.9M) master the most basic essential digital skills (ONS, 2020; Lloyds Bank, 2021).

The pandemic has accelerated the digitalisation process even further and thereby increased the need for digital skills in the general population. In 2021 alone, an additional c.1.9m people gained basic digital competencies such as the ability to access the internet independently. Basic competencies comprise a variety of skills, including the ability to use the device, connect it to a Wi-Fi network, update and change passwords, and adjust various settings to optimise its use. Furthermore, 79% of the population have more advanced essential digital skills, including communicating and performing transactions and handling information and content, staying safe and legal, and solving problems online. Lastly, around 64% of working adults have the essential digital skills needed to successfully perform their jobs (Lloyds Bank, 2021).

Despite good overall digital literacy and pandemic-related improvements, the UK still suffers from demographic discrepancies in relevant competencies (Lloyds Bank, 2021). Age is a significant factor, with just 28% of individuals aged 75 and over benefiting from foundation-level skills, compared to 97% of those in the age group 18-24. Education level and working status are also important factors determining digital competency. Those educated to a degree level and in full-time jobs are more likely to have higher digital literacy skills. Additionally, people living alone are less likely to have these basic skills, suggesting that others in the household positively affect digital literacy skills, especially for those advanced in age.

Around 6% of the UK population is entirely digitally excluded. This subgroup is most likely to be over the age of 75, with no formal education, living alone and with an impairment that affects their day-to-day lives. However, physical access to the internet seems not to be the only relevant barrier, as over 22% of those who qualify as digitally excluded have theoretical access to a smartphone or computer/tablet in their home.

The digitally excluded experience severe disadvantages compared to their digitally adept counterparts in day-to-day life. This has been further emphasised by the restrictions imposed during

the pandemic when they faced increasing challenges spanning from satisfying basic needs online (e.g., consumption or social interaction) to more serious health-related activities such as being unable to attend online medical appointments.

3.2 Digital literacy in the health care workforce

Amongst decision-makers and healthcare providers, the level of digital literacy is less clear. Education, income and industry are the most important determining factors for essential digital skills for work, suggesting that individuals who require a degree-level education have greater digital capabilities, which is the case for most healthcare and decision-making roles. Furthermore, it is estimated that 62% of people working in the medical sector and 58% of people in the public service have the digital skills required for their job. The proportion of working adults who have reported an improvement in digital ability in the previous year was 58% for medical and 64% for public service (Lloyds Bank, 2021). These figures are likely to be even greater as a result of the pandemic, which encouraged workers to advance their digital skills rapidly and pushed individuals to be more reliant on digital and online services.

3.3 Measuring digital literacy

There are various frameworks for measuring digital literacy within the general public and, more specifically, within the workforce of the health care sector. The *Essential digital skills framework* provided by the Department for Education (DfE) (2018) is an excellent example of a framework of significant influence. It covers foundation-level skills and more advanced essential skills for life and work, such as those described in the previous paragraphs.

The framework measures foundation-level skills by assessing one's ability to perform simple digital tasks, such as turning on a device, interacting with the device's home screen, and successfully connecting to the internet. More advanced skills and some examples of corresponding assessment criteria are outlined in table 1. These are all underpinned by the ability to maintain a safe, legal and confident self online.

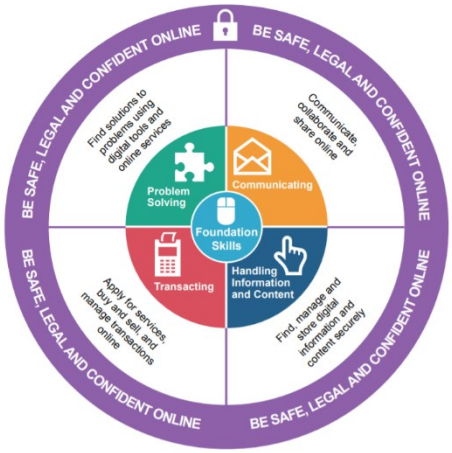


FIGURE 7: Essential Digital Skills Framework
Source: (Department for Education, 2018)

TABLE 1: EXAMPLES OF DIGITAL SKILLS FOR THE GENERAL POPULATION AND HOW THEY ARE MEASURED.

	Skill	Assessment criteria example
	Communication	Setting up an email account Communicating with others using video tools
	Handling information and content	Recognising if content accessed is reliable Organising information using folders and files
	Transaction	Managing money and online transactions safely Using various payment methods, including direct bank transfer
	Problem-solving	Using the internet to find answers to questions Using online tutorials or advice forums to solve problems or improve skills

Although these measures are generally broad, they provide a foundation for creating more specific measuring tools. For example, Health Education England (HEE), one of the bodies responsible for digital literacy in the healthcare sector, has developed a *Health and care digital capabilities framework* based mainly on the structure of the DfE framework (NHS, 2018). HEE defines digital literacy broadly as *those capabilities that fit someone for living, learning, working, participating and thriving in a digital society.*

The HEE framework is tailored to healthcare workers and delves into more detail on their specific digital skills to succeed in their roles. It follows a similar structure as the DfE framework, outlined below, with some examples of how these are measured. Similarly, the skills are underpinned by safety, security and digital identity, which is supposed to be maintained to a high standard. Each skill domain is further split into four levels, increasing in difficulty, with level one generally displaying basic confidence in the specific skill and level four showing full proficiency.

HEE is also developing an interactive Digital Literacy Self-Assessment Diagnostic Tool to help individuals identify and measure their current digital literacy competencies and potential shortcomings. On a larger scale, this will enable managers and decision-makers to measure current digital literacy across healthcare workers and understand where gaps are to enable strategies to overcome these.

TABLE 2: EXAMPLES OF DIGITAL SKILLS FOR HEALTHCARE WORKERS AND HOW THEY ARE MEASURED.

	Skill	Measuring tools
	Communication, collaboration and participation	Working collaboratively with others using digital technologies Participating actively across digital networks
	Information, data and content literacies	Finding, managing, organising, storing and sharing digital information and content Critically analysing and interpreting information
	Teaching, learning and self-development	Using digital technologies for personal learning and development Designing digital tools to support the teaching of others
	Technical proficiency	Using a range of software and hardware for professional use individually and with others Using technical knowledge and problem solving to achieve the expected output
	Creation, innovation and research	Creating new digital resources Using digital tools in research, quality improvement, audits and scholarly activities

3.4 Actions taken to improve digital literacy

Different stakeholders provide several resources to improve digital literacy and tackle digital inequality. These include how-to guides, videos, and short courses. They can also involve digital champions who support individuals in understanding the benefits of digital tools and teaching others how to use them. These resources are made available to the public by charities, government initiatives or independent organisations. In the case of healthcare staff, the NHS works in partnership with several organisations to provide training and support for adequate digital literacy among its staff.

3.4.1 Improving digital literacy for the public

General digital literacy for the public

The English government recognises the importance of adult basic digital skills and values. As a result, digital skills are seen of equally high importance as maths and English in terms of relevance to employability and participation in society. To this effect, it has introduced an entitlement to fully-funded digital qualifications for adults with low or no digital skills, with a curriculum based on the national standard framework discussed above. The government also supports external organisations that share its vision of diminishing digital inequalities, such as charities. (Department for Education, 2019)

Other charitable and for-profit organisations are involved in improving public health literacy. Their projects enable access to equipment and encourage the use of digital tools with volunteers and digital champions. Table 3 outlines some of these examples alongside the type of work and the target population.

TABLE 3: EXAMPLES OF ORGANISATIONS AND THE TYPE OF WORK THEY DO TO IMPROVE DIGITAL LITERACY.

Organisation	Type	Target population	Initiatives
The Good Things Foundation	Charity	Digitally limited or excluded people	- *Online centres network*: thousands of grassroots organisations tackling digital health exclusion where people can go and access a computer in a safe space, supported by volunteers - *Learn my way*: online learning platform - *Get Online Week*: digital inclusion campaign
Age UK	Charity	Elderly people	- One-to-one support and larger community awareness sessions - *Digital angels project* (with aid from the *Time to Shine Programme*) - *One Digital project* (with aid from the *Big Lottery Fund*)
Action Foundation	Charity	Refugees, asylum seekers or other migrants	- Provision of devices and free data - Training on using devices and basic competency skills for online activities
Vodafone	Private, for-profit	Pandemic support for young people and families	- Supporting remote education by providing free data SIMs - *Great British Tech Appeal*: connecting and redistributing used smartphones and tablets
Lloyds banking group	Private, for-profit	General population	- *Lloyds Bank Academy*: Access to essential skills, working and money management videos - Creating reports on the state of health literacy

Digital health literacy for the public

The NHS has developed several guides to improve digital health literacy among the patient community. The digital health inclusion guide for Health and Social Care was designed to help healthcare providers ensure that digital services are accessible to everybody in the patient community. (NHS Digital, 2019) Additionally, the NHS provides patient guides to services such as online GP consultations (NHS, 2016).

The NHS has funded a three-year programme to reduce digital exclusion in partnership with the Good Things Foundation. The *Widening Digital Participation* programme resulted in an additional over 200,000 people being trained to use digital health resources, and over half of the learners reported feeling more confident using online tools to manage their Health. (Good Things Foundation, 2016)

The NHS app is a service owned and run by the NHS which provides patients with access to a range of NHS services online. Its popularity increased dramatically following the COVID-19 pandemic as it acted as proof of vaccination which was needed to access most venues during the pandemic. The app was launched in 2018 and has over 22 million users, with more than 18 million new users since May 2021. The app already allows patients to access some features of their health records, such as prescriptions, but the NHS is keen to extend this access to additional entries such as test results. This supports the NHS Long-Term Plan by providing patients with access to their medical records.

The implications of this will increase patient empowerment to manage their health while reducing the burden on NHS staff by decreasing queries to GP offices. (NHS Digital, 2022a)

3.4.2 Improving digital literacy for healthcare workers

The current system's shortcomings and the need for digitalisation in the NHS have been highlighted in the past. Important milestones are the framework for action published by the National Information Board (2014), the Wachter review (Wachter, 2016) on the need for the digitalisation of the NHS and the Topol Review highlighting specific areas of change and encouraging a *culture of learning* in the NHS to support its growth in this direction (Topol, 2019).

In response, HEE, as the branch of the NHS responsible for the training and education of NHS staff, highlights the challenges, sets priorities and provides solutions to improve digital literacy across the NHS workforce (HEE, 2017). The organisation aims to provide easy access learning to staff, ranging from simple tasks such as accessing patients' digital health records to more complex ones such as interpreting genomic information. HEE also encourages digital health champions who support others in building their confidence using DHTs (HEE, 2021). Their *Health and care digital capabilities framework* serves as a target and supports objective setting to improve digital literacy among staff.

HEE also powers the e-learning for healthcare (elfh) platform, which provides a range of programmes free of charge to health sector workers, enabling them to learn and practice a wide range of skills needed in the workforce. Some generic modules included are summarised in the table below. However, the programme's menu includes more specialised topics such as disease-specific modules (e-learning for healthcare, 2022).

TABLE 4: SUMMARY OF MODULES AVAILABLE ON THE ELFH PLATFORM.

Module	Description	Purpose
Digital Learning Solutions	Includes basic digital literacy skills, (Microsoft) MS Office and a digital capability self-assessment.	Encourages the review of current skills against standard requirements and identifies future training requirements.
Data Security Awareness programme	Includes information on data security, information governance and GDPR rules.	Aligns healthcare workers with the standard data handling procedures.
Literature Searching programme	Includes guides to developing searching strategies and narrowing and targeting literature searches to achieve the desired outcome.	Helping healthcare workers build confidence when searching published literature relevant to their work or research.
Microsoft Teams Training	Introduces practical functions of MS Teams.	Encourage the effective use of MS Teams by staff
Guidance for teaching online	Includes tools to help educators transfer to online teaching effectively.	Enabling healthcare educators to plan and deliver online teaching successfully.

Besides HEE, there are other institutions with an objective to produce digital-savvy healthcare workers. Notable are the:

- NHS Digital Academy, which supports digital learning and development in healthcare. Established in 2017 following the Wachter review (2016), the initiative encourages digital health leadership, transformation and innovation within organisations. Its flagship programme for digital health leadership involves a 12-month fully funded and fully accredited postgraduate diploma in Digital Health Leadership. Additional programmes include a digital fellowship programme that aims to

enable participants to take initiatives in the digital health transformation of their organisation (NHS, 2021a).

- The Allied Health Professions (AHP) is an association of degree-level professions beyond doctors and nurses (e.g. physiotherapists or speech & language therapists). The AHP developed a digital framework anchored in the original HEE framework to ensure that all AHPs can utilise information and technology (AHP, 2019).

4 Health Technology Assessment of DHTs

4.1 Background

The WHO defines Health Technology Assessment (HTA) as the systematic evaluation of a health technology's properties, effects, and impacts, considering its social, economic, organisational, and ethical issues to inform policy decision-making (WHO, 2022). In England, responsibility for HTA falls under the remit of the National Institute for Health and Care Excellence (NICE), a non-departmental public body founded in 1999. NICE's guidance and recommendations inform the use of new and existing health technologies in the NHS. Any pharmaceutical intervention recommended by NICE has to be funded within three months of the guidance's publication (NICE, 2022f). While not legally bound to do so, Wales follows a similar approach, whereas Scotland and Northern Ireland do not abide by the same process.

NICE structures its HTA activities through four programmes, each tailored to different health technologies:

- the Diagnostics Assessment Programme,
- the Medical Technologies Evaluation Programme,
- the Highly Specialised Technologies Evaluation Programme and
- the Technology Appraisal Programme (NICE, 2022d).

The Medical Technologies Evaluation Programme (MTEP) was launched in 2009 (Chapman, Taylor and Girling, 2014) and was initially designed to appraise medical devices and diagnostics. The MTEP also serves as a tool for matching the medical technology with the appropriate appraisal program. Selected technologies can be assessed within the MTEP or – if required – can be re-routed to another appraisal program. Technologies are likely to be selected if they meet the eligibility criteria outlined on the NICE website while offering significant benefits to patients over current practices and are supported by evidence (NICE, 2022b).

There is also previous work by NICE that assessed digital technologies within the Improving Access to Psychological Therapies (IAPT) programme (NICE, 2022a), which was launched in 2008. In total, 14 technologies have been assessed this way.

Only recently, NICE started to design and test designated appraisal methods for the HTA of DHTs. In 2018, NICE launched the DHT Pilot, which intended to test whether the methods of the existing MTEP could also be adapted to suit the specific characteristics of DHTs when combined with a new Evidence Standards Framework (ESF) for Digital Health Technologies (NICE, 2019).

The DHT pilot is part of the existing MTEP and is still ongoing (Figure 8). It involves the development of guidance for four DHTs. After its completion, NICE has committed to reviewing the process. In January 2022, NICE published an update to the general HTA methods of each of its programmes (NICE, 2022d). Therefore, the results of the pilot will have to be analysed in the context of these revised methods.

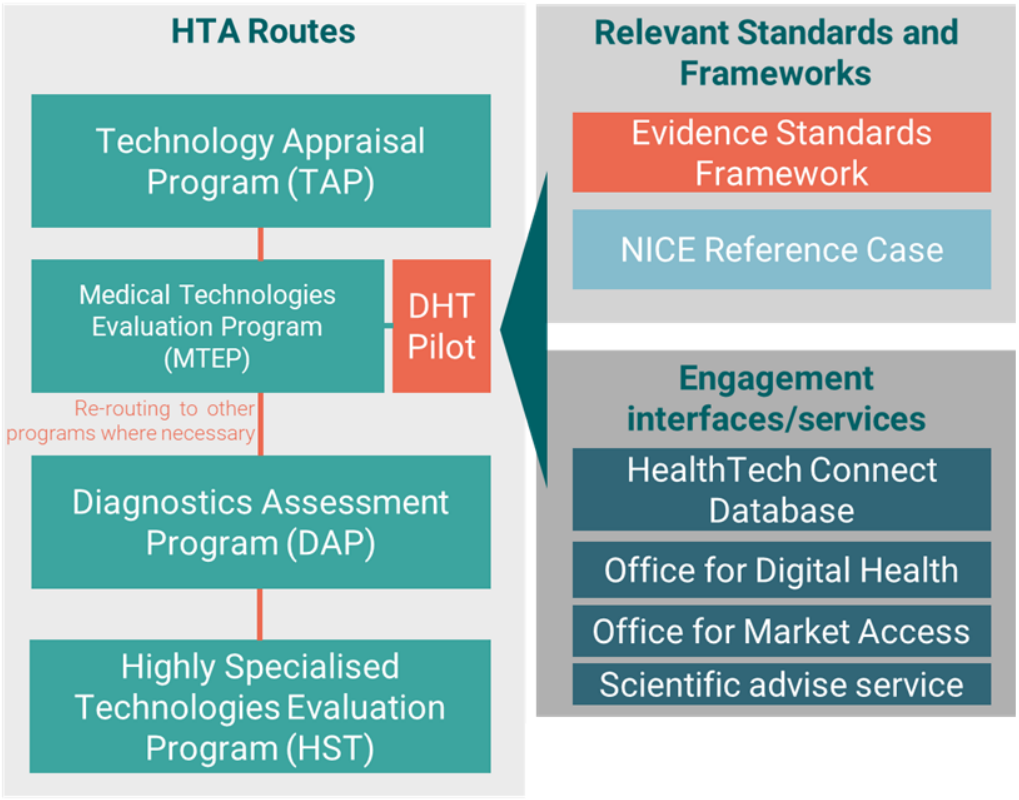


FIGURE 8: OVERVIEW OF NICE'S PROCESSES, STANDARDS AND SERVICES RELEVANT TO DHTS. SOURCE: OHE.

4.2 The Evidence Standards Framework

The ESF (NICE, 2021) summarises the evidence requirements for a DHT to demonstrate its effectiveness relevant to its intended use(s) *and* its economic impact relative to its financial risk from a payer perspective. It is a crucial document intended to be used by developers to guide their evidence development plans and decision-makers considering the commission of a DHT. Thus, the framework is most relevant for DHTs commissioned within the health and social care system and less so for those DHTs that are directly downloaded or purchased by users. The ESF is currently being updated to include AI requirements in scope as well as a subset of requirements for 'early deployment'[4].

[4] *Please note that this report is based on the update of the ESF issued in April 2021. Since the completion of this report, NICE updated its ESF in August 2022 and the related user guide to include (AI) and data-driven technologies with adaptive algorithms in August 2022 (NICE, 2022e). It also made the framework easier to use. Please find the updated version under: Evidence standards framework for digital health technologies (nice.org.uk)*

The framework embraces the diverse spectrum of DHTs as it links the function of a DHT to its evidence requirements. The functional classification of DHTs is aligned with the regulatory risk class classification described in section 1.3.

FIGURE 9: DHTS CLASSIFIED BY FUNCTION AND STRATIFIED INTO EVIDENCE TIERS AS DEFINED BY THE ESF (NICE, 2021).

The clinical evidence standards vary with the tier, with low-risk items associated with a more relaxed set of standards than higher-risk technologies. For example, evidence requirements are minimal for the lowest tier, which comprises specific system services that do not treat patients but may produce other benefits (e.g., organisational benefits). Hence, their focus is more on feasibility (e.g., successful pilot, acceptability with users) rather than demonstrating clinical outcomes. This flexibility enables technologies where measurable outcomes per patient are not easily estimated to be considered for appraisal. This avoids the risk of a 'one-size-fits-all' approach that places substantial requirements for relatively low-risk DHTs.

In contrast, technologies that fall within the highest tier require evidence in the form of observational or quasi-experimental data, and, in specific cases, they need to be generated through RCTs. The ESF provides useful best practice standards that guide developers in identifying the suitable evidence requirements for their technology. Table 5 summarises these requirements according to each tier.

TABLE 5: SUMMARY OF EVIDENCE REQUIREMENTS.

Tier	Description	Minimum evidence standard	Best practice standard (in addition)
Tier A	Digital health technologies (DHTs) with potential system benefits but no direct user benefits.	Evidence of: • Credibility with UK Healthcare professionals (HCPs) • Successful pilot in the UK • Acceptability with users Accuracy of data generated, recorded or transmitted by the DHT	Evidence of Successful implementation in the UK
Tier B	DHTs that help users to understand healthy living and illnesses but are unlikely to have measurable user outcomes.	As above, plus evidence of: • Accuracy of information provided by the DHT • Commitment to ongoing data collection on usage and value of the DHT Appropriate safeguarding	Evidence of: Endorsement of information content by NICE/ NHS England/ relevant professional body
Tier C	DHTs for preventing, diagnosing and managing diseases. They may be used alongside other treatments and will likely have measurable user benefits.	As above, plus: High-quality observational or quasi-experimental studies demonstrating relevant outcomes (for preventative interventions) or improvement in relevant outcomes (for treatments)	High-quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the digital health technology (DHT) with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures

A significant difference between the MTEP programme and the other assessment programs at NICE is the outcome measure of any benefit arising from the DHT's use. Conventionally, NICE relies on the Quality-adjusted Life Year (QALY) to measure the combined effect of technology on patients' length and quality of life. However, the MTEP process provides more flexibility and allows assessing the benefit of technology using multiple outcomes. This procedural adjustment embraces the broader product spectrum of medical devices and DHTs.

4.2.1 Economic evidence

The ESF states requirements for the key economic information to be collected, the selection of the appropriate type of economic analysis and how to report the resulting outputs.

Similar to the requirements for clinical evidence, the process offers flexibility as the type of economic analysis depends on the financial consequences of adopting the technology from a payer perspective (Figure).

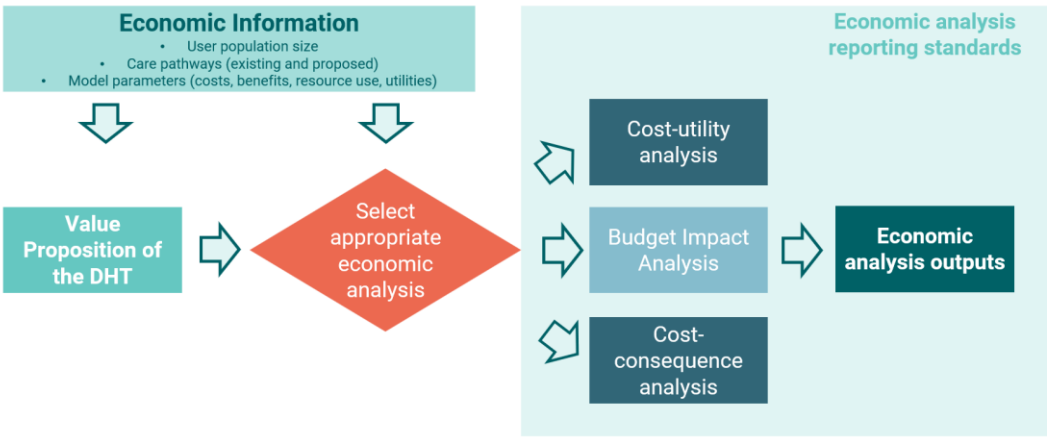


FIGURE 10: THE EVIDENCE STANDARDS FOR THE ECONOMIC IMPACT OF A DHT. SOURCE NICE (2021).

The ESF states that the type of economic analysis required depends on the expected financial consequences of implementing the technology from both a payer and commissioner perspective. From this, three different levels of analyses are possible, while a budget impact analysis is generally required within each level:

- **Basic** – a budget impact model is usually sufficient.
- **Low financial commitment** – usually requires a cost-consequence analysis that may inform a budget impact model.
- **High financial commitment** – where possible, a cost-utility analysis should be performed. For technologies that might lead to a high financial commitment but outcomes that goes beyond the clinical outcomes observed in clinical studies, such as organisation measures, cost-consequence analyses might be used alternatively. Both results may be used to inform a budget impact analysis.

Finally, the ESF provides guidance on how to report all results adapted from the NICE reference case (NICE, 2013) and Consolidated Health Economic Evaluation Reporting Standards (CHEERS) (Husereau et al., 2013, 2022).

4.3 The HTA pilot process for Digital Health Technologies

The DHT Pilot process is based on the medical technologies guidance development process within the MTEP but adapted, taking into account some characteristics of DHTs (NICE, 2019). As with the MTEP, the technology must be initially registered with NICE's online database, *Healthtech Connect* – which is due to be replaced by the AAC Innovation Service. NICE develops a draft scope based on the information provided by the company on this platform, in combination with opinions from other stakeholders. The main steps in the scoping process include a start-up meeting with the company, stakeholder engagement, drafting of the scope followed by comments, and finalising the scope followed by publication. The main difference in the approach to scoping is that for DHTs, NICE allows an initial start-up meeting with the company *ahead* of drafting the scope. In contrast, for the HTA of

pharmaceuticals, the meeting with the company comes further down the scope drafting stage. For DHTs, the scoping stage can take up to five weeks, as shown in Figure 11.

Additional phases could be added to the process based on the complexity of the technology. The evidence submission stage happens simultaneously with the scoping stage, where the company provides clinical evidence and proposes an economic model on the *Healthtech Connect* platform. The medical technologies advisory committee (MTAC) is the independent advisory body that considers the evidence presented and makes recommendations. It comprises members with different expertise in regulation and evaluation of healthcare technologies, NHS workers, and those who can provide a lay perspective on issues affecting patients.

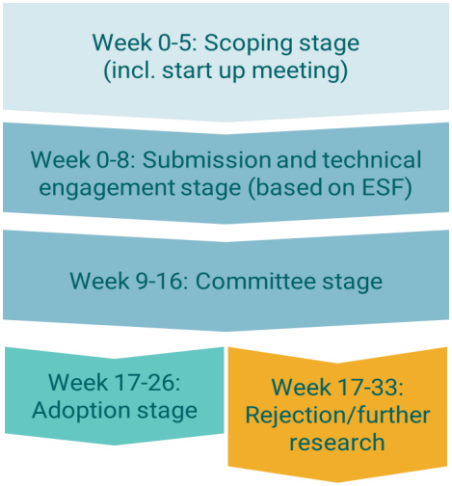


FIGURE 11: STAGE OF THE NICE DHT PILOT

Evidence provided by the manufacturer should follow the standards defined in the ESF. NICE then commissions an External Assessment Centre (EAC), which is usually selected through tendering from various organisations, including the health and social care system and academic bodies that have knowledge and expertise in the appropriate evaluation methods. The EAC provides independent assessments of the evidence and reports the results back to the committee, deciding whether the evaluation should continue to the next stage or require further data collection.

If the evaluation reaches the committee stage, the company is invited to provide an executable economic model for the technology to be assessed by the EAC and reviewed by other stakeholders. This forms the basis of the committee meeting where the decision about whether to recommend the technology is made. This stage can take up to eight weeks, and the resulting guidance will result in a recommendation to use the technology or to conduct more research. If adoption is recommended, the guidance goes through a stage of quality assurance by key stakeholders before it reaches publication. Alternatively, if the adoption of the technology is not recommended, a public consultation would take place on the NICE website, where stakeholders would be able to comment on the draft guidance.

The main difference in the process for DHTs compared to the general technology appraisal of other health technologies is the slightly faster timeline and that a positive recommendation by NICE mandates funding only for those technologies that fulfil specific criteria. These include that the technology has demonstrated its effectiveness, is cost-saving within three years of adoption or does not lead to a budget impact for the NHS greater than £20m in any of the first three years (NHSE, 2022). Additionally, DHT developers report early collaborative engagement with NICE, highlighted by the inclusion of the "start-up" meeting early in the scoping stage. This could be attributed to the general uncertainty surrounding the evaluation of DHTs and a willingness to learn together with DHT developers. It is not clear if this will continue post-pilot once a more established process for evaluating DHTs is founded.

In February 2022, NICE published their updated manuals for methods, processes and topic selection relevant to the value assessment of all health technologies. This will impact the design of the four different appraisal programs and potential findings and consequences drawn from the DHT pilot. While the MTEP process described above is unchanged in the new manual, the ultimate arrangements for DHTs will only be known after the pilot has been completed and NICE publishes formalised methods and processes.

4.4 Commissioning and Funding

NHS STRUCTURAL OVERVIEW

The NHS is a structurally complex system with varying levels of funding and autonomy. This section provides a simplified overview to help understand funding and accountability relationship flow within the system. However, it is important to note that this is constantly changing and evolving to support the provision of care to patients.

The majority of funding for health services coming from the DHSC is funnelled through NHS England. NHS England is then responsible for allocating these resources to Clinical Commissioning Groups (CCGs) and local authorities as well as directly to certain services on a national level, such as specialised services.

CCGs work on a local level and are responsible for the majority of NHS services, including urgent and emergency care, elective hospital care and community health services. NHS Trusts are providers of care and are responsible for acute, community and mental health care. Foundation trusts are self-governing bodies that have a higher level of autonomy over financial and operational matters, such as borrowing commercially, generating surpluses, and reinvesting those in the service. Most primary care services, such as GPs and dentists, are provided by independent bodies that have direct contracts with the NHS (Powell, 2020).

To ensure a successful homogenisation of these local-level bodies involved in the provision of care, the NHS introduced recently so-called Integrated Care Systems (ICSs). ICSs are partnerships which bring together providers and commissioners of services to plan and deliver healthcare in a specific area. Their main aim is to integrate care across various bodies and to link areas such as hospital and community-based care with mental health, physical health and health and social care. ICSs were set up to enhance productivity and sustainability while reducing inequalities and improving population health. CCGs fall within the wider ICS.

Reimbursement

There are currently no standard reimbursement pathways specific to DHTs. However, some technologies can benefit from already existing systems. Nationally, the Innovation and Technology Payment (ITP – finished in 2021) was a programme that aimed to support the NHS to adopt innovations by removing some of the financial and procurement barriers. The process to gain reimbursement through this system was competitive and only applied to technologies that had already proved their clinical effectiveness and were ready to be rolled out nationally. Generally, specific DHTs are most likely to be paid for from the same budgets as their substitutes and complement, i.e. from CCG/ICS allocations, primary care prescribing budgets and specialised commissioning budgets. While the MedTech funding mandate covers cost-saving technologies endorsement by NICE, the requirements can be considered somewhat restrictive.

In most cases, NHS Trusts and CCGs rely on direct engagement with DHT manufacturers, usually through commercial agreements, public tenders and procurement through the NHS Supply Chain. This means that many DHTs take part in local commissioning without being involved in national reimbursement schemes. It's important to note that while a positive recommendation from NICE can support DHTs in their adoption within the healthcare system, it doesn't always guarantee to fund, unlike technologies assessed via the NICE technology appraisal program.

In addition to national and local reimbursement schemes, the UK has a wide range of awards and grants to support innovation, such as the NHS's AI in Health and Social Care award. However, the downside of these is that they can be highly competitive and often offer limited availability.

5 Case studies of NICE assessments

SLEEPIO

Sleepio is an online sleep improvement programme which uses Cognitive Behavioural Therapy (CBT) for insomnia and is accessible on a smartphone or computer. In May, Sleepio became the first DHT providing therapeutic treatment to patients to be recommended by NICE (Big Health, 2022).

Classification
Evidence Tier: C
CE Mark – class I device

Value proposition	Benefit to patient	Benefit to healthcare system
• Replacement for CBT-I accessible via smartphone for improving sleeping patterns • Clinically proven to help individuals fall asleep faster, stay asleep through the night and improve energy levels during the day	• Easy to use technology, accessible on personal device, no need for extra gadgets • Personalised treatment which can be used at individual's leisure • Avoids the possible side effects of pills	• Relieving pressure on healthcare system by providing the care directly to the patient at home

Clinical Evidence

Sleepio (NICE, 2022c) fell within Tier C of the ESF, meaning that the manufacturers were expected to provide at least some high-quality observational or quasi-experimental evidence on outcomes. The device received a CE mark in 2018 as a class I device for adults with sleeping difficulties.

The treatment recommended by NICE for persistent insomnia is cognitive behavioural therapy for insomnia (CBT-I), but its provision is limited to a few Trusts and private clinics in the UK. The comparator for Sleepio was treatment, as usual, meaning a mixture of sleep hygiene information and hypnotics. This treatment option is more challenging to present evidence of cost-saving against than face-to-face CBT. However, Sleepio was expected to be cost-saving at the point of submission.

The clinical evidence supplied by Sleepio consisted of 28 studies, 12 of which being RCTs. Four of the RCT studies done in the UK were found to be effective when compared to treatment as usual or no treatment. There are no studies comparing Sleepio to face-to-face CBT.

Economic Evidence

Real-world economic evidence shows that Sleepio is more expensive than usual treatment after one year but is projected to be cost-saving after three years due to patients' lower healthcare costs, mostly because of fewer GP appointments and sleeping pills prescribed.

Recommendation

The guidance concluded that Sleepio is recommended as a cost-saving option for treating insomnia and insomnia symptoms in primary care for people who would otherwise be offered sleep hygiene or sleeping pills. For people who may be at higher risk of developing other sleep disorder conditions, such as in pregnancy or in people with comorbidities, a medical assessment should be done before referral to Sleepio. More research or data collection was recommended on Sleepio for people who

are eligible for face-to-face CBT-I in primary care. This is because there is limited clinical evidence to show how effective Sleepio is compared with face-to-face CBT-I.

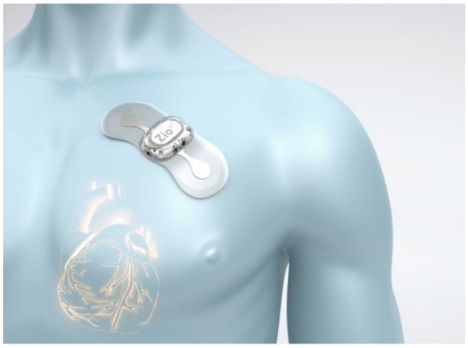
6 Examples of publicly reimbursed DHTs

Zio XT

Zio XT is a remote cardiac monitoring service used to detect cardiac arrythmias comprising of three parts: a wearable single-lead electrocardiogram (ECG), a software platform which can store, analyse and sort ECG data and a clinically actionable summary of the recorded data (NICE, 2020).

Classification
Evidence Tier: 3B
CE Mark – class IIa medical device

Value proposition	Benefit to patient	Benefit to healthcare system
• Zio XT enables longer monitoring period than continuous ECG monitors used in NHS standard care • Does not use any leads, which reduces artefacts in the data	• Easy to use technology that aids the detection of cardiac arrhythmias with continuous monitoring for up to 14 days while allowing the patient to get on with their everyday life	• AI analyses recordings and reduces the time needed for NHS staff to analyse the continuous monitoring data.



Clinical Evidence

The treatment recommended for suspected atrial fibrillations is a 12-lead ECG, considering the possibility of not detecting arrhythmias in some patients. Ambulatory ECG is recommended based on symptom presentation and frequency in those cases. This would usually be done using a Holter monitor for 24-hours for people who have episodes less than 24 hours apart or an event recorder (external or implantable) for people with episodes more than 24 hours apart. The proposed treatment with Zio XT would monitor the patient for 14 days.

The clinical evidence comprised 30 published studies, including one UK-based RCT (Kaura, 2019), which was considered of the highest quality. The study compared the diagnostic performance of Zio XT to that of a 24-hour Holter monitor in stroke patients.

Four comparative studies revealed a preference for users towards ZioXT compared to standard NHS care, which usually involves wearing a continuous ECG monitor such as a Holter monitor. Furthermore, ZioXT showed improved wear time compared to standard of care, as well as how many people were diagnosed with arrhythmias.

Economic Evidence

The economic evidence comprised five published studies, two of which reported that the technology was cost-saving and could avoid delays between clinic and diagnosis confirmation.

The long-term economic effects of adopting the device were uncertain due to a lack of evidence about long-term use. Nevertheless, estimated costs suggested that the device could be cost-saving or cost-neutral compared to the standard of care.

Recommendation

NICE recommends Zio XT as an option for people with suspected cardiac arrhythmias who would benefit from remote ECG monitoring for longer than 24 hours under certain conditions.

7 Stakeholder Mapping

A mapping of the relevant high-level stakeholder groups across the DHT's lifecycle is depicted in Figure 73. Idea generation can include members from almost all corners of the digital health ecosystem. Innovators can be found within academic institutions or research centres or be part of the industry. Funders also play a key role in providing the means for developing innovations. These can be private companies like venture capital and angel investors, public ones like the NIHR, or accelerators that help scale up the approval process. Individual patients, patient groups and healthcare professionals can also be involved in the initial stages of development, especially in defining the idea's underlying medical need.

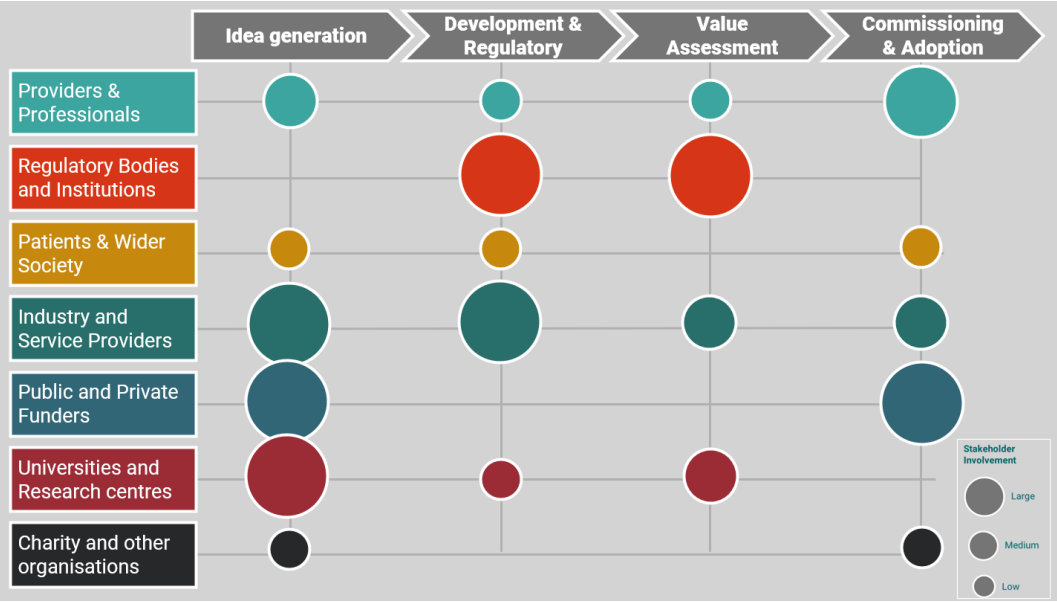


FIGURE 7: STAKEHOLDER INVOLVEMENT OVER THE DHTS LIFECYCLE.

The idea generation stage features developers, manufacturers and funders most predominantly, joined by providers of health and professionals to a lesser degree and finally, society and other organisations. Although regulators are not directly involved at this stage, some manufacturers would still keep their frameworks in mind if they want their technologies to be recognised and adopted by the NHS.

In the development stage, the main drivers are regulatory bodies. As described in the regulatory landscape chapter, these institutions work together to provide a regulatory framework for the technology. Alongside the regulators themselves, which provide support services, Commercial service providers such as ORCHA and DHACA can also support the manufacturers through the process, which can often be complex to navigate, especially in the case of a small company. Patients, patient groups and healthcare professionals are also involved in the development stage as they are often the direct users of the technology.

When it comes to value assessment, NICE is the main organisation responsible for HTA, specifically the Medical Technologies Advisory Committee (MTAC), which helps make recommendations on medical devices.

The last stage of the approval pathway is the commissioning and adoption of the technology. Regulatory bodies and funders play an important role in making the technology available and accessible to patients. However, it is down to the commissioners, healthcare professionals and patients themselves to adopt these new technologies.

We provide a list of all stakeholders mentioned in the paper and a brief description of their role in the appendix.

8 Lessons Learned

Figure 8 summarises the strengths and weaknesses of the digital health landscape in England and derives external associated opportunities and threats.

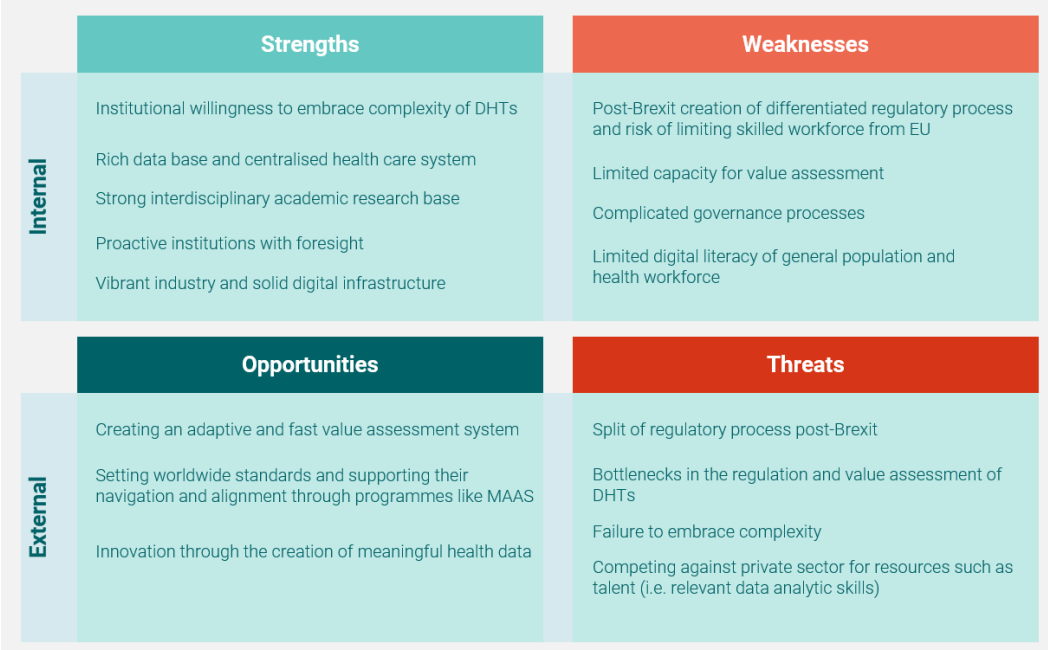


FIGURE 8: SWOT ANALYSIS OF ENGLAND DHT LANDSCAPE

While this overview is far from comprehensive, it helps to summarise four key insights that help to learn from the English experience of futureproofing its health care system for the digital revolution:

1. **Harvesting the benefits of digital health technologies requires digital skills within the general public and the health workforce beyond physical-digital access.**

   England is a highly digitalised country, and its population has outstanding access to digital technologies and the internet. However, at the same time, there is an evident shortcoming in the digital skills of its general population and its health workforce. The latter is exacerbated by the competition between the NHS and the private sector for talents with relevant capabilities such as data analysis in post-Brexit times.

   This gap between having access to digital technologies and having the basic skills to utilise them hinders the exploitation of their full potential. Multiple stakeholders from all three sectors in the UK demonstrate how to take action to close this gap using standardised frameworks & metrics and action-related measures.

2. **Practical regulatory frameworks may separate between hard and soft regulation to address the variety of regulated medical devices and unregulated products and services**

   DHTs comprise both regulated medical devices and unregulated consumer health products. Avoiding unnecessary regulation while minimising risks associated with unregulated products might be possible. A feasible approach to faster market entry for low-risk technologies would be encouraging the use of soft regulation for those technologies which would otherwise fall in the unregulated products bracket.

   An excellent example is provided by the DTAC standards and the digital playbooks, which bundle a range of products that adhere to a minimum standard of regulations. This can boost user confidence and uptake.

3. **Value assessment approaches of DHTs require flexibility**

   Due to the complexity and variety of DHTs, England attempts to avoid a one-size-fits-all approach for its value assessments. This leads to a relatively lower evidence requirement for clinical and economic low-risk technologies while adopting higher evidence requirements and assessment methodologies for technologies associated with higher clinical or economic risk.

   This approach is flexible but can become overly complex. The presence of methodological guidance documents with different uptake cycles might confuse the users. Hence, while dedicated frameworks, templates and transparent guides to help digital health innovators are essential, they should be complemented by dedicated interfaces and platforms to facilitate early exchange between the HTA agency and potential innovators.

   We recognise that the NICE 2022 manual streamlined multiple types of guidance for different appraisal pathways, and we would encourage a similar approach when it comes to producing the DHT guidance.

4. **AI & Machine Learning requires interdisciplinary efforts in regulation, value assessment and ethics**

   Incorporating AI & machine learning methods into DHTs involves a wide array of unprecedented challenges for various stakeholders. The definition of the related process, frameworks, and methods cannot and should not be defined by one institution alone.

   With the envisaged Multi-Agency Advisory Service (MAAS), England spearheads international activities to ensure that future data-driven technologies are safe, effective and free of bias and discrimination.

9 Appendix

NOTE ON METHODOLOGY

This report is based on a targeted literature review between March and May 2022. We retrieved, reviewed and - where required - interpreted relevant official documents, regulatory guidance, and grey literature published by a variety of stakeholders within all three sectors.

We searched websites of key regulatory and HTA agencies, official policy websites, OHE in-house literature and a set of core papers and reports on digital health developed through several research projects.

All documents were retrieved.

AN OVERVIEW OF PUBLIC BODIES AND INITIATIVES

Name	Description of role
Academic Health Science Network (AHSN)	Support innovators with the adoption of their technology by NHS, with several specific digital health programmes.
Approved Bodies	Designated by the MHRA to assess whether manufacturers and their medical devices meet the regulatory requirements
Clinical Commissioning Groups (CCG)	Commissions most of the hospital and community NHS services in the local areas
Care Quality Commission (CQC)	Monitors, inspect, and regulates medical and social care services to make sure they meet the set standards of quality and safety
Department of Health (DHSC)	The government department responsible for policy matters on Health and social care in England
Digital Health & Care Alliance (DHACA)	Association dedicated to driving innovation which supports a range of organisations to scale innovation
External Assessment Centre (EAC)	Independent groups commissioned by NICE to review and critically evaluate the evidence submitted by companies for appraisal.
Genomics England	A company dedicated to sequencing whole genomes, with a focus on cancer and rare disease patients
General Medical Council (GMC)	A public body that maintains the official register of medical practitioners within the UK and maintains high standards of medical education and practice
Health Education England (HEE)	Supports the NHS through the delivery of education and training of the workforce
Health Research Authority (HRA)	Regulates different aspects of health and social care research to protect and promote the interest of patients in research
Information Commissioner's Office (ICO)	Independent body set up to uphold information rights in the public's interest
Innovate UK	The UK's national innovation agency supports companies to grow and navigate the commercialisation and adoption pathway for their innovative technologies.

Multi-agency advice service (MAAS)	Collaboration to provide cross-regulatory advisory service for developers and adopters of AI and other data-driven technologies in healthcare.
Medicines and Healthcare products regulatory agency (MHRA)	Regulates and maintains the standards of quality, efficacy and safety for medicines, medical devices and blood components for transfusion
Medical technologies advisory committee (MTAC)	Committee of NICE, which makes recommendations on medical devices with the potential to improve patient outcomes or efficient use of resources
National Information Board (NIB)	Works in partnership with other organisations to develop strategic priorities for data and technology
NHS Digital	Branch of the NHS involved in the design, developing and operating of the national IT and data services underpinning the work of clinicians within the NHS
National Institute for Health and Care Excellence (NICE)	Produces evidence-based guidance and advice for health, public health and social care practitioners and develops quality standards and performance metrics for healthcare technologies.
Organisation for the Review of Care and Health Applications (ORCHA)	Review and certify digital health technologies and provide safe, accredited and compliant digital health libraries to healthcare professionals. Can also provide advice for navigating the DHT landscape to companies.
National Institute for Health Research (NIHR)	Fund health, public health and social care research that lead to improvement in patient outcomes
Standards Bodies	Organisations involved in the creation and promotion of standards and protocols to meet the needs of businesses and users
UK Biobank	large-scale biomedical database and research resource that provides access to medical and genetic data to improve medical care

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