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Towards identifying good practices in the assessment of digital medical devices: Insights from several OECD countries

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Towards identifying good practices in the assessment of digital medical devices

Insights from several OECD countries

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Abstract

The rapid evolution of digital health technologies presents new opportunities for healthcare systems while increasing pressure on public budgets. Governments and insurers face growing challenges in determining what to fund and at what price. Health technology assessment (HTA) remains a critical tool for informing these decisions, and several OECD countries are exploring ways to adapt existing approaches to the fast-changing and diverse landscape of digital medical devices. The absence of a common taxonomy, coupled with the rapid pace of technological advancement, further complicates evaluation, driving global momentum toward more harmonised HTA approaches that support effective and equitable decision-making.

Through desk research and interviews, this paper aims to explore how France, Germany, Israel, Korea, Spain, and the United Kingdom – OECD countries with emerging practices in this field – assess certain types of digital medical devices, including digital therapeutics for individual use in ambulatory care and digital diagnostics. It describes HTA approaches, focusing on relevant pathways, technology remits, and evaluation methods. Drawing on practical experiences, it highlights key challenges and potential learning opportunities. This paper contributes to ongoing discussions on adapting HTA frameworks to improve the assessment and integration of digital medical devices into healthcare systems.

Résumé

L'évolution rapide des technologies de santé numériques offre de nouvelles opportunités aux systèmes de santé tout en augmentant la pression sur les budgets publics. Les gouvernements et les assureurs sont confrontés à des difficultés croissantes pour déterminer ce qu'il convient de financer et à quel prix. L'évaluation des technologies de la santé (ETS) reste un outil essentiel pour éclairer ces décisions, et plusieurs pays de l'OCDE étudient les moyens d'adapter les approches existantes à l'évolution rapide et à la diversité du paysage des dispositifs médicaux numériques. L'absence d'une taxonomie commune, associée au rythme rapide des avancées technologiques, complique encore l'évaluation, incitant à adopter des approches d'ETS plus harmonisées qui favorisent une prise de décision efficace et équitable.

S’appuyant sur recherches documentaires et des entretiens, ce document explore la manière dont la France, l'Allemagne, Israël, la Corée, l'Espagne et le Royaume-Uni - des pays de l'OCDE ayant des pratiques émergentes dans ce domaine - évaluent certains types de dispositifs médicaux numériques, notamment les thérapies destinées à un usage individuel en ambulatoire et les diagnostics numériques. Il décrit les approches de l'ETS, en se concentrant sur les voies pertinentes, le champ des technologies évaluées et les méthodes d'évaluation. S'appuyant sur des expériences pratiques, il met en évidence les principaux défis et les possibilités d'apprentissage. Ce document contribue aux discussions en cours sur l'adaptation des cadres d'ETS afin d'améliorer l'évaluation et l'intégration des dispositifs médicaux numériques dans les systèmes de santé.

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The views expressed in this document are those of the author and do not necessarily reflect the views of any OECD country or individual expert.

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Executive summary

1. Digital health technologies – a broad term encompassing systems that use computing platforms, connectivity, or software for healthcare and related uses – are evolving rapidly, offering new opportunities for health systems while increasing pressure on already stretched public healthcare budgets. Payers, including governments and insurers, face growing challenges in determining what to fund and at what cost. Health technology assessment (HTA) remains a critical tool for informing these decisions for medicines and medical devices, but several OECD countries are exploring how to adapt existing approaches to the fast-changing and diverse landscape of digital health technologies, and in particular to the subset of these technologies that are regulated as medical devices (i.e. digital medical devices). The absence of a common taxonomy, coupled with the rapid pace of technological advancement, further complicates evaluation. In response, there is increasing global momentum towards more harmonised HTA approaches to support effective and equitable decision-making.

2. This paper examines how **France**, **Germany**, **Israel**, **Korea**, **Spain**, and the **United Kingdom** – OECD countries with emerging practices in this field – assess certain types of digital medical devices, including digital therapeutics used directly by patients in ambulatory care that offer treatment or therapeutic benefits (e.g. cognitive behavioural therapy via a mobile application) and digital diagnostics, which are clinically validated tools for detecting disease. Approaches vary reflecting differences in legislative frameworks and in the scope of technologies evaluated; the latter is often much broader than the initial paper scope, making it challenging to isolate and compare specific findings. While HTA informs coverage decisions in all countries, recommendations do not always lead directly to national coverage or reimbursement, impacting uptake. Digital medical devices can follow the same pathways as non-digital devices, but most countries, except Spain, have introduced fast-track or early access pathways for certain technologies. While core evaluation criteria remain similar to non-digital medical devices, requirements for data privacy, security, interoperability, and patient usability are also included, though sometimes addressed outside HTA. The breadth of experience also varies considerably, with some countries evaluating hundreds of digital health technologies - albeit beyond this paper's initial scope - while others are in the early stages of formal assessment. As of October 2024, key country highlights include:

- **France:** A fast-track evaluation system for digital therapeutics and remote monitoring tools was introduced in 2023. Six technologies have passed through, including one digital therapeutic for mental health, while another followed the standard evaluation process not specific to digital technologies.
- **Germany:** Since 2020, 65 technologies have entered the supply – either temporarily or permanently – through a dedicated pathway for low-risk, patient-facing digital health applications, with nearly half targeting mental and behavioural health. More than 374 000 activations for patient use had been made until September 2023.
- **Korea:** An integrated review pathway introduced in 2022 streamlines regulatory, HTA, and insurance evaluations, with four digital therapeutic mobile applications entering the market at the time of review.

- **United Kingdom:** Over the preceding two years, more than 100 digital technologies have been evaluated through an early value assessment pathway in England, with each review assessing between 3 and 14 promising technologies addressing the same clinical need and guiding further evidence generation. Since 2023, around 10 digital technologies have been evaluated in Scotland, comprising around a quarter of their evaluations.
- **Spain:** A digital-specific HTA methodology was published in December 2023, and the HTA network of regional agencies has begun national-level evaluations using this framework.
- **Israel:** While no digital therapeutics have yet been formally assessed for inclusion in the national benefit basket, Israel has developed an adaptable evaluation framework to support the development of early-stage digital tools, drawing on experience from evaluating hundreds of technologies. Many digital health technologies, including digital therapeutics, have been evaluated as part of Ministry of Health grant programmes.

3. Interviews with HTA bodies from these countries reveal that while digital medical devices face many of the same HTA challenges as non-digital medical devices, they also present some unique ones. Analysis across five key areas – (1) the approach to HTA, (2) the evaluation process, (3) evidence generation, (4) evaluation criteria, and (5) implementation and adoption – identifies some of these distinct challenges:

- In the unique digital ecosystem, some products can quickly enter and exit the market without the constraints of extensive manufacturing chains, creating **market volatility** that challenges their assessment.
- **Rapid software evolution**, including advancements in artificial intelligence, also challenges traditional HTA processes and safety assurance processes, which are designed for fixed products and not well-suited for ongoing assessment.
- **Information asymmetry** between developers and evaluators can lead to misalignment in expectations, creating gaps between the evidence submitted and what is required for assessment.
- Evaluations require specialised expertise, as **technical complexities** like data privacy, cybersecurity, interoperability, and usability considerations add an extra layer of technical assessment, although often addressed outside HTA.
- **Uptake and adherence** to digital medical devices remain key challenges, as their effectiveness depends heavily on context of use, relying on (local) infrastructure (e.g. mobiles, computers) and user ability to operate the technology effectively. Equity concerns and the digital divide can further impact access.

4. Across these same five areas, emerging insights from the interviewees highlight learnings from recent experiences, some applicable to other medical devices and others specifically relevant to the digital medical device space. In the latter, experts point to the need for:

- **Context-specific and tailored approaches** to account for rapid development cycles, a high volume of products, often less mature clinical evidence, and unique data considerations.
- **Inclusive and collaborative evaluation** processes that engage, for example, technical experts on the digital aspects, ethics in the use of artificial intelligence, and patients on the context of use.
- **Bridging information asymmetry** through clearer communication, shared terminology (e.g. glossaries), and early engagement between developers and evaluators.
- Alongside safety and clinical effectiveness, **additional considerations** to the technical aspects of technologies (e.g., cybersecurity, interoperability), user-centred design, as well as privacy protection, equity, ethics and environmental impacts. Economic evaluation of these technologies is also an evolving space.

- **Better integration between HTA, funding, and implementation**, along with a more streamlined evaluation process that aligns with technology development and allows for updates as software evolves.

5. While it is too early to establish definitive 'good' or 'best' practices for the HTA of digital medical devices, this paper contributes to the growing understanding of their evaluation and the broader effort towards shared learning and harmonising HTA frameworks. The insights presented are drawn from the reviewed systems and their intended scopes, and while they offer valuable perspectives, they may not be universally applicable. As digital health technologies continue to evolve, OECD countries are encouraged to review their healthcare contexts and evaluation methods to determine whether to refine existing frameworks, maintain current practices, or explore new approaches.

6. To strengthen digital medical device assessment, key overarching considerations for OECD countries include ensuring **clear pathways from market entry to implementation**, adopting **adaptive and iterative HTA processes** that evolve with digital health advancements**,** ensuring **transparency in methods and published assessments** to facilitate shared learning, leveraging **real-world data** to monitor usage, patient satisfaction, and health outcomes, and **drawing on international collaboration** to build on existing experiences.

Acronyms and abbreviations

AI	Artificial Intelligence
ANS	Digital Health Agency (France) - *Agence du Numérique en Santé*
AQuAS	Agency for Health Quality and Assessment of Catalonia (Spain) - *Agència de Qualitat i Avaluació Sanitàries de Catalunya*
BfArM	Federal Institute for Drugs and Medical Devices (Germany) - *Bundesinstitut für Arzneimittel und Medizinprodukte*
CBT	Cognitive Behavioural Therapy
CDA	Canada's Drug Agency
CE	Conformitée Européene
CEESP	Economic and Public Health Evaluation Committee (France) - *Commission d'Évaluation Économique et de Santé Publique*
CEPS	Pricing Committee (France) - *Comité Économique des Produits Santé*
CNEDiMTS	National Committee for the Evaluation of Medical Devices and Health Technologies (France) - *Comission en charge de l'évaluation de dispositives médicaux*
COPD	Chronic Obstructive Pulmonary Disorder
DHT	Digital Health Technology
DiGA	Digital Health Applications (Germany) - *Digitale Gesundheitsanwendungen*
DMHT	Digital Mental Health Technologies
DTA	Digital Therapeutics Alliance
DTAC	Digital Technology Assessment Criteria (United Kingdom)
DTx	Digital Therapeutic
EEA	European Economic Area
EMA	European Medicines Agency
ESF	Evidence Standards Framework for Digital Health Technologies (United Kingdom)
EU	European Union
EU IVDR	European Union In Vitro Diagnostics Medical Device Regulation
EU MDR	European Union Medical Device Regulation
EUnetHTA	European network for Health Technology Assessment
EVA	Early Value Assessment (United Kingdom)
FAMHP	Federal Agency for Medicines and Health Products (Belgium)
G-BA	Federal Joint Committee (Germany) - *Gemeinsamer Bundesausschuss*
GKV-SV	National Association of Social Health Insurance Funds (Germany) - *Gesetzliche Krankenkassen- Vereinigung-Spitzenverband*
HAS	French National Authority for Health (France) - *Haute Autorité de Santé*
HIPDC	Health Insurance Policy Deliberation Committee (Korea)
HIRA	Health Insurance Review and Assessment (Korea)

HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
IMDRF	International Medical Device Regulators Forum
INAHTA	International Network of Agencies for Health Technology Assessment
IQWiG	Institute for Quality and Efficiency in Health Care (Germany) - *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*
ISO	International Organization for Standardisation
IVD	In Vitro Diagnostic
KHIDI	Korean Health Industry Development Institute (Korea)
LATM	Reimbursement List for Remote Monitoring Devices (France) - *Liste des Activités de Télésurveillance Médicale*
LPPR	Reimbursement List (France) - *Liste des Produits et Prestations Remboursables*
MFDS	Ministry of Food Drug and Safety (Korea)
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MOHW	Ministry of Health and Welfare (Korea)
NECA	National Evidence-based healthcare Collaborating Agency (Korea)
NHS	National Health Service
NICE	National Institute for Health and Care Excellence (United Kingdom)
NIHDI	National Institute for Health and Disability Insurance (Belgium)
NLHS	National List of Health Services (Israel)
OECD	Organisation for Economic Co-operation and Development
PECAN	Fast-track Pathway for Digital Devices (France) - *Prise En Charge Anticipée Des Dispositifs Médicaux Numériques*
RedETS	The Spanish Network of Agencies for Assessing National Health System Technologies and Performance (Spain) - *Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del SNS*
SaMD	Software as a Medical Device
SHI	Social Health Insurance
SHTG	Scottish Health Technologies Group (Scotland, United Kingdom)
SiMD	Software in a Medical Device
UK	United Kingdom
UKCA	United Kingdom Conformity Assessment
WHO	World Health Organization

1. Background

1.1. Introduction

7. Advances in digital health technologies (DHTs) are growing at a rapid rate, fast expanding the range of products available to health systems and offering potential alternatives to improve care and increase efficiency, while also putting pressure on already stretched public health spending. Payers, including governments and healthcare insurers, are increasingly faced with the challenge of what to pay for and how much, and how to incorporate value-based judgements on new products. Health technology assessment (HTA) is considered by many countries and payers as a useful instrument to inform such decisions, particularly for medicines and for some medical devices. However, there is a lack of consensus or standard approach to the assessment of different types of digitally based health technologies, with DHTs evolving faster than the methods used to assess them.

8. The landscape of DHTs is very broad, and regulatory and HTA bodies in different jurisdictions have different remits when it comes to approving and assessing these types of products. To illustrate the complexity, Table A A.1 in Annex A links to the various terms defined according to the International Organization for Standardization (ISO), while Figure A A.1 depicts an example of the different categories of DHTs, according to the Digital Therapeutics Alliance (DTA; an industry trade association). Digital health technologies can cover products that are used by prescribers and/or patients and include anything from electronic prescribing systems and telemedicine platforms to wellness mobile applications, to medical devices such as diagnostic tools and monitoring products, as well as digital biomarkers and therapeutics. Section 1.2 describes the landscape further.

9. Previous OECD work has identified good practices in the adoption of new health technologies, including in the range of benefits covered by respective health systems. For example, a 2016 report described how OECD countries define the range of goods and services to be financed collectively, including the role of HTA and other appraisal and decision-making processes (Auraaen et al., 2016[1]). It focused on medical procedures, medicines and medical devices more generally, but did not describe the assessment or evaluation of digital technologies, notably because it has become more of a policy issue in recent years. Another OECD report in 2017 discussed how OECD countries should adapt to the changing environment of new health technologies, in terms of the development, assessment and uptake of health technologies (OECD, 2017[2]). It describes the regulatory, coverage and pricing landscape for medical devices in OECD countries and some of the challenges with the emergence of mHealth (mobile applications and portable devices using digital technology) at that time. More recently, a report prepared by the OECD's Insurance and Private Pensions Committee in early 2024 reviewed the landscape of digital tools used by the insurance industry to prevent, detect and manage health and wellness-related risks, including wearable devices and mobile applications (OECD, 2024[3]). Similarly, an OECD paper published in mid-2024 used four case studies to describe the opportunities and challenges of using digital tools and innovative technologies to promote health in the workplace (Vazquez-Venegas et al., 2024[4]).

10. Some HTA agencies and academics have already identified the need to adapt HTA processes, methods, and frameworks for the assessment of DHTs specifically, albeit with varying scope in the types of products considered and the approaches taken. The challenge of assessment or evaluation of DHTs

has also been increasingly recognised at global level. For example, HTA bodies from Australia, Canada, New Zealand and the United Kingdom are collaborating on a range of topics, including digital evaluation (CDA, 2023[5]). Several ongoing projects in the European Union (EU) are also looking at HTA of DHTs, in terms of framework development and harmonisation as well as in preparation for future joint clinical assessments (e.g. (ASSESS DHT, 2024[6]; EDiHTA, 2024[7]). Non-government stakeholders, such as industry associations, have also produced several resources to support the industry to better understand the regulation and reimbursement landscape across countries (e.g. (DTA, 2024[8]; APACMed, 2020[9])).

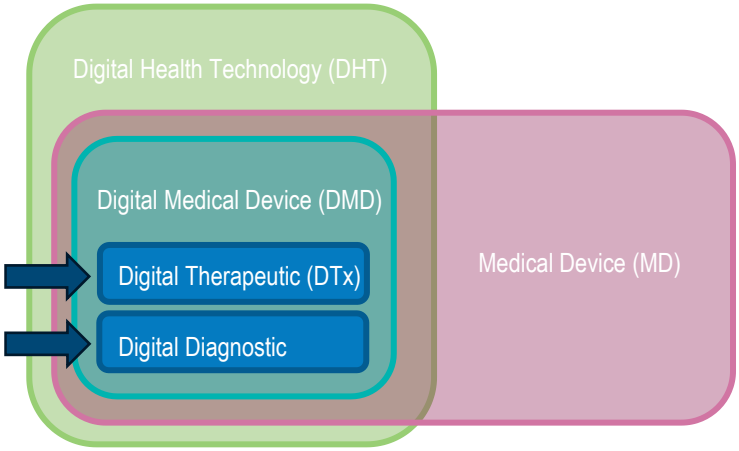
11. This paper aims to make progress towards identifying good practices in the health technology assessment of digital health tools for governments and health insurers to make decisions on coverage and price. Given the vast array of digital health technologies and the different remits of health technology assessment bodies, the scope intended to focus on the assessment of certain types of digital medical devices – namely **digital therapeutics** prescribed by healthcare practitioners and used directly by patients in ambulatory care that offer treatment or therapeutic benefits, and **digital diagnostics** – for inclusion in the range of benefits covered by health systems. These represent a small subset of digital health technologies that are generally required to undergo evaluation by regulatory authorities for safety and efficacy or performance and are likely to also subsequently undergo HTA (see Figure 1.1 for a schematic, and Box 1.1 for definitions). The analysis reviews HTA approaches in selected OECD case study countries that have interesting practices in the field of digital health technologies (**France, Germany, Israel, Korea, Spain,** and the **United Kingdom**) and draws on related experiences. The analysis is informed by desk research and interviews with experts from HTA bodies in these countries. Experts involved in other international or regional initiatives were also consulted to ensure alignment of activities.

12. In some jurisdictions, HTA bodies already assess certain medical devices, aiming to evaluate comparative clinical and cost-effectiveness over standard care and make some type of assessment on value for patients. These assessments can be used to support decision-making on coverage and price of products, for example to be included in national benefit baskets. However, existing HTA methodologies and frameworks do not necessarily include dimensions or criteria related to the digital aspect of such medical devices. The findings of the paper therefore intend to inform policy makers in OECD countries and beyond about different approaches taken when considering what digital technologies to pay for, and how much. The findings may also encourage a move towards harmonisation of different HTA frameworks and methodologies in the assessment of these products across jurisdictions.

13. While the paper intended to originally narrow the scope to digital medical devices that met the definition of *digital therapeutics* or *digital diagnostics*, it is acknowledged that the main findings primarily pertain to the former, reflecting the insights gained and available evidence during the research process. It is also important to recognise that the remit of HTA agencies is much broader than the intended paper scope and thus some learnings from other types of digital medical devices or technologies are also included as they could not be delineated.

14. Section 1. first introduces the topic of HTA of digital medical devices, describing the broad and evolving landscape of digital health technologies and the context of assessment. Section 2. describes the specific approaches to HTA of digital medical devices in the case study countries, with an emphasis on the relevant pathways, technology remits, approaches to assessment and evaluation, and role of HTA. Section 3. draws on practical experiences from the case study countries to identify some of the challenges and learning opportunities moving forward, while Section 4. summarises the main conclusions of the analysis.

Figure 1.1. Schematic of the landscape of digital health technologies and focus of this paper



Note: Digital therapeutics and digital diagnostics were the intended focus of this paper, although the main findings primarily pertain to digital therapeutics, reflecting the insights gained during the research process. This schematic is not intended to be exhaustive nor to scale.
Source: Adapted from (Spreafico, A. et al., 2023[10]).

Box 1.1. Definitions used in this paper

No single widely used definition of 'digital health technology' (DHT) exists. It is a broad, evolving term encompassing technologies used by prescribers, patients or administrators for various purposes. Examples include electronic prescribing systems, telemedicine platforms, wellness mobile applications, diagnostic tools, monitoring products, digital biomarkers, and therapeutics. A key challenge is the lack of harmonised nomenclature and taxonomy across jurisdictions. For this paper, the following definitions are used, though clear definitions are not always available from all sources referring to these terms.

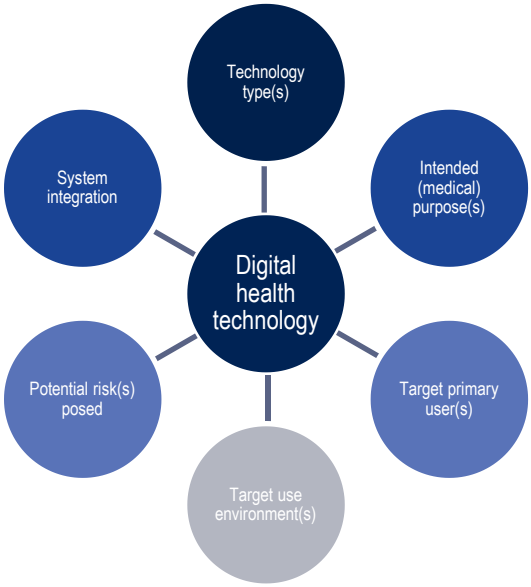
- **Digital health technology:** system that uses computing platforms, connectivity or software for healthcare and related uses.
- **Medical device:** instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which can be assisted in its intended function by such means.
- **Digital medical device:** digital health technology that also meets the definition of a medical device (and is usually considered as such for regulatory approval purposes).
- **Digital therapeutic**: health software intended to treat or alleviate a disease, disorder, condition, or injury by (directly) generating and delivering a medical intervention that has demonstrable positive therapeutic impact on a patient's health (e.g. cognitive behavioural therapy via mobile application).
- **Digital diagnostic:** clinically validated digital tools for detecting and characterising disease, measuring disease status, response, progression, or recurrence.

Source: (ISO, 2023[11]; Health Advances, 2023[12]; IMDRF, 2014[13]; FDA-NIH Biomarker Working Group, 2016[14]). See also Annex A.

1.2. The landscape of digital health technologies is vast and evolving

15. The landscape of DHTs - as defined in Box 1.1 - is vast and constantly changing with new technologies being developed and introduced into health systems at a rapid pace. A significant challenge is the lack of harmonisation or standardisation in the nomenclature and taxonomy used across jurisdictions. Comprehensive characterisation can support decision-making - for patients, clinicians, and healthcare decision-makers - and help to ensure product safety, effectiveness and use. Without harmonisation, reaching consensus around the levels of evidence required for different technologies to be included in national benefits baskets and adopted by health systems is challenging. Nevertheless, efforts have been made by various stakeholders in recent years to categorise and classify DHTs, albeit according to different perspectives or purposes. For example, technologies can be categorised according to the type(s) of technology they use, their intended medical purpose(s), intended user(s) and use environment(s) and the risk(s) they pose (Figure 1.2). Some examples of different classification systems are described below, although this is not intended to be exhaustive.

Figure 1.2. Considerations in the definition or classification of a digital health technology



Note: This list of considerations is not intended to be exhaustive.
Source: Authors, based on desk research.

16. The **International Organization for Standardization (ISO),** a worldwide non-governmental organisation consisting of national standard setting bodies, publicly defines various terms relevant to the landscape of digital health technologies and its constructs (Table A A.1, Annex A). For example, ISO defines a digital health technology as a *"system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses*" (ISO, 2023[11]). It can span a wide range of uses, from patient-facing wellness applications, clinician-facing electronic prescribing systems, and telemedicine platforms, to diagnostic tools and digital therapeutics. Certain DHTs can be considered medical devices, which are intended to be used in the diagnosis, prevention, monitoring or treatment of a disease, among other purpose(s). These types of technologies may fall under the category "software as a medical device" (SaMD), i.e. software designed for one or more medical purposes that functions independently without being integrated into a hardware medical device. Alternatively, they may fall under "software in a medical device" (SiMD), whereby the software that is used is integral to the hardware or is intended to drive the

hardware of a medical device. The **Digital Therapeutics Alliance** (DTA; an industry trade association) has produced a number of tools to help industry developers and healthcare decision-makers interpret ISO definitions and categorise DHTs (DTA, 2024[8]). Figure A A.1 in Annex A depicts an example of the different categories of DHTs according to DTA.

17. The **World Health Organization (WHO)** released a second edition of the *Classification of digital interventions, services and applications in health* in 2023 (WHO, 2023[15]). This taxonomy characterises the way in which digital and mobile technologies are used to support individual and healthcare needs based on their intended purpose(s). It is based around (1) identifying the targeted primary user of the technology (e.g. persons, healthcare providers, health systems management personnel, data services), (2) characterising the technology according to the type(s) of digital health interventions it may be delivering (e.g. transmitting information to the individual, providing simulated interactions with the person, etc.) and (3) linking this with the type of software, information and communication technology systems that deliver the intervention. This taxonomy can be used to support various stakeholders in identifying digital health interventions that will meet their specific needs (e.g. public health interventions), articulating the type of intervention delivered by a technology, and understanding the landscape of DHTs available and their capabilities.

18. The **International Medical Device Regulators Forum (IMDRF)** comprises a voluntary group of medical device regulators across the world working towards harmonisation and convergence in international medical device regulation. The IMDRF has developed a range of internationally agreed documents related to medical devices and in 2013 first introduced the concept of SaMD, which has since evolved to the changing landscape of software. SaMD categories according to the IMDRF are shown in Table 1.1. The framework is based around two aspects of the technology: the significance of the information provided by the technology and the state of the healthcare situation or condition. In 2024, the IMDRF proposed a possible risk characterisation of medical device software that is relevant for regulatory purposes (IMDRF, 2024[16]). The scope applies to the subset of software that meets the definition of a medical device, including SaMD, irrespective of the technology or platform used (e.g. mobile apps, cloud, server, hardware medical device).

Table 1.1. IMDRF's SaMD categorisation and level of impact on patients or public health

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

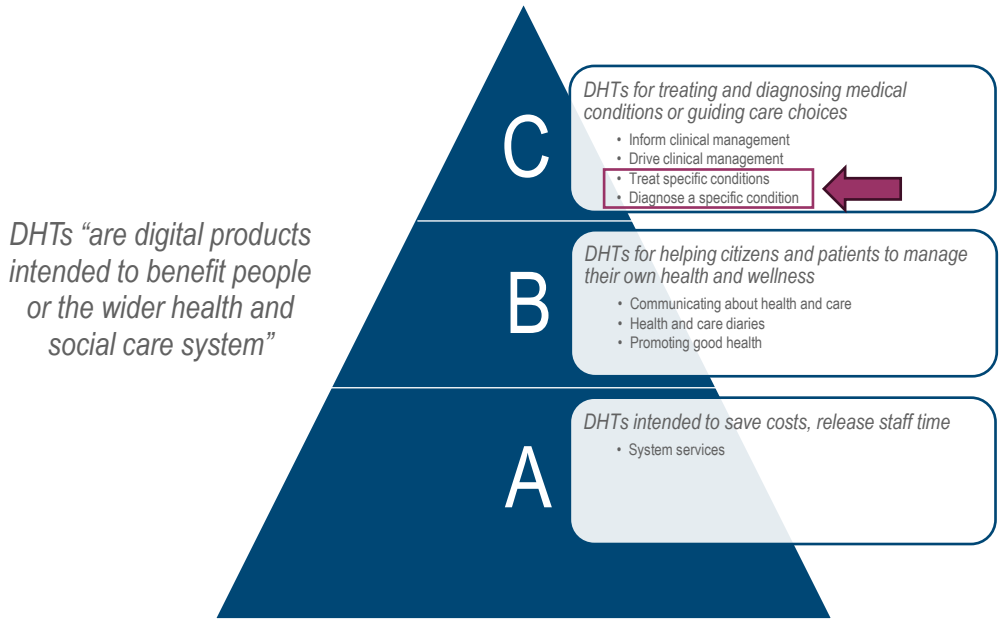
Note: IMDRF International Medical Device Regulators Forum; SaMD software as a medical device.
Categories reflect how critical the information provided by the SaMD is for health outcomes. The higher the risk to the patient or public health, the higher the category: IV = very high impact; III = high impact; II = medium impact; I = low impact.
Source: (IMDRF, 2014[13])

19. From an HTA perspective, and therefore of high relevance to this paper, the **United Kingdom's** (UK) National Institute for Health and Care Excellence (NICE) devised a comprehensive classification system for digital health technologies in its *Evidence Standards Framework for Digital Health Technologies* (ESF) (NICE, 2018[17]). This ESF classification system was designed to support the development and subsequent evaluation of DHTs that are likely to be implemented in the UK health and care system, including those regulated as medical devices or in vitro diagnostics (IVDs). The audience for the ESF is developers and commissioners of DHTs, and although NICE currently does not explicitly use the ESF, its components generally fall within NICE's broader methods and processes for health technology evaluation.

The ESF classifies technologies by their intended purpose and is designed to complement existing regulatory and technical standards. This classification, albeit slightly adapted, is also used by the group of regional Spanish HTA agencies in their adapted health technology assessment framework for digital health technologies (AQuAS, 2023[18]). According to the ESF, DHTs *"are digital products intended to benefit people or the wider health and social care system"* (e.g. smartphone applications; standalone software; online tools for treating or diagnosing conditions, preventing ill health, or for improving system efficiency; programmes that can be used to analyse data from medical devices such as scanners, sensors or monitors). The ESF is not used to evaluate the following types of DHTs: SiMD (software that is integral to, or embedded in, a medical device or IVD); DHTs designed for providing training to health or care professionals (e.g. virtual reality, augmented reality surgical training); or DHTs that facilitate data collection in research studies. Figure 1.3 depicts the classification used by the ESF, which categorises DHTs into tiers based on the level of risk to service users and the system. Most regulated medical devices and IVDs would appear in Tier C. Tier C is further divided into four classes to align with the IMDRF's SaMD framework. Tables 1 and 2 in the ESF document itself provide a more detailed overview of the information in Figure 1.3 below, while also mapping Tier C to the likely medical device risk classes in UK regulation (NICE, 2018[17]).

Figure 1.3. NICE's classification of digital health technologies into tiers, according to risk stratification

Classification developed by NICE to help support evaluation of DHTs

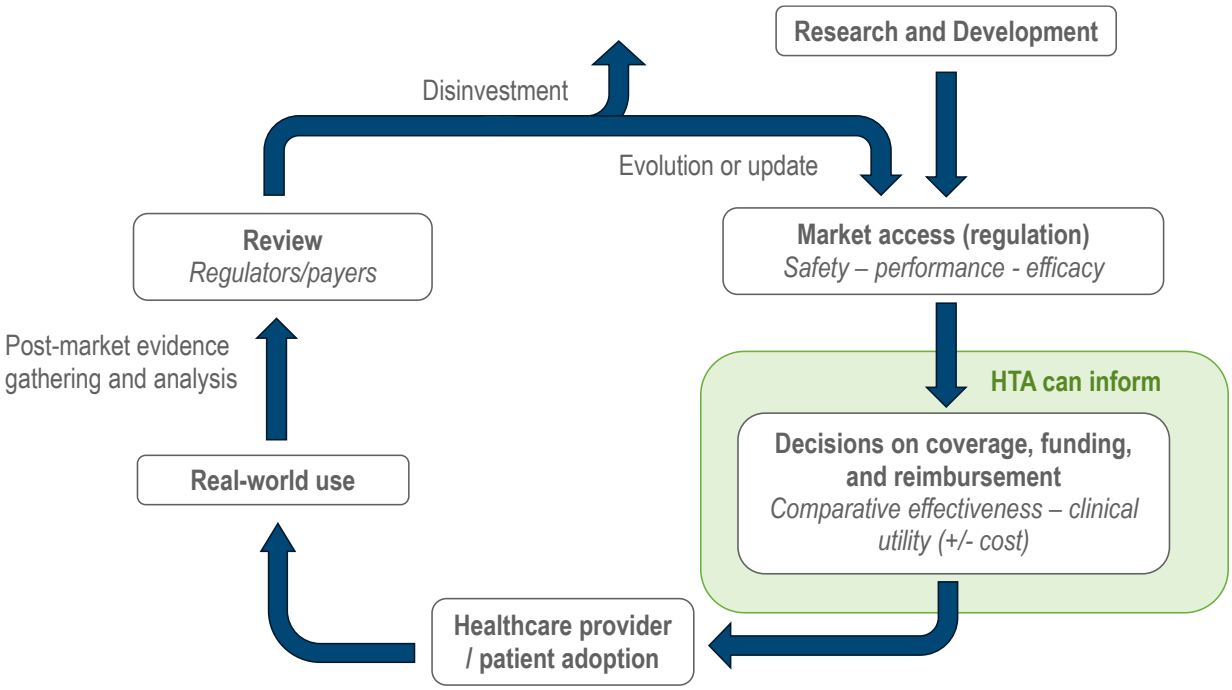


Note: NICE National Institute for Health and Care Excellence; DHT digital health technology.
Tiers A, B and C also correspond to the evidence standards. Purple arrow denotes the types of digital technologies within intended scope of this paper. It is important to note that NICE does not necessarily refer to this taxonomy when undergoing its health technology assessment evaluations.
Source: Adapted from (NICE, 2018[17]); see Tables 1 and 2 in the document for further details and mapping with medical device risk classes.

1.3. Increasing interest in a lifecycle approach to assessing devices

20. Some stakeholders are increasingly advocating for a life cycle approach to the evaluation and assessment of medical devices, including digital medical devices (see Figure 1.4). This recognises that there are various stages, beginning from research and development, to market access and regulation, decisions on coverage and funding, healthcare provider and patient adoption, and real-world use of the devices. Ongoing post-market evidence gathering and analysis and subsequent review, based on real-world use, is important, particularly in the case of existing uncertainties or insufficient evidence base. The rapid evolution cycle of digital health technologies also includes disinvestment or considerable technological software updates, as well as artificial intelligence (AI) learning. As an example of the life cycle approach, a proposal for building an integrated, rules-based medical technology pathway in the United Kingdom went out for consultation in 2024 (see also section 2.1) (NICE/NHSE/DHSC, 2024[19]). The following paragraphs describe the general process for regulation, and how HTA can inform coverage and decision making.

Figure 1.4. Illustration of the evaluation cycle of digital medical devices



Note: This illustration may not be exhaustive. It intends to show a high-level overview of the evaluation cycle of digital medical devices. It does not necessarily include some of the elements more specific to AI.
Source: Authors, adapted from (OECD, 2017[2]) and review of the literature.

21. DHTs within scope of this paper are classified as medical devices and are regulated as such. To gain access to the market, they must undergo regulatory review to ensure they are safe and function as intended. Regulations outline the laws and policies for assessing medical devices for market approval, generally in terms of safety (i.e. if the risk associated with the intended use is acceptably low in comparison to the benefits), and performance (i.e. whether the device functions as intended), and/or in some cases effectiveness (i.e. whether the benefits of a device used in clinical circumstances outweigh the risks and achieves the desired results) (OECD, 2017[2]). The registration process generally includes submission of detailed documentation about the device, including clinical data, safety, and quality control information (often from clinical trials). Regulation requirements vary across jurisdictions and device categories, depending on various factors including risk, and one technology might be subject to several different

regulatory requirements. In **Israel** and **Korea**, for example, the relevant part of the Ministry is responsible for the regulatory assessment and approval. In **European Union** countries and the **United Kingdom**, the assessment is generally undertaken by independent entities called notified bodies, with the relevant government agencies responsible for registering the device on the market (see Box 1.2).

Box 1.2. Example: Regulation of digital medical devices in the EU and UK

European Union

In the European Union, medical devices must undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. The EU Medical Devices Regulation (Regulation 2017/745) (EU MDR) has applied since 26 May 2021, and the In Vitro Diagnostic Medical Devices Regulation (Regulation 2017/746) (EU IVDR) has applied since 26 May 2022. They define rules for "conformity assessment", which can be self-declared by the manufacturer or conducted by accredited Notified Bodies, depending on the risk class associated with the medical device. The Medical Device Regulation classifies medical devices into four risk classes depending on their intended purpose and inherent risks: class I (lowest risk), class IIa (low to medium risk), class IIb (medium to high-risk) and class III (highest risk) (see Table 1.2) (European Commission, 2024[20]).The conformity assessment involves an audit of the manufacturer's quality system and, depending on the device type, a review of technical documentation on the safety and performance of the device. For some high-risk devices, notified bodies also require the opinion of expert panels before issuing certificates. In others, the notified body may require a scientific opinion from the European Medicines Agency or national competent authority before issuing a certificate (e.g. medical devices with an ancillary substance, companion diagnostics etc) (EMA, 2024[21]). If the device has been successfully assessed, it gets "CE marking" and can be sold in all countries in the European Economic Area (EEA).

Table 1.2. Example of EU medical device classification as it applies to software

Risk class	Rule	Examples
Class III (highest risk)	Software intended to provide information to take diagnostic or therapeutic decisions, for which decision impact can cause death or irreversible deterioration on health	Software intended to diagnose and make treatment decisions in patients with acute stroke
Class IIb (medium to high risk)	Software intended to provide information to take diagnostic or therapeutic decisions, for which the decision impact can cause a serious deterioration of a person's state of health or a surgical intervention	Mobile app intended to analyse a user's heartbeat, detect abnormalities, and inform a physician; software for diagnosing depression based on a score from patient inputted data
	Software intended to monitor vital physiological parameters, where the nature or variation could result in immediate patient danger	Software intended for continuous surveillance of vital physiological processes in anaesthesia or intensive care
Class IIa (low to medium risk)	Other software intended to provide information to take diagnostic or therapeutic decisions	Software that ranks chemotherapy options; cognitive therapy where a specialist determines the necessary therapy based on the outcome provided by the software
	Other software intended to monitor physiological processes	Software to monitor non-vital physiological processes; devices to obtain readings of vital signs in routine check-ups
Class I (lowest risk)	All other software	Software apps intended to support conception by calculating fertility status based on inputs and a validated algorithm

Note: This may not be exhaustive.
Source: Adapted from (MDCG, 2021[22]).

United Kingdom

Since 1 January 2021 in the United Kingdom, there have been changes with how medical devices are placed on the market. This includes a new route to market and product marking – the UKCA (UK Conformity Assessed) marking. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market; all devices must be registered with the MHRA before they can be placed on the market. The MHRA is responsible for the designation and monitoring of UK conformity assessment bodies, to conduct conformity assessments against the relevant requirements for UKCA marking. All devices will be required to conform to the UK MDR 2022, with transitional measures to extend the acceptance of previously CE marketed devices until, at the latest, 30 June 2030 depending on device type and classification (MHRA, 2024[23]).

22. After regulatory approval, medical devices follow various assessment, coverage and funding pathways depending on the country and clinical setting. Devices and their associated services need to be incorporated into relevant financing instruments, which may differ by type of device (and/or associated service) and clinical setting (inpatient and outpatient use). Coverage and funding decisions made for technologies used for individual use (e.g. digital therapeutics) may be made at the level of individual coverage schemes (e.g. insurer), institution (e.g. hospital), regional (e.g. municipality), or national level. Health technology assessment can inform coverage and price decisions, for example to be included in national benefit baskets. HTA has been defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "*a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.*" (INAHTA, 2020[24]). The key difference to the regulatory review process is that HTA often considers incremental benefits - and often costs - compared to existing standards of care. The following sections provide insights to the digital-specific HTA approaches in the case study countries.

1.4. A growing body of literature identifies insights into the regulation and evaluation of digital health technologies

23. Recent research offers insights into some of the challenges to the assessment and adoption of digital technologies and the learnings so far, albeit this space is rapidly evolving. These challenges include the rapid pace of technological development, the complexity of devices with diverse functionalities, and evolving regulatory frameworks. Digital health technologies, particularly innovations using AI, require careful consideration of ethical, privacy, data integrity and security, and safety and clinical implications (Farah et al., 2023[25]; Bélisle-Pipon et al., 2021[26]; Farah et al., 2024[27]). Many digital solutions require supporting infrastructure or tools, raising issues of accessibility and equity in reimbursement landscapes, among other factors that affect uptake (van Kessel et al., 2023[28]). Important practical considerations include usability and user compliance as well as willingness among healthcare providers to adopt and integrate these innovations into their practice (Dahlhausen et al., 2022[29]; van Kessel et al., 2023[28]). Furthermore, there are challenges in evaluating the comparative clinical and cost-effectiveness of digital interventions (van Kessel et al., 2023[30]; Haig et al., 2023[31]; Segur-Ferrer et al., 2024[32]). In response, the literature has identified several types of assessment frameworks, primarily from an academic perspective, for example targeting specific technologies such as those for chronic disease management (von Huben et al., 2021[33]; Main et al., 2023[34]; Haig et al., 2023[31]) or a wider group of technologies (Segur-Ferrer et al., 2024[32]; ICER and PHTI, 2023[35]).

2. Approaches to HTA of digital medical devices: insights from several OECD countries

24. This section summarises the approaches to HTA of digital medical devices taken in several OECD jurisdictions - **France, Germany, Israel, Korea, Spain,** and the **United Kingdom** - drawing on desk research and interviews with country experts. The selection of case studies was done in consultation with the OECD Expert Group on Pharmaceuticals and Medical Devices. It is not intended to be exhaustive. Interesting practices from other countries are included throughout, where relevant. Several ongoing international and regional initiatives are described in Section 3. It is important to recognise that the context of evaluation and assessment is complex and differs significantly by country. As a result, comparisons between systems are made at a high level and may not be detailed enough to reflect the differences and nuances in the systems. While this paper initially aims to focus on digital medical devices, such as therapeutics and diagnostics, intended for individual patient use and covered under national schemes, it is acknowledged that HTA bodies evaluate a much broader range of digital health technologies, making it challenging to isolate and compare specific learnings. The findings primarily pertain to digital therapeutics such as mobile applications. The following sections describe the coverage and funding pathways in the case study countries (section 2.1), the applicable technology scopes (section 2.2), approaches to the assessment of value (section 2.3), evaluation frameworks and criteria (sections 2.4 and 2.5), submission prioritisation (section 2.6), handling software updates (section 2.7) and finally the role of HTA in pricing and coverage/reimbursement (section 2.8). Annex B contains brief country snapshots of the case study countries along with the lists of sources used to create them.

2.1. Coverage and funding pathways vary substantially depending on the country and context, but HTA commonly informs these decisions at national level

25. Countries' approaches to assessing digital medical devices for the purposes of inclusion in national benefit baskets are diverse and shaped by context and legislative landscape. It is first important to consider the existing systems in place for evaluating other non-digital medical technologies, as well as the relevant processes and available resources to carry out the assessments. In comparison to pharmaceuticals, where HTA to make coverage/reimbursement decisions may be systematic and centralised, for medical devices, HTA may not be mandatory and made only in some circumstances (OECD, 2017[2]). The following sections provide a high-level snapshot of the relevant evaluation pathways towards national coverage of digital medical devices in scope of this paper, summarised in Table 2.1. Across all countries included, HTA helps support coverage decision-making, albeit the recommendation may not necessarily lead directly to national coverage or reimbursement. Evaluation pathways for hospital-only products are out of scope, as they do not generally encompass coverage of digital health technologies for individual use in the community.

Table 2.1. Overview of evaluation pathways in six countries, for which HTA can inform national coverage of digital medical devices

	France	Germany	Israel	Korea	Spain	United Kingdom (England)[1]
Standard evaluation pathway towards national coverage	*Same as non-digital medical devices:* inclusion on positive lists (LATM for remote telemonitoring, LPPR for all other medical devices used by patients)	*Same as non-digital medical devices:* reimbursement decision by G-BA	*Same as non-digital medical devices:* inclusion in national benefit basket, i.e. NLHS	*Same as non-digital medical devices:* review via New HTA Programme	*Same as non-digital medical devices:* inclusion in national benefit basket, i.e. Common Benefit Package	*Same as non-digital medical devices:* possible review via full NICE guidance with view to enhancing NHS adoption
Alternative evaluation pathway towards national coverage (may be conditional and temporary)	Fast-track / early access pathway for digital medical devices for therapeutic purposes and remote telemonitoring: PECAN	Fast-track for eligible digital health applications and other digital medical devices: DiGA	Early research and development, piloting or deployment grant programmes applicable to a wide range of digital health technologies	Fast-track / early access pathways for some devices: Integrated Review and Assessment Programme for Innovative Medical Devices	None	Fast-track / early access pathway for promising medical technologies, including digital: EVA
Agency responsible for HTA (type of organisation)	HAS (national HTA body)	G-BA (decision-making authority); IQWiG (national HTA body); BfARM (national regulatory authority) for DiGA	Ministry of Health (government department)	NECA (HTA research institution); HIRA (national agency for reimbursement assessment)	RedETS (network of regional HTA bodies)	NICE (national HTA body for England)
Model of HTA	Mainly clinical (comparative), quality of life, organisational	Mainly comparative clinical benefit	Clinical and economic evaluation	Mainly clinical, although cost-effectiveness conducted separately	Clinical and economic evaluation	Clinical and economic evaluation
HTA approach	Assessment, then appraisal by committee	Assessment and appraisal by BfARM for DiGA	Assessment, then appraisal by committee	Assessment, then appraisal by committee	Assessment, then appraisal by committee	Assessment, then appraisal by committee
Role of HTA and recommendation towards coverage/ funding decisions	Advisory, non-binding	Advisory (G-BA) and binding for DiGA (BfArM)	Advisory, non-binding	Advisory, non-binding	Advisory, non-binding	Advisory, non-binding
Institution responsible for coverage / funding / reimbursement decision	Ministry of Health	BfArM for DiGA	Ministry of Health, Ministry of Finance, and the Government	Ministry of Health and Welfare	Ministry of Health (considering votes from autonomous communities)	NHS England, integrated care boards
Pricing	Price negotiation with CEPs; pre-defined tariffs for some technologies (LATM) written in the law	For DiGA: manufacturer sets price for 12 months, then it is renegotiated	Price negotiation between Health Maintenance Organisations and manufacturers	Price proposed by the developer is reviewed by HIRA, with final decision made by HIPDC		Prices negotiated individually with integrated care boards, NHS Trusts or individual NHS practices

Note: See list of acronyms and abbreviations. Acronyms are also explained in Section 2.1. 1. In Scotland's healthcare system, the standard evaluation pathway towards national coverage is the same as for non-digital medical devices: review via full guidance by the Scottish Health Technologies Group, with a view to enhancing NHS adoption.
Source: Authors' compilation based on desk research and semi-structured interviews with country experts, 2024. Annex B contains more detailed country snapshots and associated sources.

2.1.1. France – a new system for evaluating digital therapeutics and remote monitoring systems

26. In France, to qualify for reimbursement under the national insurance system, medical devices intended for individual use in the community must be listed on the List of Reimbursement Products and Services (**LPPR** - *Liste des Produits et Prestations Remboursables*) i.e. the positive list. Before 2023, the evaluation of digital medical devices (known as *dispositifs medicaux numériques or DNM*) followed a similar process to the assessment for reimbursement and pricing purposes of traditional medical devices, albeit with some additional considerations for learning systems. The national HTA agency's (HAS - *Haute Autorité de Santé*) National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS - *Commission en charge de l'évaluation de dispositifs médicaux*) undertakes the medical and technical evaluation, while the Economic and Public Health Evaluation Committee (CEESP - *Commission d'évaluation économique et de santé publique*) oversees the economic evaluation, if required. HTA plays an advisory role to decision-makers. A new technology may be assessed by HAS and included in the LPPR for up to five years before review. If the medical device corresponds to an existing category of medical devices called a "generic line", then the device does not need to undergo HAS assessment. All digital devices must, however, meet minimum technical specifications as validated by the Digital Health Agency (ANS - *Agence du numérique en santé*), such as interoperability and data standards.

27. Since 2023, a new system was created to evaluate digital medical devices. This new system involved the creation of a new reimbursement pathway for remote medical monitoring devices, particularly in the context of chronic diseases. This pathway is known as **LATM** (*Liste des activités de télésurveillance médicale*) and can be considered alongside the LPPR as the common pathway for digital medical devices to be reimbursed under the national insurance system[1]. It also allows inscription for up to five years before review. The new system also introduced the concept of early coverage, upstream of the LPPR and LATM, for digital medical devices for individual use for therapeutic purposes and digital medical devices for remote medical monitoring presumed to be innovative. This fast-track pathway, known as **PECAN** (*Prise en charge anticipée des dispositifs médicaux numériques*), provides temporary reimbursement of a promising technology for up to one year, non-renewable, while further evidence is generated. Basic uniform reimbursement rates for therapeutic digital medical devices under PECAN are set in French law (see also Table A B.1, Annex B). The company must make a full application through the regular LPPR or LATM pathways within six and nine months, respectively.

2.1.2. Germany – a specific pathway for low-risk, patient-oriented digital health applications

28. In Germany, the Federal Joint Committee (**G-BA -** *Gemeinsamer Bundesausschuss*) is responsible for the evaluation of additional benefit of medical devices covered by the German statutory health insurance system. G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to make a detailed assessment based on evidence submitted by the company, upon which it bases its decision. This decision affects the price negotiation of the product between manufacturers and the National Association of Statutory Health Insurance Funds (GKV-SV - *Gesetzliche Krankenkassen-Vereinigung-Spitzenverband*).

29. Germany's 2019 Digital Healthcare Act led to the creation of a new, combined, regulatory approval and reimbursement pathway for low-risk (i.e. risk class I or IIa according to the Medical Device Regulation) patient-centred digital health care applications (in German, "*digitale Gesundheitsanwendungen*," or DiGA for short) to be covered in the German health insurance system - called the **DiGA** Fast-Track. The German regulatory agency for pharmaceuticals and medical devices – BfArM – is responsible for evaluating these

[1] Although this pathway is not applicable for digital therapeutics or digital diagnostics, it was included for completeness.

technologies according to general requirements (data protection, data security, functionality, interoperability) and positive care effects. After an initial assessment within three months of application, DiGA may be directly listed in the DiGA directory to be prescribed and reimbursed if they have enough evidence of clinical benefit, while others may be provisionally listed (i.e. eligible for reimbursement for 12 months while further evidence is generated, albeit the timeline can and has been extended), or rejected. The DiGA manufacturer freely sets the price for the first year, within maximum limits, after which the reimbursement amount is negotiated between the manufacturer and the GKV-SV with support from an arbitration body, threshold values and maximum prices.

30. While the DiGA process is not an HTA process per se, it is considered as one in the context of this paper. Coming into force in March 2024, the DiGA framework has been extended to include higher risk class IIb medical devices (Federal Government, 2024[36]). However, these devices are not eligible for provisional listing and evidence on medical benefit must be provided upon listing.

31. Digital medical devices that do not meet the criteria of DiGA can be evaluated through the standard G-BA pathway.

2.1.3. Israel – grant programmes to support development of digital tools

32. In Israel, health technologies are included in the **National List of Health Services (NLHS)** (i.e. national benefit basket) by way of 'entitlements', rather than as stand-alone products. Entitlements refer to the type of service that a technology offers, such as its clinical pathway or the medical service provided. The National List of Health Services Update Committee, part of the Ministry of Health, makes yearly recommendations on which regulatory approved medical devices and technologies should be included in national healthcare coverage, based on health technology assessments and considering the budget allocated by the government to the addition of technologies to the NLHS for the next budget year. The NLHS update process is traditionally suited for established health technologies such as pharmaceuticals and medical devices with sound clinical evidence to support their claims and is less adaptable for digital health technologies that currently may not meet its requirements.

33. Although somewhat outside the initial scope of this paper, interestingly, various **grant programmes**, funded by the Ministry, have been established as 'mid-way' support for research and development, scale up and deployment of digital health technologies that currently lack sufficient clinical and/or economic evidence to be included in the NLHS. Three distinct active programme types include: (1) programme to accelerate pilots for the development of early-stage digital health technologies in healthcare organisations; (2) healthcare organisation support programme; and (3) real-world data utilisation programme (see Section 2.3). There are two ways in which grant programmes can eventually support the inclusion of a digital health technology in the NLHS: (a) for an early-stage technology, the grant programme can support the generation of clinical evidence which would serve in applying to the NLHS for a new entitlement, or (b) healthcare organisations can use the programme to start a pilot or conduct implementation of a technology that would serve an existing entitlement.

2.1.4. Korea – integrated regulatory, HTA and insurance review pathway with faster evaluations

34. After regulatory approval in Korea, HIRA (Health Insurance Review and Assessment, an agency under the Ministry of Health and Welfare) evaluates whether medical services involving the medical device can be included in national health insurance by comparing them to existing alternatives. If a newly approved device is deemed similar to an existing one, it will be classified under the same category, and a decision will be made regarding its insurance coverage based on the existing classification. If the device is determined different from existing ones, and using new technologies, it must undergo the New Health Technology Assessment procedure conducted by NECA (National Evidence-based Healthcare

Collaborating Agency, also under the Ministry of Health and Welfare) before any decision on insurance inclusion is made. The New HTA procedure is systematic and not targeted to specific items (Department of New Health Technology Assessment, 2020[37]). The New HTA framework consists of four main categories: the New HTA Program, the New HTA Referral Program, the Innovative Medical Device Assessment Program, and the **Integrated Review and Assessment Program for Innovative Medical Devices**. The latter is relevant to digital medical devices in scope of this paper, such as digital therapeutics.

35. The Integrated Review and Assessment Program for Innovative Medical Devices is designed for non-invasive software-based medical devices using advanced technologies, such as artificial intelligence, big data, or digital technology, from the broader Advanced Technology category of Innovative Medical Devices. To reduce evaluation time, this program integrates the processes of designation as an Innovative Medical Device (by the regulator, the Ministry of Drug and Food Safety), provisional insurance listing (by HIRA) , and assessment of innovative medical technology in terms of potential safety and effectiveness in clinical settings (by NECA) into a single process which takes a total of 80 days (rather than the usual 250 days total) (Department of New Health Technology Assessment, 2020[37]; Ministry of Health and Welfare, and HIRA, 2023[38]). After approval, the device can enter the market for 3 years, either with provisional insurance coverage (with 10% reimbursement) or as a non-reimbursed product (Ministry of Drug and Food Safety, 2020[39]). The developer may request provisional insurance coverage, but the final determination is made by the Health Insurance Policy Deliberation Committee (HIPDC). After this period, the device undergoes the New HTA process, and a formal decision is made regarding insurance coverage. This program was introduced in October 2022, with provisional listings starting in August 2023. Non-invasive digital therapeutics products fall under the 'Digital and Wearable Technology' category (Ministry of Health and Welfare, and HIRA, 2023[40]; Kim, 2023[41]).

2.1.5. Spain – collaborative HTA using a dedicated digital framework

36. In Spain, the population benefits from several medical services as described in three benefits packages: the **Common Benefit Package,** defined at national level, Complementary Benefit Packages, determined at regional level – of the autonomous communities in Spain – and in Hospital Benefit Packages at hospital level. HTA evaluations are used to inform decision-making about inclusion of medical services in all of them but are conducted by different institutions. The Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS) is responsible for HTA to advise on inclusion in the Common Benefit Package for all Spanish residents. Evaluations are shared between the network of eight regional HTA agencies to develop reports following the same methodology, in collaboration with each other. Once an HTA is performed by RedETS, recommendations and deliberations occur with different stakeholders until an interministerial commission reaches the final decision on coverage level. The final decision is by the Ministry of Health but takes into consideration the votes of members of the interministerial commission, including representatives of the autonomous communities. Once a new service is part of the Common Benefits Package, it is the responsibility of every autonomous community to ensure it is available and provided locally (e.g. in hospitals). Regional HTA agencies are responsible for HTA that informs the inclusion in Complementary Benefits Packages of regional health services.

37. The evaluation pathway of digital medical devices is the same as that of traditional medical devices, although a new HTA evaluation framework targeted towards digital health technologies was published at the end of 2023 (see section 2.4). At the time of review, Spain is undergoing a revision of its whole HTA system.

2.1.6. United Kingdom – multi-technology appraisals with evidence generation plans to meet unmet needs

38. In England, HTA of medical devices by the National Institute for Health and Care Excellence (NICE) is not compulsory but can accelerate adoption within the National Health Service (NHS) at national level. A positive NICE assessment does not directly lead to funding by the NHS as sub-national or local NHS organisations decide on procurement, pricing and reimbursement. Nevertheless, several evaluation pathways exist that are also applicable to digital medical devices. Technologies with already robust clinical evidence can undergo **full NICE guidance** (i.e. HTA evaluation) through several pathways, in terms of guidance and committees, depending on the technology and clinical pathway and its expected impact on health and social care spend. Separate advisory committees are responsible for the evaluations in each programme, with the development of full guidance taking around a year. NICE is currently consulting on its methods and processes for health technologies with the aim of unifying the health technologies evaluation programme[2].

39. Recently, **NICE's Early Value Assessment (EVA)** pathway was set up as a fast-track process for promising technologies, including digital, that meet specified unmet needs in high priority clinical areas but require further evidence. Recommendations on the prioritised topic areas come from the NHS and other stakeholder engagement, with a focus on those that can make the most impact. **EVA** allows the review of multiple technologies that serve the same purpose to identify the most promising solutions and develop an evidence generation plan to evaluate real-world effectiveness. Technologies are reviewed by a committee and the assessment gives rise to three options of recommendations: conditionally recommended for use in the NHS while further evidence is generated (with NICE support); recommended in research, or not recommended for use. A conditional recommendation does not directly lead to funding by the NHS but companies can apply for funding support for evidence generation. EVA allows contingent recommendations of up to a maximum of four years, with re-evaluation expected before this point when further evidence becomes available.

40. Digital medical devices should have undertaken a national **Digital Technology Assessment Criteria (DTAC**) assessment by NICE or the NHS organisation procuring the technology, in addition to MHRA regulatory approval and registration to be placed on the market. DTAC ensures that products meet national standards in clinical safety, data protection, technical security, interoperability, usability, and accessibility.

41. At the time of writing, NHS England and NICE were engaging in a consultation process to simplify the process for developers to bring their technologies to market, with the aim of building an integrated, rules-based medical technology pathway. While this is for medical technologies more broadly, digital health technologies fall into the scope. The pathway aims to adopt a life cycle approach, with clear links from evaluations and recommendations to available funding sources to ensure scaled adoption. Under this proposed framework, several evaluation pathways would be possible: (1) early value assessment guidance for promising technologies that might be eligible for conditional recommendation for early use in the NHS, (2) multi-tech guidance for technologies that might have sufficient evidence to be recommended for NHS commission, and (3) late stage assessment guidance for technologies that are already being used in routine care to identify best value technologies or those that should no longer be supported (NICE/NHSE/DHSC, 2024[19]).

42. In Scotland, HTA of medical devices by the Scottish Health Technologies Group (SHTG) is not compulsory but can accelerate adoption within the National Health Service at national level. A positive

[2] The proposed NICE HealthTech programme combines the former Diagnostics Assessment programme, Interventional Procedures programme and Medical Technologies Evaluation programme. For more information, see https://www.nice.org.uk/guidance/gid-pmg10010/documents/html-content, last accessed 18 April 2025.

SHTG assessment does not directly lead to funding by the NHS as sub-national or local NHS organisations decide on procurement, pricing and reimbursement. Nevertheless, several evaluation pathways exist that are also applicable to digital medical devices. Technologies with already robust clinical evidence can undergo rapid HTA (SHTG recommendation, assessment or adaptation). Technologies at an earlier stage of emerging evidence can undergo an innovative medical technology overview.

2.2. The scope of technologies evaluated under existing evaluation pathways goes beyond digital therapeutics and diagnostics

43. With the broad and changing landscape of digital health technologies, it can be challenging to determine the technology scope applicable under certain HTA or evaluation approaches. In some cases, the concept of a 'taxonomy' or 'classification' may be more conceptual and theoretical, and used to help provide a common terminology for developing health technologies and understanding the processes and evidence required for an evaluation (e.g. in the case of the UK's ESF). Nevertheless, Table 2.2 provides an overview of the technology scope that may fall under the assessment processes or frameworks in the reviewed countries. The scope differs substantially per country. For example, **France's** PECAN pathway focuses on digital medical devices for individual patient therapy and remote monitoring, while **Germany's** DiGA framework applies to CE-marked, low-risk digital medical devices used directly by patients, and only recently expanding to include medium-risk devices in March 2024. **Korea's** Integrated Review and Assessment Program categorises digital therapeutics under the "Digital and wearable technology" sub-category within its innovative medical devices framework, whereas **Spain's** HTA framework evaluates all digital health technologies for use in the national health system, primarily covering software as a medical device while excluding embedded medical software.

Table 2.2. Applicable technology scope under various evaluation pathways

Country	Applicable pathway or framework	Scope of digital medical devices falling under specific evaluation pathways
France	Fast-track / early access temporary coverage (PECAN)	Digital medical devices used by individual patients for therapeutic purposes; digital medical devices for remote medical monitoring (i.e. tele surveillance).
	Inclusion on positive list for individual use (LPPR)	Other medical devices that might include a software component (e.g. implantable cardiac prostheses, glucose monitoring devices, application for sleep disorders).
	Inclusion on positive list for telemonitoring (LATM)	Digital medical devices for remote medical monitoring. Scope is the same as for PECAN.
Germany	Fast-track for eligible digital health applications and other digital medical devices (DiGA)	Medical device of risk class I or IIa (now also IIb from March 2024), whose main function is based on digital technologies and has to be used by the patient or the patient and the healthcare provider. Mostly includes digital health web or mobile applications, but can also comprise devices, sensors or other hardware in addition to software, such as wearables, provided that the main function is predominantly digital and the hardware is necessary to achieve its main function.
	Reimbursement decision on statutory health insurance (G-BA)	Digital medical devices that do not meet the criteria for DiGA.
Israel	Inclusion in national benefit basket (NLHS)	No specific taxonomy used, includes broad scope of technologies.
	Various grant programmes and evaluation framework	No specific taxonomy used, applicable to a wide spectrum of products or services. Some programmes may be more specific e.g. digital health applications for the diagnosis and treatment of mental health disorders. Others may include early-stage technologies (i.e. those in the pre-market stage).
Korea	Fast-track / early access pathway (Integrated Review and Assessment Program for Innovative Medical Devices)	Broad technology scope: non-invasive software-based medical devices using advanced technologies, such as artificial intelligence, big data, or digital technology, from the "Advanced Technology" category of Innovative Medical Devices, which has 10 subcategories. Digital therapeutics would fall under the 'Digital and wearable technology' category, and include e.g. biosensor-based wearable devices, digital therapeutic products, medical apps etc.

Country	Applicable pathway or framework	Scope of digital medical devices falling under specific evaluation pathways
Spain	Methodological framework for digital health technologies, for inclusion in Common Benefits Package	All digital health technologies for medical, health or wellness or system efficiency purposes. It is applicable to medical therapeutic and diagnostic technologies, including in vitro diagnostics and screening technologies. Excludes software embedded in medical devices, digital health technologies for professional training or used in research studies.
United Kingdom	NICE (England) Guidance for early use (Early Value Assessment)	No specific taxonomy used, applicable to all types of medical technologies, including devices, diagnostics, and therapeutics that may be digital, although digital technologies are not the primary focus. These devices must have appropriate regulatory approval and meet DTAC requirements.
	NICE (England) Guidance for routine adoption	No specific taxonomy used, although a guidance for developers outlines a taxonomy for digital health technologies that classifies them according to their intended purpose and function using tiers. These devices must have appropriate regulatory approval and meet DTAC requirements.
	SHTG recommendation (Scotland) for routine adoption	No specific taxonomy used, applicable to all types of medical technologies, including devices, diagnostics, and therapeutics that may be digital, although digital technologies are not the primary focus. These devices must already have a regulatory approval and a completed DTAC is preferable.

Note: See list of acronyms and abbreviations. Acronyms are also explained in Section 2.1.
Source: Authors' compilation based on desk research and semi-structured interviews with country experts, 2024. Annex B contains more detailed country snapshots and associated source references.

2.3. Approaches to assessment of the value of technologies for health systems differ substantially across the reviewed countries

44. Gaining a comprehensive understanding of how HTA agencies evaluate digital medical devices is challenging, particularly given the rapid pace of evolution in this space and the heterogeneity of evaluated technologies. While methodologies, guidance or frameworks that are published online provide a high-level overview of the different methods and evaluation criteria that might be used in assessments, they are often targeted towards manufacturers, health professionals, or other agencies, and may not necessarily reflect the latest methods and standard operating procedures used in-house (see Table A C.1, Annex C for a list of relevant documents for the case study countries). Several countries also reported that they are currently reviewing their approaches and evaluation methods. In addition, assessments are usually tailored towards the medical device or technology in question and its particularities on a case-by-case basis.

45. In general, the HTA in the countries reviewed is mostly assessment or appraisal based, with the HTA recommendation not binding to any funding decisions, with the exception of Germany's combined regulatory and reimbursement DiGA system. Various stakeholders are involved in the HTA committees, with external stakeholder consultation also used in some circumstances. The HTA may mainly look at comparative clinical benefit (e.g. **France, Germany, Korea**), or integrate clinical and economic evaluation (e.g. **Israel, Spain, United Kingdom**) (see Table 2.1)

46. Alternative access and review pathways have been implemented in several countries to overcome challenges with evaluating these digital technologies. HTA is a robust evaluation process and traditionally relies on good quality evidence to be able to support decision-making. Several challenges already exist in the evaluation of non-digital medical devices. There are limitations in the scientific evidence, often with a lower evidentiary basis with a higher degree of uncertainty than for pharmaceuticals, as well as difficulties in assessing expected scope and future costs. These challenges are compounded for digital medical devices. Given some of these issues around evidence generation, several countries are looking to deviations to the usual access pathway for some digital medical devices. For example, early access coverage pathways for some digital medical devices are possible in **France** (PECAN), **Germany** (DiGA), the **United Kingdom** (Early Value Assessment) and **Korea** (Integrated Review and Assessment Programme for Innovative Medical devices). In these countries, provisional coverage is possible that is contingent on the generation of further evidence, particularly in real-world settings, with view to

reassessment. Although mostly beyond the initial scope of this paper, **Israel** has an interesting system whereby the Ministry of Health has implemented early funding support through different grant programmes, aimed to help organisations assess implementation feasibility, usability, clinical value, economic impact and other aspects of digital health technologies (see Box 2.1).

Box 2.1. Various grant programmes in Israel to support early development and implementation of digital health technologies

- ***Programme to accelerate pilots for the development of early-stage digital health technologies in healthcare organisations*** (e.g. facilities, hospitals, primary care institutions). This is a mutual programme shared between the Ministry of Health and the Israel Innovation authority, whereby a technology company submits a request for funding the development of a product in its early research and development stages. Selected proposals receive between 30-50% of funding for the pilot (for a duration of 2-3 years for the development and implementation). After this time, the health organisations are responsible for the funding of the technologies, if they choose to adopt them;
- ***Healthcare organisation support programme***. The Ministry of Health provides grants directly to healthcare organisations to develop their own technology or purchase a new technology from an outsource – according to specific priority areas identified by the Ministry of Health. This program is designed to fund the development and implementation of digital health technologies within healthcare organisations; and,
- ***Real-world data utilisation programme***. This relatively new programme supports the use of digital health technologies by collecting real-world data to prove their effectiveness. This is the programme via which the Ministry of Health will fund the use of digital health applications (e.g. mHealth), and insights gathered could potentially inform future inclusions in the national benefit basket (NLHS), although future NLHS inclusion would require meeting its specific criteria. The programme currently only applies to digital health applications for the diagnosis and treatment of mental health conditions, as created in 2024. A specialist committee constructed of experts in the relevant field reviews the technology and makes a recommendation on funding for a period of 12 months, during which time the health organisation needs to evaluate the effectiveness of the technology.

Source: Information shared by country experts, 2024.

2.4. Spain has developed a comprehensive digital HTA framework drawing on experience from the United Kingdom

47. In **Spain**, the general directorate of the Common Benefits Package of the Ministry of Health recognised that the usual evidence to assess technologies at the core level (safety and efficacy) is not enough to assess the value of digital health technologies and commissioned the development of a specific framework to one of the regional HTA agencies (AQuAS – the Agency for Health Information, Assessment and Quality in Catalonia) in 2021 (AQuAS, 2023[18]). AQuAS worked in collaboration with all the Spanish regional HTA agencies and other relevant stakeholders to develop the framework. The methodological framework has been adapted for digital health technology assessment and describes the assessment items and standards of evidence that should be considered in the HTA evaluation. It is based on a scoping review (January 2011 to December 2021) of methodological HTA frameworks for digital health technologies in the scientific and grey literature (Segur-Ferrer et al., 2024[32]), a survey with different HTA

agencies at international level and two consensus agreement exercises. The framework draws heavily on the NICE ESF (NICE, 2018[17]), which distinguishes different medical devices into tiers according to the risk for the patient and suggests relevant evidence standards according to the associated tier.

48. The Spanish HTA framework for digital health technologies published in December 2023 divides assessment items into 13 domains, 41 dimensions and 9 subdimensions (see Figure 2.1 for a high-level overview, and Table A C.2 in Annex C for further details) (AQuAS, 2023[18]). The framework document describes each of these items and provides indicative questions and sources of information that can be used to generate the evidence (e.g. scientific articles, HTA reports, specialised databases etc). Each assessment item is linked with relevant evidence standards. Most of the domains correspond to those of the HTA Core Model® Version 3.0 of the European network for Health Technology Assessment (EUnetHTA), which was a methodological framework previously defined for collaborative HTA at the EU level and applicable to various medical technologies (EUnetHTA, 2016[42]). Domains that correspond with the HTA Core Model® include description of the health problem, safety, clinical efficiency and effectiveness, economic aspects, ethical aspects, legal and regulatory aspects.

Figure 2.1. Domains in the Spanish HTA framework for digital health technologies

Source: Adapted from presentation by AQuAS, 2024.

49. The comprehensive framework operates on a pick and choose basis. An HTA assessment of a technology does not necessarily have to consider every one of these domains. The core domains are safety, effectiveness, and the technical aspects. Cost-effectiveness analysis and budget impact are only assessed if a technology is considered to be effective and likely to have a high budget impact. The focus is primarily on the technical aspects. Some dimensions may be particularly relevant to digital health applications, for example, such as user experience, usability and accessibility. The Spanish framework also flags some items that are most relevant to artificial intelligence (AQuAS, 2023[18]), namely:

- **Ethical aspects:** control, user autonomy, and accountability; responsibility; transparency, explainability and interpretability;
- **Legal and regulatory aspects:** [3] privacy (including data protection); transparency; and

[3] Note that cybersecurity would also be considered relevant here, although not explicitly mentioned as a dimension or subdimension in the Spanish framework.

- **Technical aspects:** adaptability (interoperability, scalability, data integration, transferability); technical effectiveness and performance (reliability, validity, accuracy, sensitivity); generalisability and reproducibility; interpretability and explainability.

50. The digital-specific framework comes with 21 accompanying evidence standards that relate to different aspects of the product lifecycle – design factors; describing value; demonstrating performance; delivering value; deployment considerations (based on the NICE ESF – see Box 2.2). The standards relate to the domains, dimensions and subdimensions outlined in the framework – the relevant standard depends on the classification of the digital health technology (e.g. Tier C might have a higher standard of evidence required than Tier A). The scope of technologies applicable in this framework is outlined in Table 2.2.

Box 2.2. NICE's Evidence Standards Framework for Digital Health Technologies

First published in 2018 and updated in 2022, NICE developed an evidence standards framework (ESF) targeted towards digital health technologies (NICE, 2018[17]). The aim of this framework is two-fold, to (1) help evaluators, decision makers, and purchasers in the health and care system to make more informed and consistent decisions about buying digital health technologies and (2) help companies that develop digital health technologies to understand the types and level of evidence required over the lifecycle of a technology to support its update in the system. The ESF is applicable to a range of digital health technologies, classified in tiers, as described in section 1.2. While aspects of the ESF framework are relevant to NICE's HTA evaluations of digital health technologies, NICE does not directly use this framework to conduct its assessments. Some elements common to NICE evaluation programs include demonstrating effectiveness, a value proposition, and assessing health inequalities, while the deployment considerations in the ESF would be considered out of scope for a NICE guidance or advice.

The ESF includes 21 evidence standards across five groups relating to different aspects of the product lifecycle. Standards are applicable depending on the tier classification, with all standards applying to digital medical devices including digital therapeutics.

- **Design factors**: 9 standards applying to good design principles, most of which are also in the remit of published technical standards or of regulation of medical devices. These include, for example, ensuring appropriate technical standards for safety and quality, user acceptability, sustainability, bias mitigation and good data practices.
- **Describing value**: 4 standards provide the key information about positioning of the DHT in the healthcare system, including identifying the target population and current or proposed care pathway in which the DHT is involved.
- **Demonstrating performance**: 3 standards describe the level of evidence required to establish performance, such as clinical (ideally comparative) effectiveness and real-world evidence.
- **Delivering value**: 2 standards identify the affordability and value for money, including budget impact and/or cost-effectiveness analysis.
- **Deployment considerations**: 3 standards apply to considerations for successful deployment and implementation of a technology, such as ensuring transparency, communication and training, and scalability.

The ESF also outlines some standards that are particularly relevant to data-driven DHTs that have fixed or adaptive machine learning algorithms, which may have particular risks not seen with other types of technologies. Key design factors include addressing health and care inequalities, mitigating bias, embedding good data practices, and clearly defining professional oversight. Performance standards emphasise demonstrating real-world evidence of claimed benefits and establishing a plan for ongoing

performance evaluation. Deployment considerations focus on ensuring transparency regarding requirements, along with effective communication, consent, and training strategies to support user understanding.

The ESF framework is supported by a user guide and other tools, including a budget impact analysis tool.

Source: (NICE, 2018[17]) last accessed 13 December 2024.

2.5. The evaluation criteria in other countries are similar to non-digital medical devices, albeit with some additional considerations

51. The HTA evaluation criteria and methods used for assessing digital medical devices, in general, are similar to those used for other medical devices, albeit with some further considerations in some countries. Table 2.3 summarises these comparisons in the reviewed countries, and Table A C.1 in Annex C has further details. It is important to recognise that digital medical devices such as digital therapeutic applications, may not meet the more stringent requirements of traditional HTA evaluations, given challenges around evidence generation, data issues, patient usability and accessibility. As mentioned earlier, some countries are currently revising their processes. Section 3. reports on some of the identified challenges with HTA of digital medical devices.

52. In some countries, HTA does not cover digital-related aspects which are considered in other review processes (e.g. regulatory review, meeting national data standards etc). For example, in **France**, all digital medical devices need to comply with data security and interoperability standards through the *Agence Numérique en Santé*. In **Germany**, digital health applications must comply with technical requirements on security, functionality, quality, data protection, data security and interoperability. In the **United Kingdom**, all new digital health technologies, including digital medical devices and those assessed through the EVA pathway, should comply with DTAC[4]. These are NHS England standards around clinical safety, data protection, technical assurance, interoperability, usability and accessibility. The Scottish Health Technologies Group also uses DTAC as an additional domain when undertaking HTA evaluations within their remit. AI driven technologies may also be subject to other requirements in countries.

Table 2.3. Comparison of evaluation to non-digital medical devices

Country	Comparison of evaluation to non-digital medical devices
France	- Same criteria as traditional medical devices are also used for digital medical devices for individual use by patients (LPPR) - New criteria specific to remote telemonitoring devices (LATM) - Possible fast-track for digital therapeutics (e.g. applications) and telemonitoring (PECAN) - All digital devices must meet data security and interoperability standards through the *Agence Numérique en Santé*
Germany	- Fast-track for certain digital medical devices, with different criteria (DiGA): Focuses on compliance to technical requirements (security, functionality, quality, data protection, data security, interoperability) and positive effects (either medical benefit or patient-relevant structural and procedural improvements) criteria. Medical benefit can include improvement of the state of health, reduction in disease duration, prolongation of survival or improvement in quality of life. Patient-relevant improvement of structure and processes can include, for example, coordination of treatment procedures, adherence, patient safety, health

[4] DTAC is applicable to all new digital health technologies (e.g. staff facing and patient facing digital health technologies; health apps; medtech and devices with an associated app; systems; web-based portals etc.) that meet the definition of "*a product used to provide electronic information for health or social care purposes where the product may include hardware, software or a combination of both*". For more detail, see https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/, last accessed 05 March 2025.

Country	Comparison of evaluation to non-digital medical devices
	literacy, facilitating access to care. The studies needed as proof of positive care effects are similar to traditional medical devices. The main evidence that has been used by manufacturers to date still focuses on traditional medical benefits such as morbidity, mortality and quality of life, using randomised controlled trials etc. - Same criteria as traditional medical devices for other digital medical devices (G-BA)
Israel	- Same criteria as other medical devices are also used for digital medical devices included in national benefits (NLHS) - Adapted digital-specific framework to evaluate of technologies as part of the various grants and programmes described in Box 2.1. Considers health value and feasibility, organisational benefits and suitability, economic value and feasibility, usability and social considerations, company capabilities.
Korea	- Digital-specific assessment programme, although criteria are fairly similar to assessment of non-digital medical devices. The main difference in evaluations is procedural, with multiple agencies conducting evaluations simultaneously within a shorter period of time for digital technologies.
Spain	- Digital-specific HTA evaluation framework with 13 domains, 41 dimensions and 9 subdimensions for digital health technologies (see Section 2.4).
United Kingdom	***England*** - Same criteria as other medical devices, informed by some elements from ESF (full NICE evaluation) - Early value assessment with no structured framework or methodology, adapted to evidence base available (EVA) - All digital technologies for NHS procurement should comply with Digital Technology Assessment Criteria (DTAC) requirements, which cover other aspects important to digital technologies such as clinical safety, data protection, technical assurance, interoperability, usability and accessibility. ***Scotland*** - Same criteria as other (non-medicine) health technologies, preferably with a completed DTAC

Note: See list of acronyms and abbreviations. Acronyms are also explained in Section 2.1.
Source: Authors' compilation based on desktop research and semi-structured interviews, 2024. See country snapshots and list of associated source references in Annex B and Table A C.1, Annex C, for further details on the relevant frameworks or documents describing evaluation criteria or domains applicable to digital medical devices.

53. In **Korea**, for example, digital medical devices are assessed for their potential, under the Innovative Medical Device Assessment Programme and the Integrated Review and Assessment Program for Innovative Medical Devices. There are ten specific criteria for assessing the potential of devices, with each criterion scored individually and then evaluated based on the total score (Ministry of Drug and Food Safety, 2020[39]). Three institutions—the Korea Health Industry Development Institute (KHIDI), NECA, and HIRA—are responsible for conducting these assessments (see Table 2.4.).

Table 2.4. Criteria for assessing the potential of medical devices, under Korean specific assessment programmes

Institution responsible	Assessment type	Criteria
Korea Health Industry Development Institute (KHIDI)	Market potential assessment	1. Review the current status of the overseas market for the technology and assess any potential for global market entry.
		2. Evaluate domestic production performance, import and export levels, and assess whether the technology could foster domestic market growth or reduce reliance on imports.
		3. Examine the status of technology development for similar products and the feasibility of domestic utilisation.
		4. Review the current status of nursing care benefit claims related to the technology to determine its potential applicability in the domestic market.
National Evidence-based healthcare Collaborating Agency (NECA)	Impact on health and patient outcomes	5. Assess if the technology can address significant physical or mental impacts associated with the course of a disease, such as mortality, complications, disability, or long-term aftereffects.
		6. Determine whether, compared to existing technologies, the technology could reduce the physical burden on patients or improve their quality of life through customized diagnostic or treatment solutions.
		7. Evaluate the clinical usefulness of the technology in the medical field, considering potential improvements in diagnostic accuracy and error reduction.
Health Insurance Review and	Compatibility with Existing	8. Assess if the medical service shares any similarities in terms of purpose, target, or method with existing health insurance benefits or non-benefit items.

Institution responsible	Assessment type	Criteria
Assessment (HIRA)	Medical Practices	9. Review if any changes in purpose, target, or method of current practices could affect the safety and effectiveness of the technology.
		10. Consider whether the technology can significantly improve accuracy, reduce errors, provide new information beyond the scope of current practices, or offer a viable replacement for existing high-cost medical procedures.

Source: (Ministry of Drug and Food Safety, 2020[39]).

54. In **Israel**, for example, the Ministry has been using an internal assessment model to evaluate digital health technologies for inclusion in early research and development (R&D), piloting or deployment programmes for several years. A standardised process and guidebook for the evaluation of early-stage (not mature) digital health technologies, targeted towards healthcare organisations, was subsequently published in 2021 (see Box 2.3). Adapted versions of this health technology assessment framework are used in the different programmes (described earlier in Box 2.1), adjusted to the needs of the evaluation (e.g. clinical need/benefit) and the perspective to be taken (e.g. from the Ministry of Health, individual healthcare organisation etc). The Ministry has also recently published a guide to support economic evaluation of digital health services for specific conditions (Box 2.4).

Box 2.3. Early-stage evaluation of digital health technologies in development in Israel

Development of a Digital Health Technology Evaluation Framework for Healthcare Organisations

Acknowledging the lack of standardisation in evaluating early-stage technologies, the Digital Health Unit of the Israel Ministry of Health published a guidebook with a framework for assessing digital health technologies during their R&D phase in 2021 (Ministry of Health, 2021[43]). This adaptive framework is targeted towards innovation promoters and technology managers in healthcare organisations[1] as a practical tool to support them to examine the *value* and *feasibility* of digital health technologies in the early R&D stage (i.e. early stages of their lifecycle) for informed decision-making. While this approach differs from the evaluation of mature and commercial technologies, the framework can support healthcare organisations to decide whether to work with companies on pilot R&D projects. Digital health technologies here include a wide spectrum of products or services, including digital medical devices (therapeutics and diagnostics). The development of the framework was based on an internal assessment model with insights from evaluations of around 400 different digital technologies intended for inclusion in R&D, piloting or deployment programmes by the Digital Health Division of the Ministry of Health over the preceding 5 years. It was also informed by interviews with innovation promoters in healthcare organisations and industry.

Organisational processes should be in place before commencing technology evaluation

The framework is accompanied by recommendations of organisational processes that healthcare organisations should put in place to integrate early-stage technology evaluation into their processes. This includes best practices in:

- **Organisational readiness** e.g. establishing formalised standards; identifying and engaging personnel and stakeholders with relevant expertise; and tailoring the evaluation method to the organisation's needs.
- **Working with startups** e.g. be transparent about digital solutions of interest and evaluation methods and timelines; outline potential challenges in data cleaning; setting early expectations around commercial terms and conditions and data security and privacy requirements.

- **Defining unmet needs** e.g. methodological definition of the healthcare organisation's specific unmet needs, with consistent parameters about how to assess clinical, economic and operational implications.

The adaptive evaluation framework is composed of five assessment categories

The evaluation framework contains five assessment categories: health value and feasibility, organisational benefits and suitability, economic value and feasibility, usability and social considerations, and company capabilities. Each category is associated with key questions and relevant sets of criteria/ parameters (see Table 2.5). The parameters may be adjusted to meet the needs of the healthcare organisation as well as the maturity of the evaluated product. The framework allows a textual assessment of the evaluation per category, which can be quantified with a score from one to five. A visualisation of the score in each category can then be used to help compare different technologies that serve the same purpose, including those that proved successful (or unsuccessful) in each assessment category (see Figure 2.2). Each healthcare organisation can determine the relative weights of individual scores according to its own context.

This framework, which shares a lot of similarities with standard HTA approaches for non-digital technologies, gives more weight to the context of use of these technologies, which becomes highly important as it will greatly impact its effectiveness.

The guidebook further highlights several considerations for healthcare organisations evaluating technologies in the early stages of development. First, there may be limited evidence of clinical effectiveness, so the guidebook recommends looking closely into the clinical and economic rationale behind the technology's claims and potential of success. Second, organisations have a role as a design partner to guide R&D projects and identify any opportunities for improvement. Third, there is potential for flexibility in product design changes, so it is a good opportunity to address any concerns around patient safety, inequities etc.

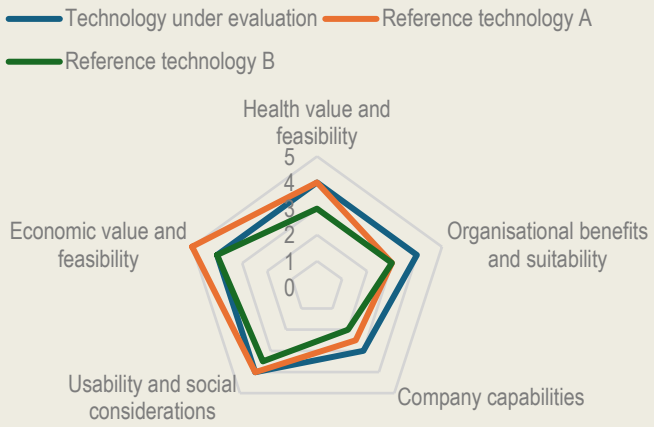
Table 2.5. Assessment categories for early-stage digital health technology evaluation

Assessment category	Key questions	Parameters
Health value and feasibility	To what extent does the technology provide a solution to the unmet health need?	Scope of affected population
		Severity of unmet need
		Comparison to current standard of care
		Clinical potential and feasibility of realization
		Risks to patient health
Organisational benefits and suitability	To what extent do the technology and R&D programme promote strategic organisational goals? To what extent will they successfully integrate into current work processes?	Organisational benefits
		Suitability to databases and information systems[1]
		Integration into existing workflows
		Preparedness and necessary resources
Economic value and feasibility	Does the technology's operational model guarantee long-term economic feasibility?	Target population
		Impact on budget – preparing for deploying the product
		Impact on budget – expected operating costs
		Identifying economic benefit and its components
		Economic measures and targets
		Cost-benefit evaluation
		Missing information
Usability and social considerations	To what extent is the technology suitable for use by the intended population(s)?	Characterizing the target populations
		Core suitability of the technology to the target population
		Usability
		Health equity considerations

Company capabilities	Does the company have the experience, capabilities, and motivation to guarantee execution of the R&D project, as well as long-term success? What advantages does it have over its competitors?	Motivation
		Professional and teamwork skills
		Technological capabilities
		Business capabilities
		Technological maturity and company preparedness to complete development
		Advantages over competitors

Note: 1. Includes how privacy and data security of patient information is to be ensured.

Figure 2.2. Example visualisation of evaluation results to compare technologies



Source: Adapted from (Ministry of Health, 2021[43])

Periodic reviews of past evaluations can support improvement of evaluation processes and methods

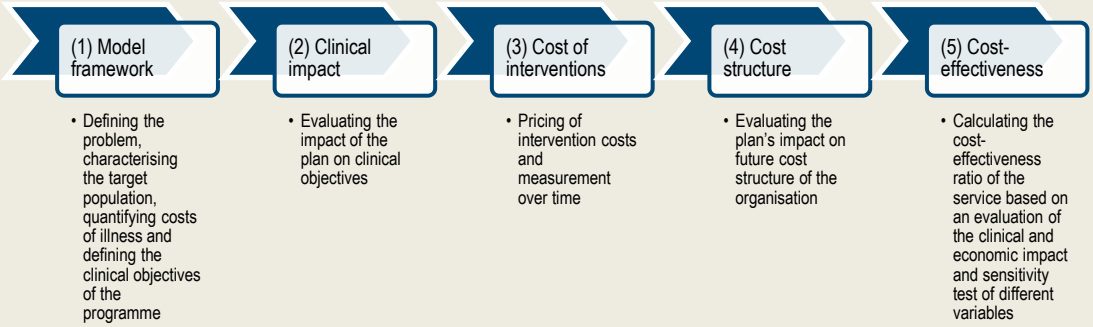
The guidebook advises periodic review of the evaluation method and process implemented. For example, these reviews should consider the specific parameters used in the evaluations and any methodological issues raised. They should also determine whether the evaluation team felt they had the necessary tools and knowledge to conduct the evaluation, how information was collected, as well as collaboration with relevant partners. The results of the review are intended to tailor the method to the organisation's needs and should ideally be actionable.

Note: 1. Healthcare organisations refers to any organisation that offers health services, such as facilities, hospitals, primary care institutions, specialist institutions etc.
Source: (Ministry of Health, 2021[43]).

Box 2.4. Guide to Economic Evaluation of Digital Health Services in Israel

The Ministry of Health's Digital Health Department has also developed a guide to support economic evaluation processes of new digital health services for specific conditions, published in 2024 (Ministry of Health, 2024[44]). It outlines a standardised process towards the development of an economic model to assess a service based on digital health technologies. Health services covered by the guide include those for early disease detection, prevention of disease progression, treatment, as well as process optimisation during the stages of diagnosis and treatment. The guide is targeted towards various stakeholders, including decision-makers within healthcare organisations to help them prioritise cost-effective services. While several approaches exist, the economic model chosen in this guide is Cost-Effectiveness Analysis, from the perspective of the payer / insurer. Figure 2.3 describes the outline of the guide.

Figure 2.3. Outline of the guide



Source: Adapted from (Ministry of Health, 2024[44]).

2.6. Most reviewed countries assess all submissions without a process for prioritisation

55. All frameworks or pathways in the reviewed countries begin with submission of an application (usually by the developer/manufacturer). In general, and with the exception of Spain (Box 2.5), there is no defined process in place to prioritise HTA evaluations and all requests are reviewed based on their arrival date. This is context specific, and how countries deal with the number of submissions is largely dependent on factors such as review timelines and frequency, team capacity, availability of relevant experts, quality of the dossiers etc. In **France**, CNEDiMTS is required to review all requests based on their arrival date, every two weeks, and subject to material constraints particularly recruitment of external experts. In **Israel**, the Public Committee reviews all requests that meet threshold conditions for yearly inclusion in the NLHS, and the Ministry of Health also evaluates all applications it receives for the various grant programmes throughout the year. In **Germany**, there is no formal prioritisation for the DiGA pathway, although the submissions are expected to be initially evaluated within a 3-month timeline. In **Korea**, among various new medical devices, those designated as innovative medical devices (e.g. digital therapeutics) are given a higher priority for assessment (Department of New Health Technology Assessment, 2020[37]). In England in the **United Kingdom**, NICE can receive notifications of potential topics from a wide range of stakeholders and identifies the priorities of the health and care system by engaging with national policy teams, clinical leaders, patient groups, system partners, national innovation awards and commissioners.

Potential topics are considered by the NICE Prioritisation Board to ensure that NICE guidance reflects the national priorities for health and care. (NICE, 2024[45]).

Box 2.5. In Spain, the PriTec web application is a multi-criteria analysis tool to facilitate prioritised selection of technologies for HTA

In **Spain,** an online tool prioritises which potential health technologies (including digital) should be assessed by the HTA agencies each year. The PriTec web application is a multi-criteria analysis tool that facilitates decision-making in the selection of technologies to be considered in a healthcare context i.e. which technologies to evaluate for introduction into the system, which to monitor after their introduction, and which technologies may have become potentially obsolete. The tool is based on criteria and prioritisation domains selected and weighted by a multidisciplinary group of agents (managers, clinicians, and patients). Each year, different stakeholders, including the autonomous communities, can propose technologies to be included in the tool based on what they think is needed in their systems. The Ministry of Health collects the information in the submissions and uses the tool to provide an output which is the prioritisation (or ranking). Technologies that meet unmet needs or for vulnerable populations, for example, may be weighted higher for the final score. The annual plan from the Ministry of Health then outlines which technologies each of the HTA agencies in the network will assess (i.e. shared the burden of assessment among the regional agencies). The tool is for all technologies. A framework from the Ministry of Health was released in 2018.

Source: Ministry of Health 2024, PRITECTOOLS, https://pritectools.sergas.gal/ and confirmed with national experts. For more information, also see (Varela Lema et al., 2018[46]) and (Varela Lema et al., 2022[47]).

2.7. None of the reviewed countries have fully tackled how to handle re-assessments in the context of continuously evolving technologies

56. In all six OECD countries, HTA evaluations are made on a certain software version of the digital medical device, which has generated associated evidence on its safety, performance and effectiveness. Digital medical devices are expected to evolve over time, with technical software updates necessary to maintain standards related to data protection, security, safety, interoperability, usability, and other user benefits, among others. From expert interviews, it appears that countries have not yet fully tackled how to handle the challenge of continuously evolving products. Nevertheless, there is some consensus among reviewed countries around what type of update might require a re-assessment, which is in line with the processes for non-digital medical devices:

- A **significant change** that alters the intended purpose of the digital medical device or impacts its overall effectiveness or safety would require reassessment first by the regulatory authority and followed by a new HTA evaluation.
- An **incremental software update** (e.g. minor technical updates to maintain necessary data standards) may not require full re-assessment. Developers should still notify any changes to regulators and/or HTA evaluators, and the evaluation team can decide if the technology needs to be reassessed based on the changes.

57. Some pathways have an element of ‘re-assessment’ built into their systems. For example, in **France**, the re-assessment process is scheduled at the end of inscription in the LPPR or LATM, after five years. For temporary or conditional coverage schemes (e.g. PECAN in **France,** EVA in the **United**

Kingdom, Integrated Review and Assessment Programme for Innovative Medical Devices in **Korea**), a full HTA re-evaluation is needed at the end of the period to ensure continued coverage.

2.8. The role of HTA differs in its influence on coverage and/or pricing decisions

58. The role of HTA varies across countries in its influence on coverage/reimbursement decisions for digital medical devices. In all six reviewed OECD countries, HTA is advisory, and the outcome of the assessment is not necessarily binding to a reimbursement or coverage decision in all of them. **Germany** (DiGA)**, France, Israel** (NLHS), and **Korea** integrate assessment outcomes with reimbursement, whereas in **Spain** and the **United Kingdom**, they remain separate. **Spain'**s digital HTA framework is used for assessments but has not been fully adopted for national coverage decisions, and in the **United Kingdom** a positive or conditional recommendation does not directly lead to funding by the NHS as sub-national or local organisations decide on procurement, pricing and reimbursement. Countries also differ in methods of coverage/reimbursement, with some countries like **France** and the **United Kingdom** covering individual technologies, whereas others, such as **Israel** (NLHS), fund the clinical pathway it supports. Although not a case study country, Belgium has an interesting system (Box 2.6). A recent article published in October 2024 further outlines the diverse range of assessment and reimbursement approaches applicable to digital medical devices across EU countries (Tarricone, Petracca and Weller, 2024[48]).

59. HTA can be used to inform pricing decisions. In **France**, prices for LPPR-listed medical devices are negotiated between the French pricing committee (CEPS – *Comité économique des produits santé*) and the developer based on the HTA assessment and price of the comparator. For telemonitoring and therapeutic PECAN products, pre-defined fixed compensation have been set by the law (see Annex B). In Germany, the DiGA manufacturer freely sets the price for the first year within maximum limits, after which the reimbursement amount is negotiated between the manufacturer and the GKV-SV with support from an arbitration body, threshold values and maximum prices. In the **United Kingdom**, NICE in England provides a recommendation based on cost-effectiveness but price negotiations occur individually with the integrated care boards. Price negotiations can also happen nationally and through procurement.

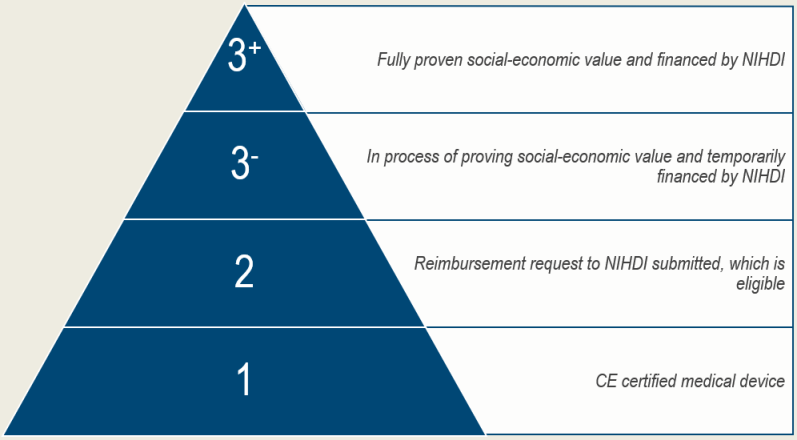
Box 2.6. Integration of medical mobile applications into the Belgium healthcare system

The Belgian authorities, comprising the Federal Agency for Medicines and Health Products (FAMHP), eHealth and the National Institute for Health and Disability Insurance (NIHDI) are collaborating to evaluate medical mobile applications. The FAMHP is responsible for checking the CE-mark of the medical device and eHealth defines the minimal technical criteria, while the NIHDI oversees their integration into the reimbursement system. In the past, a validation pyramid was used for the evaluation of medical mobile applications. The current iteration is, however, not part of any government classification, but is a classification organised by Belgian industry federations, beMedTech and Agoria, on the digital platform mHealthBelgium.

The current validation pyramid consists of three certification levels: Level 1, Level 2, and Level 3 (Level 3+ and 3-) – see Figure 2.4. To be validated as Level 1, the parent company submits a CE declaration confirming the application's regulatory compliance as a medical device. The FAMHP will verify if the application meets regulatory requirements. For reimbursement eligibility, the parent company must apply for an NIHDI evaluation. During the evaluation, mobile healthcare applications are classified as Level 2. NIHDI assesses the device's socio-economic value, relevance in the care pathway, and

compliance with information and communication technology criteria. Applications are classified as Level 3 if they receive temporary funding (Level 3-) or definitive funding (Level 3+) (mHealthBelgium, 2024[49]).

Figure 2.4. The mHealthBelgium validation pyramid



Source: Adapted from (mHealthBelgium, 2024[49]).

NIHDI reviews the validity and completeness of all applications for reimbursement within 30 days (INAMI, n.d.[50]). If valid, the application proceeds to a review by a multidisciplinary working group[1]. The entire evaluation process typically takes 270 days, resulting in a positive (temporary or permanent) or negative (rejection) outcome. The final proposal is then sent to the Insurance Committee and other relevant bodies, adding an additional 90 days for review. Once approved, implementing the reimbursement may take 2 months. If legal amendments are required, this process could extend to 6 months. These timings are, however, indicative.

Note: 1. The multidisciplinary working group is composed of 23 permanent members, drawn from healthcare providers, medical professionals, paramedical representatives, insurers, universities, professional organisations, and public health authorities. In addition, 13 ad hoc members with voting rights participate based on the specific care process or technology under review.

3. Experiences with HTA of digital medical devices: insights from several OECD countries

60. This section summarises insights from the reviewed countries' experiences with HTA of digital medical devices, drawn from desk research as well as interviews with experts from the selected OECD countries - **France, Germany, Israel, Korea, Spain,** and the **United Kingdom.** Section 3.1 examines the numbers and types of products assessed by the countries in recent years. The following two sections describe some of the general themes related to challenges (Section 3.2) and learnings (Section 3.3), drawing from the semi-structured interviews with country experts from national HTA or evaluating bodies. The opinions expressed are not assigned to any expert or country and are intended to be included as examples of insights from experts working in the field of HTA of digital medical devices.

3.1. The breadth of experience varies widely across countries, with different scopes and practices

61. A review of publicly available technology assessments and interviews with country experts reveals significant variation in the breadth of experience across countries. At the time of writing, the evaluation of digital medical devices within the scope of this paper has primarily focused on mHealth applications, particularly in mental health. However, the digital health technologies assessed by HTA agencies in some of the selected countries extend well beyond individual-use digital therapeutics and digital diagnostics. As a result, this section provides a **broader perspective, encompassing a wider range of technologies beyond the original scope**.

62. While this remains a fast-evolving field, a review as of the end of October 2024[5] found that,

- **Germany** evaluated the highest number of digital medical devices in scope of this paper, including digital health applications through the DiGA fast-track. Between 2020 and October 2024, 65 DiGA have been added to the directory and entered the supply in total[6]; 36 with a full listing, 19 with provisional recommendation which requires further evidence generation, and 10 have been delisted. Most of the applications are available via mobile application and/or web-based platforms,

[5] The data presented here reflect the comparative status across the case study countries as of a review at the end of October 2024. Since then, some countries have reviewed or added additional devices. However, updated figures were not available for all countries at the time of writing. For consistency and comparability, the data presented refer to the October 2024 snapshot. Where relevant, developments since that time are mentioned.

[6] The Germany DiGA directory can be accessed here: https://diga.bfarm.de/de/verzeichnis (last accessed 31 October 2024).

and a few are also coupled with wearables or sensors. The majority of these DiGA are intended to treat specific conditions (i.e. digital therapeutics), while others aim to inform or drive clinical management. Around 46% of the DiGA are intended for mental health and behavioural disorders, offering cognitive behavioural therapy support for several disorders, including depression, anxiety, panic disorder, and agoraphobia. Around 12% of the DiGA are intended to support diabetes mellitus management, through supporting lifestyle modification, monitoring and self-management. Other digital health applications cover other therapeutic areas such as oncology, cardiology, and musculoskeletal disorders. Box 3.1 summarises additional information on the experiences and use of DiGA from the literature. Additional DiGA have been added since the time of review.

- **France** has seen six technologies through the PECAN pathway in 2023 and 2024, including one digital therapeutic (Hellobetter®), and the others for remote telemonitoring[7]. One digital therapeutic (Deprexis®) has also gone through the LPPR evaluation pathway. Many other medical devices on the LPPR also include a software component (e.g. implantable cardiac prostheses, glucose monitoring devices). There have been seven opinions issued through the LATM process (remote monitoring), mostly telemonitoring for patients taking systemic anticancer treatments.
- In **Korea**, four digital therapeutic devices have entered the market through the Integrated Review and Assessment Program for Innovative Medical Devices since 2023[8]. Among them, one (Somzz®) had been included on the temporary non-reimbursement list of the national health insurance at the time of initial review, with another (SleepQ®) since included. Of these four devices, two are mobile medical applications for cognitive behavioural therapy for chronic insomnia, one is a doctor-prescribed mobile medical app and wearable device for pulmonary rehabilitation exercise treatment, and the last is a virtual reality-based mobile medical app with virtual perceptual training for stroke patients.
- In the **United Kingdom**, **NICE** (England) has evaluated more than 100 digital technologies over the past two years, with most assessments taking place under the early value assessment programme[9]. One digital application has received full NICE guidance, Sleepio®, a digital therapeutic for insomnia. Several other DHTs have since received recommendations for routine adoption. The EVA programme approaches value assessment differently to the other countries, first defining priority topics of interest to the NHS and reviewing several technologies at once in multi-technology, rather than single-technology, appraisals. Multi-technology appraisals so far have looked at anywhere from 3 to 14 technologies within one prioritised topic area, with recommendations outlined in a single appraisal document. A wide range of technologies have been evaluated, including web or mobile-based applications, clinician-facing imaging systems, and telemonitoring software, using a consistent decision framework that can be tailored to the relevant scenario. Of around 100 reviewed technologies more than half have been recommended to be used only in research and not for wider NHS adoption. There have also been several cases of a company taking a technology off the market, despite a conditional recommendation for use being given. However, over 85% companies with a conditionally recommended product are engaging in evidence generation with a view to being considered for routine adoption by NICE in no more than 4 years. Through EVA, the most frequent topic area for web or mobile-based applications is mental

[7] Published evaluations in France are accessible using the search function on the HAS website https://www.has-sante.fr/, filtering for medical devices. Last accessed 31 October 2024.

[8] Information gathered through communication with country expert, 2024.

[9] All products on digital health from NICE are available at this link: https://www.nice.org.uk/guidance/health-and-social-care-delivery/digital-health. Evaluations through the Early Value Assessment pathway are published as 'Health Technology Evaluations', while evaluations through the standard pathways are published as guidance, depending on the programme. NICE is currently consulting on its methods and processes for health technologies with the aim of unifying the health technologies evaluation programme.

health, accounting for around 45%, similar to Germany. In Scotland's healthcare system, the Scottish Health Technologies Group (SHTG) has evaluated 10 digital technologies, spanning digital health programmes, mental health applications, theatre planning and clinician-facing imaging systems.

- In **Israel**, at the time of review, while medical devices that include a software component have been included in the NLHS, there is no pure software as a medical device[8]. Some digital therapeutic technologies, however, may be upgrades of existing technologies already included in the NLHS and therefore there is no requirement to submit through a separate inclusion process. The health organisation interested in adopting the technology will conduct an assessment and examine compliance with regulatory requirements. Israel has had extensive experiences evaluating different types of digital health technologies, particularly those that are in the earlier development stages, through their various grant programmes. As mentioned earlier in Box 2.3, the evaluation framework for these technologies was developed from an internal assessment model using insights from evaluations of around 400 technologies, albeit beyond the technology scope of this paper. Hundreds of products have since been assessed using an adapted version of this framework through the various programmes. The framework is adjusted according to the specific need of the evaluation and the perspective to be taken and is considered generally fit-for-purpose. It is not known how many of these technologies would meet the definition of a digital therapeutic or diagnostic. The Ministry of Health has, however, co-funded over 70 pilots with digital health technologies, more than 300 digital health service development and implementation projects, and, to date, one treatment with a digital health application (in the real world utilisation program).
- In **Spain**, the HTA framework adapted for digital health technologies was only published in December 2023 and was being piloted at the time of review. At the time of initial review, no digital health applications or telemonitoring services had been included in the Common Benefits Package[8]. However, the HTA network of regional agencies has started national-level evaluations using the framework.

Box 3.1. Use of and experiences with DiGA in Germany

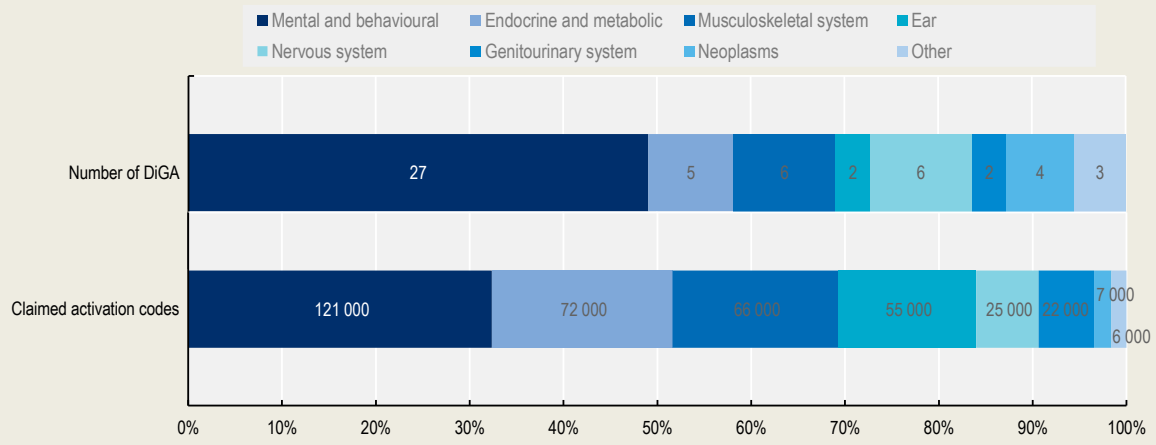
Annual reports from the National Association of Statutory Health Insurance Funds have important statistics

The National Association of Statutory Health Insurance Funds in **Germany** publishes annual reports on the use and development of the provision of DiGA applications (see here: Digital Health Applications (DiGA) - National Association of Statutory Health Insurance Funds). Some results from the annual report covering the period September 2020 to September 2023 (GKV-SV, 2023[51]) are described below. A new edition was just released in April 2025, the results of which are not described here.

- DiGA are increasingly used in healthcare although numbers have not yet reached levels expected at the time of introduction. Over the entire reporting period, more than 374 000 DiGA were activated for patient use[1] (41 thousand in the first year, 124 thousand in the second year, and 209 thousand in the third year) and the statutory health insurance system spent a corresponding 113 million euros.
- The proportion of DiGA that have proven benefits from the outset has fallen over time; in 2023 only 5% of introduced DiGA received permanent approvals. Of 45 DiGA with provisional listing —those included without initially demonstrating a positive care effect— over the whole reporting period, 30 had their trial period extended beyond the first year, while six were removed from the directory. Additionally, for seven of these DiGA, only some of the originally listed indications received permanent approval, as the benefit could not be proven for the remaining indications or patient groups.

- DiGA are most frequently indicated to treat mental illnesses, followed by diseases of the nervous and musculoskeletal system and metabolic diseases. In practice, most DiGA are approved for indications with high prevalence (e.g. obesity, anxiety disorders, sleep disorders, back pain etc). See Figure 3.1.
- DiGA are most frequently used by women (71%). General practitioners prescribe around 39% of DiGA, followed by specialists in orthopaedics (16%) and ear, nose and throat (14%).
- Utilisation varies considerably for each DiGA. The three most frequently used DiGA account for around 40% of the activations in the reporting period.
- Average age of use is 45 years, with the highest use in 50 to 60 year olds, although it varies by DiGA. There are some regional differences, with city states of Hamburg and Berlin having highest DiGA utilisation overall with more than 640 redemptions per 100 000 insured persons.
- Overall, 83% of redeemed prescriptions are first-time prescriptions, with the rest as follow-up prescriptions.
- Manufacturer prices for DiGA vary from 119 euros (for 3-month duration of use) to 2077 euros (unlimited use with one-time payment), with the average price per DiGA in the first year of 529 euros. The reimbursement amounts agreed between GKV-SV and the manufacturers or determined by an arbitration board after the first year is 221 euros – on average this is around 50% lower than respective previously applicable manufacture prices.

Figure 3.1. DiGA and prescriptions by therapeutic area, as of 30 September 2023



Note: Data as of September 30, 2023. Total number of DiGA represented = 55, total number of redeemed activation codes = 374 377.
Source: Adapted from (GKV-SV, 2023[51]).

A growing body of literature sheds light on the evolving DiGA system

Several articles in the literature have examined elements of the DiGA programme. Schmidt et al (2024[52]), for example, recently described the evolution of the system over the last few years. The paper references previous literature that discusses evidence criteria, physician experiences, and initial experiences across different specialisations. It discusses some of the challenges, including a narrow range of applications, discrepancies between pricing and clinical benefits, delays in patient access, insufficient integration into the healthcare system, and user engagement issues. It highlights recent legislative reforms that aim to address some of these gaps, including the expansion to include higher-risk medical devices (Class IIb) with stricter evidence standards; mandating that at least 20% of the reimbursement price of DiGAs be linked to treatment success metrics from 2026, which may include adherence rates, user satisfaction and other patient-reported outcomes; requirements for health insurers to approve (and therefore provide access to) DiGAs within two

days; as well as increasing requirements for interoperability with electronic health records to enhance integration (Schmidt et al., 2024[52]). Other recent studies have looked at the complexities of DiGA market dynamics, economic factors and clinical evidence (Goeldner and Gehder, 2024[53]), and visualised the DiGA care pathway to be able to better analyse the system and its integration (Giebel et al., 2024[54]). Furthermore, Schramm and Carbon (2024[55]) identified key factors for long-term success of DiGAs, including patient-centred design, application effectiveness, ease of use, and compliance with data protection and information security standards through standardised approaches.

Note: 1. After prescription or approval for use from a health insurance company, the insured person receives an activation code to use the DiGA. Manufacturers can only claim costs when this code is redeemed. Data are only available on the first registration of the DiGA by redeeming the activation code; information on actual patient utilisation are not available.
Source: As cited.

63. Analyses across **France, Germany**, **Korea** and the **United Kingdom** reveal that few technologies have been assessed by several agencies. Several technologies were reviewed by **France**, **Germany** and **United Kingdom**, albeit with some conflicting results. Table 3.1 shows the technologies that were reviewed by at least two countries, along with the recommendation. The reasons behind the limited number of tools assessed by more than one agency is not known.

Table 3.1. Digital health applications that have been reviewed by several countries, as of 30 October 2024

Technology	Technology description	Country: recommendation (evaluation pathway)
Deprexis®	Online-based cognitive behavioural therapy programme for depression	**France**: positive opinion (LPPR pathway) **Germany**: fully listed (DiGA) **United Kingdom**: conditionally recommended (EVA)
HelloBetter Insomnia®	Online-based cognitive behavioural therapy programme to reduce insomniac symptoms	**France**: negative opinion (PECAN) **Germany**: provisionally listed (DiGA)
Kaia COPD®	Mobile application which delivers a personalised pulmonary rehabilitation programme for patients with chronic obstructive pulmonary disorder (COPD)	**Germany**: delisted (DiGA) **United Kingdom**: recommended only in research (EVA)
Kaia Back Pain®	Mobile application for adult patients with non-specific back pain, conveying guidance-based advice	**Germany**: fully listed (DiGA) **United Kingdom**: conditionally recommended (EVA)
Oviva®	Application that provides a multidisciplinary weight-management programme and weight-management medicine prescribing for patients with severe obesity.	**Germany**: fully listed (DiGA) **United Kingdom**: conditionally recommended (EVA)

Note: See list of acronyms and abbreviations. Acronyms are also explained in Section 2.1.
Source: OECD analyses based on the following sources. Germany: DiGA directory available at https://diga.bfarm.de/de/verzeichnis. France: published evaluations available at https://www.has-sante.fr/. United Kingdom: health technology evaluations available at https://www.nice.org.uk/guidance/health-and-social-care-delivery/digital-health. Korea: communication with experts, 2024. Last accessed 30 October 2024.

3.2. Several challenges to the evaluation of digital medical devices have been identified

64. The following two sections explore the challenges encountered (section 3.2) and the learnings derived (section 3.3) from the interviews with national HTA experts in the six OECD jurisdictions, structured around five key areas: (1) the **approach to HTA**; (2) the **evaluation process**; (3) **evidence generation**; (4) **evaluation criteria**; and (5) **implementation and adoption**. While interviewees had varying levels of experience with HTA of digital medical devices in practice, they were encouraged to share insights based on their own expertise and knowledge, whether related to the development of a HTA framework or the evaluation process. These views are from the perspective of a national HTA body or evaluator of digital medical devices and are not necessarily representative, nor do they consider the views of other stakeholders. As the scope of technologies evaluated in these countries goes beyond digital therapeutics and diagnostics used by individual patients, these insights are likely also applicable to the broader digital medical device space. It is important to also recognise that other reports have raised some similar challenges and opportunities in the evaluation of these technologies, including through the use of individual technology case studies (e.g. (San Miguel et al., 2023[56])).

65. Interviewees commonly acknowledged the challenges associated with evaluating digital medical devices compared to HTA of other medical devices and pharmaceuticals. This is also evidenced in the use of the various digital-specific evaluation pathways or approaches already described in Section 2. However, many of these challenges have already been discussed in the medical device sector more broadly. In some instances, interviewees considered that the traditional process of HTA may not necessarily be considered fit-for-purpose for digital medical devices, which may have a less mature clinical and economic evidence base at the time of evaluation. Key themes that emerged from the interviews, structured around the five key areas, are summarised below with examples under each:

- ***(1) Approach to HTA: Traditional HTA approaches may not fully address some of the complexities of the digital health ecosystem***
    - **Traditional HTA approaches not necessarily fit-for-purpose:** The long-standing debate about the applicability of the HTA model adopted for medicines to medical devices, is also valid for digital medical devices. For example, these technologies may have a less mature clinical and economic evidence base at the time of evaluation and may have an unclear value proposition. Different kinds of assessments may be needed at different stages in a technology's lifecycle and the challenge remains to evaluate technologies at the right stage of their development.
    - **Unique digital ecosystem:** Unlike other medical products, digital health technologies do not require extensive manufacturing and supply chains, allowing for quicker market entry, exit, and adjustments. This volatility is a challenge for HTA processes. Developers of digital tools may not be fully aware of the implications of their technologies and the evidence required by evaluators, creating information asymmetry.
    - **The transitions between regulatory approval and HTA are less clear than for other technologies such as medicines:** Digital health technologies exist in a complex regulatory and evaluation framework which differs across countries. Depending on the device and its functionalities, it may need to comply with different aspects of multiple regulations, standards, and frameworks, particularly around data.
- ***(2) Evaluation Process: Rapid technology development and evolution and technical expertise gaps can challenge the evaluation process***
    - **Constrained resources and timelines:** HTA is resource and time intensive, particularly when involving other departments, agencies or external expert consultations. This is of particular concern in the digital medical device space whereby activity is expected to increase, evidence

may be immature, and expected review timelines can be short (e.g. for fast-track pathways). On the latter, there are differences in perspectives. For example, some may view that evaluation should be at the speed of product development, while others may view that evaluation should be at the speed of health system need and the ability to adopt technologies.

- **Challenges in handling rapid evolution of technology:** HTA evaluations are done on a specific version of a technology, which has generated certain clinical evidence, and for which there might be a measurement or evidence generation plan moving forward. Digital tools inherently require software updates and improvements. Questions remain as to what changes invalidate previous HTA assessments.
- **Technical expertise gaps:** Evaluating certain aspects of digital devices may require specialised expertise that is not always readily available. In addition, as is often the case in HTA, evaluator opinions may differ, particularly when the value proposition of the technology is unclear.

- ***(3) Evidence generation: An insufficient evidence base and misalignment between evaluation needs and evidence provided poses challenges for decision-makers***
  - **Insufficient evidence base and compounding uncertainty:** Several challenges already exist in the evaluation of traditional medical devices, such as lower evidentiary basis and higher degree of uncertainty than medicines in some cases, as well as difficulties in identifying the scope and future costs. These issues are compounded for digital medical devices, which often present with less clarity around their specific use case, target population, and integration into service delivery. This makes the evidence base and decision-making even more uncertain, posing additional challenges for HTA. This is where some of the alternative temporary access (coverage) pathways come in, although there is also the potential risk of paying for a device that finally shows no added value.
  - **Misalignment between evaluation needs and evidence provided:** Developers and HTA evaluators do not always share a common understanding of assessment terminology and evidence requirements, which can create challenges, especially for companies unfamiliar with the evaluation process. For example, developers and HTA evaluators may differ in their interpretation of valid evidence for algorithm or app performance (e.g., clinical trials) and value demonstration, including the definition of 'robustness' in the assessment process.
  - **Challenges with identifying an active comparator:** Selecting a comparison group to demonstrate comparative clinical (or cost) benefit of a digital medical device can be challenging. This is particularly the case in situations where there is not already an established pathway of care to match the intended purpose of the device. The fast pace of development of other digital medical devices that could act as a comparator is also challenging.
- ***(4) Evaluation criteria: Digital health technologies require considerations beyond traditional HTA criteria***
  - **Evolving needs and adaptation:** While safety, clinical effectiveness, and in some cases, cost-effectiveness, remain key domains, evaluating the technical aspects of digital health technologies – such as data privacy, cybersecurity, interoperability, usability etc – is important to determining their value. Usability is especially important for implementation (described below). In some cases, these technical factors may be assessed separately from the HTA evaluation. New challenges are emerging, for example with artificial intelligence and these are largely yet to be reflected in the published frameworks.
- ***(5) Implementation and adoption: Adoption of digital tools face specific barriers***
  - **Equity concerns and the digital divide:** There may be inequity due to the digital divide. Some of these tools require infrastructure or tools for the user to buy (e.g. a smartphone application).

There may also be variations in local systems. Poor digital literacy can have an indirect impact on access leading to potential inequalities.

- **Lack of clear pathway from evaluation to implementation:** A lack of an established pathway between evaluation, funding (and reimbursement) and implementation, may hinder the uptake of these tools.
- **Difficulty in engagement, adherence and acceptability:** Digital medical devices are much more sensitive to where and how they are used than other technologies and real-world effectiveness depends on the infrastructure and competency of users. While user-centred design is critical, it may not be assessed in evaluations, leading to concerns around patient accessibility, usability, and adherence. Lack of acceptability by healthcare professionals can also hinder adoption. Finally, there is a paucity of data on actual usage of these tools in the real world, as well as information measuring patient satisfaction and patient-reported outcomes.

3.3. Early insights point towards some key learnings and opportunities, although it is too early to identify so-called 'good' or 'best' practices

66. Despite mixed levels of experience with assessing digital medical devices, all interviewees were encouraged to provide insights on any identified good practices or opportunities, changes needed to their own systems, or advice to others that are considering developing their own digital-specific evaluation processes or frameworks. It was clear from all interviewees that this is a rapidly evolving space, with continuous learning, and while it is probably too early to identify so called 'good' or 'best' practices, early insights have pointed towards some practical learnings and opportunities. Several countries are already in the process of updating their own processes and methodologies to reflect the learnings they have made. Key themes that emerged from the interviews, structured around the five key areas, are summarised below with examples under each:

- ***(1) Approach to HTA: The unique nature of digital health technologies may require tailored and context-specific HTA approaches and methods***
  - **Tailored approaches to digital technologies**: HTA methods may need to be flexible and adapted to account for the unique characteristics of digital health technologies, including rapid development cycles, a high volume of products, often less mature evidence, specific data considerations (e.g. cybersecurity, interoperability), user factors (e.g. user-centred design), and their sometimes-unclear role in treatment. The fast pace of development also demands timely decision-making, which can be challenging when fixed assessment timelines do not allow for pauses, for example, in cases such as incomplete data.
  - **Context-specific adaptations:** HTA methods are always adapted to the healthcare structures and legal and regulatory frameworks of individual countries or regions and cannot be directly transplanted to other countries' systems.
  - **Collaboration and learning from others:** Leveraging existing frameworks and international experiences avoids duplication of effort and accelerates progress. Existing frameworks from other countries or jurisdictions can be leveraged, updating information and incorporating domains specific to their own context. Networks, forums, and cross-border collaborations are invaluable for exchanging knowledge and experiences. Box 3.2 describes some examples of shared learning, not necessarily provided by the interviewees.
  - **Cultural shift:** Evaluating a digital medical device is not just about its inclusion in a national benefit basket but about transforming service delivery, which requires a cultural shift and, in some cases, rethinking traditional access pathways. For some, for example, this could mean

shifting towards a problem-centric approach, considering the broader healthcare challenges digital solutions could address first, with early horizon scanning helping to identity promising technologies.

- ***(2) Evaluation process: Iterative, inclusive, and streamlined evaluation processes are essential***
  - **Iterative and flexible framework development:** The evaluation process should be iterative, allowing any frameworks to evolve based on stakeholder feedback, real-world application, and new insights. For example, testing the application of a framework in real-life scenarios ensures continuous refinement and adaptability to address emerging challenges (including technological advancements) and remaining uncertainties in digital health technologies. The HTA framework and process should also be designed to accommodate organisational capacity and time constraints.
  - **Inclusivity and stakeholder collaboration:** Involving diverse stakeholders is a common practice in HTA that also applies to the digital space. This includes engaging patients, healthcare providers, policymakers, academia, developers, and experts from sectors beyond healthcare (e.g. ethics, AI) to ensure a broader range of perspectives in the evaluation and decision-making process. For example, collaboration across departments or agencies (e.g. on technical aspects), or the involvement of external experts, can help overcome gaps in the expertise of HTA evaluators. Committee decision-making rather than following strict criteria allows for flexible scope and interpretation. Patient input is important to identify the importance of a technology and how it will be used.
  - **Streamlined and harmonised processes:** Digital health technologies are characterised by a complex and overlapping regulatory landscape. Evaluation processes would benefit from being more streamlined and harmonised with the pre- and post-market evaluation stages, aligning the evaluation process with technology development. It should be aligned with the regulatory processes that precede it and consider factors like the cost and feasibility of implementation after it. A system allowing updates or amendments while maintaining sound evidence could be valuable in keeping technologies current and effective without requiring a full reassessment. Box 3.3 highlights an ongoing collaboration between the regulatory authority and national HTA body in the United Kingdom, focused specifically on digital mental health technologies.
- ***(3) Evidence generation: Evidence generation should address data gaps and uncertainties and leverage real-world data***
  - **Identifying uncertainties and addressing data gaps:** As with other technologies, digital health technologies often face challenges in generating high-quality evidence. In some countries, minimum evidence requirements are not clearly defined, which allows flexibility, but can reduce clarity for manufacturers and make consistent decision-making more challenging. Committees and evaluators might need to consider adapting to a lower evidentiary basis and remaining open to uncertainties, by adapting their methods to incorporate new insights, while maintaining robust assessments. Comprehensive frameworks can help identify evidence gaps. Developing structured plans to address evidence gaps, such as through conditional recommendations with plans for real-world validation and future re-assessment, could be an option in some cases. Early dialogue with manufacturers may help improve the quality of submissions. A mix of permanent and topic-specific assessors may also support consistency. This is not only specific to digital medical devices.
  - **Leveraging real-world data:** Real-world data can be used to support the development, validation, and demonstration of effect of a digital health technology, just as it does for other technologies. For example, existing or new national data infrastructure (such as national registries and routine healthcare data systems) could be used to track outcomes and provide evidence needed to support future decision-making. Developers would need to be made aware

of how to leverage this existing infrastructure, in line with appropriate data use, privacy, and security requirements. However, the use of real-world data can also have important limitations, such as the absence of a comparator group or differences in target populations, which can still present uncertainty and challenges for evaluation.

- **Establishing a shared understanding of terminology and evidence:** Inconsistent interpretations of terminology and evidence requirements among stakeholders—such as developers and HTA assessors—create challenges in the evaluation process. To address this, efforts like creating a glossary or engaging in early dialogues and timely feedback with developers aim to align understanding and expectations, particularly in emerging areas such as AI.

- ***(4) Evaluation criteria: Evaluation should consider additional criteria or domains beyond traditional metrics***
  - **Focus on technical aspects:** While the core domains of safety and clinical effectiveness (and cost-effectiveness in some cases) remain relevant, additional consideration to the technical aspects of digital health technologies is important to assess their value and feasibility (e.g. data privacy and cybersecurity, interoperability, and usability etc). User-centred design is a critical success factor, with technologies involving clinicians and patients tending to perform better in evaluations according to one interviewee. In some cases, these elements may be assessed outside of the HTA evaluation.
  - **Consideration to other areas**: HTA acts as a diagnostic and having different domains to explain the different considerations can be relevant. For example, as digital health evolves, areas such as ethics, equity and environmental impacts are important. These elements are particularly relevant for AI-driven solutions, which often present unique challenges and opportunities. In addition, questions around how to handle challenges with economic evaluation remain.
  - **Balancing comprehensiveness with usefulness:** It is important to balance comprehensiveness and usefulness of the assessment and engage early with the payer to manage expectations. Flexibility and interpretation are useful to making practical and timely decisions.
- ***(5) Implementation and adoption: Effective implementation depends on strong links between evaluation and procurement and ensuring scalability***
  - **Bridging evaluation and deployment:** Depending on the country context, fostering better connections between the evaluation process, funding, and procurement strategies can support more effective implementation. This includes collaboration between developers, purchasers, and healthcare providers to address gaps in evidence and ensure solutions are ready for real-world application. Practical support mechanisms, such as aligning technologies with hospital needs or facilitating partnerships, can improve uptake.
  - **Scalability and integration:** Effective implementation of HTAs and related strategies requires alignment and integration between local and national levels. While strategies may differ at each level to address specific contexts, they should be scalable and consistent to ensure efficiency and avoid duplication of efforts.
  - **Improving data on actual use:** Questions remain around patient-reported outcomes and uptake data. As more digital medical devices enter the market, countries are considering how to collect and manage usage data efficiently (e.g. national registries, integration with electronic health systems). As an example, Germany recently published a draft regulation that creates a legal framework for the processing and publication of data on actual use as well as patient-reported outcomes and patient-reported experiences in the context of DiGA (Federal Ministry of Health, 2025[57]).

Box 3.2. The importance of shared learning and harmonised frameworks: examples of ongoing initiatives

European Union

- **European Taskforce for Harmonised Evaluation of Digital Medical Devices:** The taskforce was launched in 2022 to support harmonisation of digital medical device assessment by national agencies and authorities across the EU. The main aims being to harmonise classification of digital medical devices and establish common clinical evidence requirements. See https://eithealth.eu/external-collaborations/european-taskforce-for-harmonised-evaluations-of-digital-medical-devices-dmds/
- **EDiHTA:** The European Digital Health Technology Assessment project, launched in 2024, aims to develop a flexible, inclusive and validated digital framework for the assessment of different digital health technologies (e.g. telemedicine, applications, artificial intelligence) at different technology readiness levels from different perspectives by 2028. The digital framework will be piloted in healthcare settings in 5 European hospitals. The Consortium, co-ordinated by the Università Cattolica del Sacro Cuore, includes 16 partners from 10 countries. First deliverables will be published in 2025. See https://edihta-project.eu/
- **ASSESS-DHT:** The ASSESS-DHT project, a sister project to EDiHTA and also launched in 2024, aims to develop robust and harmonised methodologies for health technology assessment of digital health technologies in Europe by 2026. The Consortium includes 14 partners from 7 countries. First deliverables will be published in 2025. See https://assess-dht.eu/

Other organisations, networks or collaborations

- **INAHTA:** The International Network of Agencies for Health Technology Assessment supports collaboration among different HTA agencies through annual meetings, workshops, and the exchange of knowledge and experiences, including approaches to assessing digital health technologies. See https://www.inahta.org/
- **HTAi:** Health Technology Assessment International is a global, non-profit organisation that brings together a wide range of stakeholders – including researchers, policymakers, HTA agencies, industry representatives and patients – at its annual and regional meetings and policy forums to *"promote the development, communication, understanding, and use of HTA around the world"*. See https://htai.org/
- **WHO:** The World Health Organization also works in data and digital health to support its member countries, and although not directly related to digital health technology assessment, publishes relevant reports on the topic. See, for example, https://www.who.int/europe/teams/data-and-digital-health and https://www.who.int/health-topics/digital-health
- **International collaboration** among HTA bodies in Australia, Canada, New Zealand and the United Kingdom on a range of topics, including digital evaluation (See (CDA, 2023[5])).

Note: Other interesting frameworks and methodologies exist that have not been explored in this report.

Box 3.3. Regulation and evaluation of digital mental health technologies in the United Kingdom

In the United Kingdom, the MHRA and NICE are collaborating on a project focusing on Digital Mental Health Technologiess (DMHT) that qualify as software as a *medical* device (SaMD). This 3-year project addresses the entire product pathway, starting from product characterisation and taxonomy alongside the clarification of applicable regulations and subsequent product classification. The project, then, explores how these products are clinical evaluated, and explores the applicability of the NICE preferred quality of life measures used to assess their effectiveness. The two agencies have produced a number of publicly available documents and resources (UK Government, 2024[58]) and most recently have published specific regulatory guidance for how DMHTs should be characterised, regulated and classified (MHRA, 2025[59]).

The guidance clarifies that, for the purposes of regulation of DMHTs, two important characteristics should be considered:

- **Intended purpose:** what the manufacturer intends it to be used for. For example, whether it is to support well-being or to aid treatment of a mental health condition.
- **Functionality:** how the product works, and how the different applications of the DMHT are delivered through the device. For example, functionalities can include, but are not limited to, education modules about understanding mental health and well-being, AI algorithms and chatbots.

If the device is intended to have a medical purpose and the product functionality is considered complex, a DMHT needs to be regulated as a SaMD product. This means that the manufacturer must meet the requirements of the medical device regulations. They will have to evidence product safety and effectiveness according to recognised standards. The guidance document helps manufacturers identify the specific characteristics of their DMHT and determine whether it is considered as SaMD. If it is SaMD, the guidance will help determine the appropriate device classification. Class I is for the lowest risk medical devices, which manufacturers can self-certify before putting them on the market. Class IIa, IIb, and III are for increasingly higher-risk medical devices and will require approved/notified body assessment to achieve the appropriate regulatory certification in the UK or Europe.

The project partnership further defined 8 dimensions to be considered during the regulatory and HTA processes, and specific challenges related to DMHT (Hopkin et al., 2024[60]):

1. **Intended purpose:** MHRA guidance requests developers to clearly indicate the purpose of the device, i.e. the clinical objective and the way the device helps to achieve it, target population and users, and the operating environment in which the device is used. These elements are essential to assess the performance of the device.
2. **Qualification and classification:** MHRA must determine whether a DMHT can be classified as SaMD, or in other words, whether it meets the definition of a medical device as set out in the Medical Devices Regulations 2002. This is a challenge in mental health, where many symptoms are not only observed in patients diagnosed with a mental health condition (e.g. sleep disorder). Digital tools improving well-being are not easy to distinguish from tools “acting as a medical treatment”. Therefore, the qualification of SaMD is based on the nature of symptoms being targeted (e.g., by using appropriate thresholds on clinical measures) and/or by the context that DMHTs are used in (e.g., use within defined clinical pathways). The classification of SaMD within established categories of medical devices, based on severity and risks, is challenging.

3. **Risk management**: DMHT recognised as medical devices must assess risks associated with their use and have risk management plans. Risk mitigation is however difficult when the device is used without follow up from health professionals to identify non-adapted tools or patient disengagement.
4. **Clinical evidence:** SaMD must demonstrate that their clinical benefits outweigh risks. At the same time, policy makers are keen to balance evidence requirements with incentives for innovation. In that respect, the NICE ESF is considered as a good example.
5. **Resource requirements and economic evidence**: DMHT used within clinical pathways must undergo economic evaluation and demonstrate that they are cost-effective by comparison of the standard of care. The extent to which they complement professional services or are an alternative may be determinant in the estimation of resource use.
6. **Post-market surveillance and life cycle assessment**: Developers of SaMD are expected to report all adverse events and any significant changes in their product once they are marketed. Safety monitoring, however, suffers from a lack specification/classification of what needs to be reported, a lack of awareness on reporting tools and a lack of pro-active monitoring.[1] Monitoring of product changes is challenged by the specificities of digital tools, which tend to change rapidly.
7. **Replicability and equity**: Having several DMHTs with the same purpose is not an issue as long as new incumbents can demonstrate they are as safe and effective as existing ones. The impact on equity must be considered from two perspectives: it improves availability of services where they are used as substitutes to less available services; but on the other hand, some patients may not be able/willing to use digital tools.
8. **Wider responsibilities**: DMHTs may be subject to other regulations, such as those pertaining to data privacy, advertising, etc.

Note1. A new piece of legislation is expected to come into force in 2025 to improve post-market surveillance/safety reporting.
Source: As cited.

4. Conclusions

67. Digital health technologies are advancing at a rapid rate, and payers are increasingly faced with the challenge of what to pay for, and how much, under already stretched public healthcare budgets. Health technology assessment is considered a useful tool to inform such decisions, but there is currently a lack of consensus or standard approach to the assessment of different types of digitally based health technologies. A major challenge is the enormous breadth of digital health technologies, with technologies evolving faster than the methods used to assess them.

68. This paper aimed to explore how **France**, **Germany**, **Israel**, **Korea**, **Spain** and the **United Kingdom** approach HTA of a subset of digital health technologies that are regulated as digital medical devices – namely digital therapeutics for individual patient use and digital diagnostics. Reflecting the insights gained and the available evidence during the research process, however, the findings primarily pertain to digital therapeutics. Approaches to evaluating digital medical devices for inclusion in national benefit packages vary widely across these countries, influenced by their unique contexts, legislative frameworks, and the breadth of technologies assessed. In all countries, HTA supports coverage decision-making, although the recommendation does not necessarily lead directly to national coverage or reimbursement, which can have downstream implications for implementation and adoption. In all six jurisdictions, digital medical devices can be evaluated through the same pathways and with mostly the same criteria as non-digital medical devices. However, all but Spain, which has a dedicated digital HTA framework, introduced some form of fast-track or early access pathway for a subset of eligible technologies to overcome some of the challenges with evaluating these technologies. While the evaluation criteria generally remain the same as for non-digital medical devices, additional considerations around data security and interoperability, patient usability and accessibility are needed for digital medical devices, although these aspects are sometimes considered in other review processes or technical assessments outside of HTA.

69. The breadth of experience with digital HTA varies widely across the reviewed countries, but transparency and accessibility of technology assessments has facilitated shared learning. The number of digital health technologies already assessed by HTA agencies extends beyond the initial focus of this paper, with some countries evaluating hundreds of technologies and others in the early stages of formal assessment, suggesting very different scopes and practices. However, to date, the evaluation of digital medical devices within initial scope of this paper primarily focused on mobile health applications in the mental health space. Insights from interviewed country HTA experts are applicable to a broader range of digital health technologies and commonly acknowledge the unique digital ecosystem and the challenges associated with HTA of digital medical devices compared to other medical devices and pharmaceuticals. This is also evidenced in the use of digital-specific evaluation pathways or approaches in these countries. At the same time, many of the themes that arose are common to medical device HTA more generally. Despite mixed levels of experience, interviewees identified that there are some practical learnings and opportunities emerging in this rapidly evolving space. Figure 4.1 summarises key challenges and learnings.

Figure 4.1. Some examples of key challenges and learning opportunities

Note: This is not exhaustive but highlights key themes from the semi-structured interviews, many of which also apply to other medical devices.
Source: Semi-structured interviews with HTA experts from the case study countries, 2024.

70. While this paper provides a high-level overview of current approaches to the assessment of digital medical devices, it does not capture the full diversity or complexity of national systems, nor the specificities of individual technologies. Future work should consider how legislative frameworks, national priorities, and specific technology characteristics shape assessment and coverage decisions. Factors such as user type, usability, integration with other systems (e.g. electronic health records), and directness of health impact can influence evaluation. While some comparisons with non-digital medical devices are noted, the paper does not provide a comprehensive analysis of these differences. In particular, AI introduces unique challenges not explored in depth here. AI raises ethical, legal, regulatory, and technical questions, including how to manage iterative algorithm updates, define oversight roles, and design post-market surveillance systems that track safety and performance over time. As digital products grow in number and complexity, deeper exploration of assessment frameworks – particularly for AI – will be key to ensuring responsible adoption into health.

71. It is too early to define 'good' or 'best practices' in the HTA of digital medical devices, but this paper contributes to the growing understanding of their evaluation. The insights are based on the reviewed systems and their intended scopes. Countries are encouraged to reflect on their own contexts and may consider alternative, or maintaining existing, approaches after evaluating their systems. Countries are actively reviewing their evaluation methods, and there is a trend toward harmonising HTA frameworks and methodologies across jurisdictions. This paper highlights the importance of collaboration and shared experiences in identifying and addressing gaps, fostering alignment, and working toward best practices. Ultimately, ongoing adaptation and transparency in shared learnings will be key to addressing persistent challenges in the assessment of digital medical devices and digital health technologies more broadly.

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van Kessel, R. et al. (2023), "Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping", *JMIR mHealth and uHealth*, Vol. 11, p. e49003, https://doi.org/10.2196/49003. [30]

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von Huben, A. et al. (2021), “Health technology assessment for digital technologies that manage chronic disease: a systematic review”, *International Journal of Technology Assessment in Health Care*, Vol. 37/1, https://doi.org/10.1017/s0266462321000362. [33]

WHO (2023), *Classification of digital interventions, services and applications in health: a shared language to describe the uses of digital technology for health, 2nd ed*, The World Health Organization, https://www.who.int/publications/i/item/9789240081949 (accessed on 5 July 2024). [15]

Annex A. Types of digital health technologies

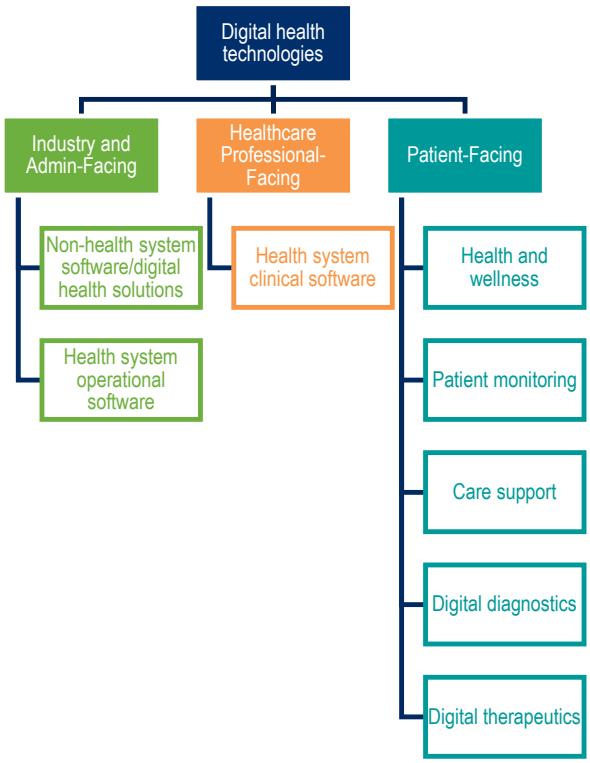
Table A A.1. Relevant terms related to digital health technologies

According to the International Organization for Standardization Technical Report 11147:2023(en)

Terms	Notes
Digital health technology (DHT)	See publicly available information on *'Terms and definitions'* here. Each term may be made up of several different components, with additional notes on inclusion and exclusion criteria.
Digital therapeutic (DTx)	
Medical device	
Health software	
Software as a medical device (SaMD)	
Software in a medical device (SiMD)	

Source: International Organization for Standardization (2023[11]), *ISO/TR 11147: Health Informatics – Personalised digital health – Digital therapeutics health software systems 2023*, https://www.iso.org/obp/ui/en/#iso:std:iso:tr:11147:ed-1:v1:en.

Figure A A.1. Digital health technology categories according to the Digital Therapeutics Alliance (an industry trade association)



Source: Adapted from Digital Therapeutics Alliance (2023[61]), *Digital Health Technology Ecosystem Categorization*, https://dtxalliance.org/wp-content/uploads/2023/06/DTA_FS_DHT-Ecosystem-Categorization.pdf.

Annex B. Country snapshots

This Annex presents snapshots of the country case studies included in this paper - **France, Germany, Israel, Korea, Spain,** and the **United Kingdom**. The selection of the case studies was done in consultation with the OECD Expert Group on Pharmaceuticals and Medical Devices. To the extent possible, each case study overviews the situation of regulation, health technology assessment and some considerations for reimbursement and pricing in the respective countries. Most of the information presented comes from desk-research found in the associated lists of additional information; links to specific evaluation documents are included in Table A C.1 in Annex C. Semi-structured interviews with experts in the selected countries were also held between July and November 2024.

France

Table A B.1. Snapshot overview: France

Area of interest	Notes
Regulatory	**Approach:** review of safety and performance/efficacy **Institution:** CE-marking through EU Notified Body, registered with French Ministry of Health
General HTA context of medical devices	**HTA approach:** if the medical device is CE-marked, HTA is mandatory only for health insurance coverage for medical devices used by patients **HTA scope:** mainly clinical, quality of life, organisational criteria. An economic evaluation is mandatory only for medical devices with a high impact on health expenditure **HTA remit:** advisory **Evaluation:** actual clinical benefit (positive or negative *SA – Service Attendu*) and clinical added value (*ASA – Amelioration du Service Attendu*, from I = high improvement to V = no improvement) **Institutions:** French National Authority for Health's (*Haute Autorité de Santé* - HAS) National Committee for the Evaluation of Medical Devices and Health Technologies (*Comission en charge de l'évaluation de dispositives médicaux* - CNEDiMTS); HAS' Economic and Public Health Evaluation Committee (*Commission d'Évaluation Économique et de Santé Publique* - CEESP) if economic evaluation required
HTA approach and methodology specific to digital medical devices	**Technology scope:** wide, from digital therapeutics to telemonitoring and connected medical devices **Evaluation:** same as other medical devices + a few additional digital considerations. For telemonitoring, evaluation is based on interest compared to comparators. **Additional requirements:** compliance with data security and interoperability standards reviewed by the Digital Health Agency (Agence du Numérique en Santé - ANS)
Assessment approach	**Assessment level:** disease/condition (generic line) and product based (brand name) **Prioritisation for assessment:** no specific prioritisation, all submissions are reviewed **Re-assessment:** if digital medical device is listed as generic or brand name, re-evaluation is required in 5 years; full re-evaluation is also needed if there is a major update
Coverage/ reimbursement listing pathways	*See Figure A B.1.* **Traditional pathway:** listed in the Reimbursement List (*Liste des Produits et Prestations Remboursables* - LPPR) for digital medical devices and in the Reimbursement list for remote monitoring devices (*Liste des Activités de Télésurveillance Médicale* - LATM) for telemonitoring **Fast-track:** fast-track pathway for digital medical devices (*Prise En Charge Anticipée Des Dispositifs Médicaux Numériques* - PECAN), reimbursement for 1 year prior to the LPPR or LATM listing
Pricing and reimbursement	**Institution:** French Ministry of Health's Pricing Committee (CEPS) **Pricing:** the price is negotiated between the CEPS and the developer based on the ASA level and the price of the comparator **Reimbursement by social health insurance:** 60% of the reference price set by CEPS for LPPR-listed medical devices.

	For telemonitoring, basic uniform monthly rates have been set according to the clinical benefit of the product (EUR 50 for organisational benefit, EUR 73.33 for improved quality of life, EUR 82.50 for reduction in morbidity; and EUR 91.67 for reduction in mortality). These rates can be adjusted according to the size of the population target. For therapeutic PECAN products, basic uniform monthly rates have been set at an initial lump sum of EUR 435 (billable once for the same patient for a period of use of no more than 3 months) followed by a monthly lump sum that can be adjusted according to invoicing frequency of EUR 38.30; the maximum amount of financial compensation is a total of EUR 780 per year per patient.

Note: See list of acronyms and abbreviations. Acronyms are explained in Section 2 of the main text.
Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

Figure A B.1. Evaluation pathways of digital medical devices in France

<table>
<tr><th colspan="2">Types of devices</th><th>Common law</th><th colspan="2">Upstream of common law</th></tr>
<tr><td rowspan="3">Digital medical devices</td><td>Remote telemonitoring</td><td>LATM</td><td rowspan="2">PECAN</td><td rowspan="4">Innovation package</td></tr>
<tr><td>Digital therapeutics</td><td rowspan="3">LPPR</td></tr>
<tr><td>Other digital medical devices</td><td rowspan="2">Transient support</td></tr>
<tr><td colspan="2">Other medical devices</td></tr>
</table>

Note: LPPR *Liste des produits et prestations remboursés* ; LATM *Liste des activités de télésurveillance médicale* ; PECAN *Prise en charge anticipée des dispositifs médicaux numérique*. LPPR applies to medical devices for individual use. This diagram does not include hospital use.
Source: Adapted from Haute Autorité de Santé 2021, *Understanding medical device evaluation*, https://www.has-sante.fr/jcms/c_928541/fr/comprendre-l-evaluation-des-dispositifs-medicaux

For additional information:

- Understanding evaluation of medical devices in France (2012, last updated 2023): Haute Autorité de Santé - Comprendre l'évaluation des dispositifs médicaux, which includes links to relevant documents such as
  - Practical guide to medical device pathway (including some information about digital medical devices) (2021)
  - Diagram of evaluation pathway for digital medical devices (2023)
  - Assessment principles to determine reimbursement eligibility of medical devices for individual use (2019[62])
- Creation of an evaluation pathway for digital medical devices (2023): Haute Autorité de Santé - Dispositifs médicaux numériques : création à la HAS d'un guichet unique pour une évaluation transversale
- Committee responsible for evaluating medical devices (2021): Haute Autorité de Santé - Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé, which includes a link to the latest annual activity report
- G-NIUS platform, a one-stop-shop for e-Health innovators, published by the Ministerial Delegation for Digital Health and led by the Digital Health Agency (ANS) (2025): Dispositif Médical Numérique : décryptage I G_NIUS

- Links to relevant decrees:
  - Common law framework for health insurance coverage of remote medical monitoring activities (2021): Article 36 - LOI n° 2021-1754 du 23 décembre 2021 de financement de la sécurité sociale pour 2022 (1) - Légifrance :
  - Early reimbursement by the health insurance scheme of digital medical devices for therapeutic purposes and remote medical monitoring activities (2021): Article 58 - LOI n° 2021-1754 du 23 décembre 2021 de financement de la sécurité sociale pour 2022 (1) - Légifrance
  - Implementing decrees for these two measures :
    - Decree 30 December (2022[63]) on the coverage and reimbursement of remote medical monitoring activities: Décret n° 2022-1767 du 30 décembre 2022 relatif à la prise en charge et au remboursement des activités de télésurveillance médicale - Légifrance
    - Decree 30 March (2023[64]) on the early coverage of digital medical devices for therapeutic purposes and remote medical monitoring activities by health insurance: Décret n° 2023-232 du 30 mars 2023 relatif à la prise en charge anticipée des dispositifs médicaux numériques à visée thérapeutique et des activités de télésurveillance médicale par l'assurance maladie au titre de l'article L. 162-1-23 du code de la sécurité sociale - Légifrance
- Links to tarriff decrees
  - PECAN for digital medical devices for therapeutic purposes (2024): Arrêté du 22 avril 2024 fixant les valeurs prévues au II de l'article R. 162-117 du code de la sécurité sociale de la compensation financière due au titre de la prise en charge anticipée par l'assurance maladie d'un dispositif médical numérique à visée thérapeutique - Légifrance
  - LATM for remote telemonitoring (2023): Arrêté du 16 mai 2023 fixant le montant forfaitaire de l'activité de télésurveillance médicale prise en charge par l'assurance maladie prévu aux II et III de l'article R. 162-95 du code de la sécurité sociale, ainsi que les modulations applicables à ces tarifs et la périodicité de leur révision - Légifrance
  - Telemonitoring specifically for prosthetic cardiac implantables (2024): Arrêté du 15 mars 2024 fixant le montant forfaitaire des activités de télésurveillance médicale inscrites sur la liste prévue à l'article L. 162-52 du code de la sécurité sociale - Légifrance
- Published evaluations: using search function on HAS website https://www.has-sante.fr/, filtering for medical devices

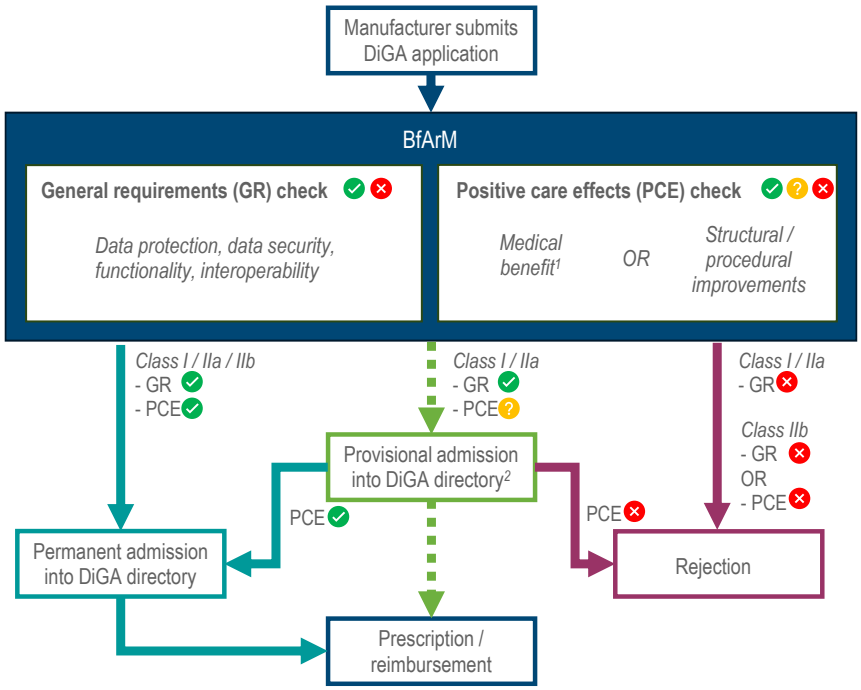
Germany

Table A B.2. Snapshot overview: Germany

Area of Interest	Notes
Regulatory	**Approach:** review of safety and performance/efficacy **Institution:** CE-marking through EU Notified Body, registered with the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* - BfArM)
General HTA context of medical devices	**HTA approach:** assessment of added benefit of traditional medical devices for inclusion in the German health insurance system **HTA scope:** mainly comparative clinical benefit **HTA remit:** advisory **Institutions:** Federal Joint Committee (*Gemeinsamer Bundesausschuss* - G-BA) and Institute for Quality and Efficiency in Health Care (IQWiG)
HTA approach and methodology specific to digital medical devices	**Technology scope:** Digital Health Applications (*digitale Gesundheitsanwendungen* - DiGA): medical device risk classes I, IIa or IIb; main function is based on digital technologies and must be used by the patient or the patient and the healthcare provider. **Evaluation:** specific approach for DiGA, including compliance with technical requirements (safety and suitability for use, functionality, quality, data protection, information security, interoperability) and demonstration of positive healthcare effect (medical benefit and patient relevant improvement of structure and process). Same criteria as traditional medical devices for other digital medical devices. **Institutions:** BfArM for DiGA; G-BA for other digital medical devices
Assessment approach	**Assessment level:** technology-based **Prioritisation for assessment:** no specific prioritisation, all submission reviewed within 3 months of application (DiGA) **Re-assessment:** no specific process currently in place, assessment made on certain version of the technology
Coverage/ reimbursement listing pathways	**Traditional pathway:** G-BA reimbursement decision on statutory health insurance **Fast-track:** For DiGA: permanent or temporary listing through statutory health insurance if DiGA has a comparative study showing positive healthcare benefit then immediate listing; if not, temporary listing for 12 months while further evidence generated. Class IIb devices are not eligible for provisional listing and evidence on medical benefit must be provided. *See Figure A B.2.*
Pricing and reimbursement	**Pricing:** For DiGA: manufacturer sets price for 12 months, then it can be renegotiated

Note: See list of acronyms and abbreviations. Acronyms are explained in Section 2 of the main text.
Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

Figure A B.2. Evaluation pathway for DiGA in Germany



Note: Illustrates process from application to admission in the DiGA directory and prescription and reimbursement. Shows different pathways depending on current evidence and medical device class.
1. Required for medical devices of class IIb. 2. No provisional admission is possible for medical devices of class IIb.
Source: Adapted from Schmidt et al (2024[52]), *The three-year evolution of Germany's Digital Therapeutics reimbursement program and its path forward,* https://doi.org/10.1038/s41746-024-01137-1 (CC BY 4.0)

For additional information:

- Information on DiGA – digital health applications: BfArM - Digital Health Applications (DiGA), (2023[65]) including links to the
  - DiGA guide (current version 3.5 of the guide 28.12.2023 only available in German)
  - DiGA directory with published decisions
- Ordinance on the Procedure and Requirements for Testing the Reimbursement of Digital Health Applications in Statutory Health Insurance (2020[66]): DiGAV - Ordinance on the Procedure and Requirements for Testing the Reimbursement of Digital Health Applications in Statutory Health Insurance
  - Last amended by Article 4 of the Digital Act of 22 March (2024[36]): Federal Law Gazette Part I - Act to Accelerate the Digitalisation of the Healthcare System - Federal Law Gazette
- National Association of Statutory Health Insurance Funds information on DiGA (last updated 2025): Digital Health Applications (DiGA) - National Association of Statutory Health Insurance Funds, which provides links to annual reports on the use and development of the supply of DiGA

Israel

Table A B.3. Snapshot overview: Israel

Area of Interest	Notes
Regulatory	**Approach:** registration process includes submission of detailed clinical data, safety and quality control information **Institution:** Medical Device Division in the Medical Technology Health Information and Research Directorate in the Ministry of Health
General HTA context of medical devices	**HTA approach:** medical devices undergo HTA evaluation to be included in the National List of Health Services (NLHS) i.e. the national benefits basket. Recommendations for inclusion are made once per year. **HTA scope:** clinical and economic evaluation **HTA remit:** advisory **Evaluation:** medical evaluation on safety and efficacy, epidemiological assessment of patient volumes and needs assessment, review of existing experience using the technology, economic evaluation of adding the technology to the basket, reference to additional social, legal aspects **Institutions:** the National List of Health Services Update Committee makes recommendations for inclusion in the NLHS to the Ministry of Health, and the Ministry of Finance and the Government make the final approval
HTA approach and methodology specific to digital medical devices	**Technology scope:** no specific taxonomy, includes broad scope of technologies as they fit under specific entitlements (i.e. according to clinical pathways or medical services provided) **Evaluation:** same criteria and evaluation process as for traditional medical devices for inclusion in NLHS; A digital-specific evaluation framework has been developed for the review of early-stage technologies through various grant programmes, which is adapted to the specific needs and perspectives of the reviewed technology. Considers health value and feasibility, organisational benefits and suitability, economic value and feasibility, usability and social considerations, company capabilities. **Institutions:** Ministry of Health, Health Maintenance Organisations
Assessment approach	**Assessment level:** based on clinical pathway **Prioritisation for assessment:** no prioritisation, all applications are considered **Re-assessment:** assessment is made on a certain version of the technology. A significant change would require reassessment by the regulatory authority
Coverage/ reimbursement listing pathways	**Traditional pathway:** addition to the NLHS as described above. Results of HTA inform inclusion in the national basket; **Alternative pathway:** various grant programmes, funded by the Ministry of Health, have been established as 'mid-way' support for R&D, scale up and deployment of digital health technologies that currently lack sufficient clinical and/or economic evidence to be included in the NLHS, or are not entitled to support under the NLHS.
Pricing and reimbursement	**Institutions:** Ministry of Health, Health Maintenance Organisations **Pricing:** for NLHS: there is a dedicated subcommittee that decides on the price for all technologies discussed in the NLHS (including digital health solutions or apps), but the actual price is negotiated between each of the Health Maintenance Organisations and the manufacturer.

Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

For additional information:

- National List of Health Services (NLHS)
  - Public Committee for Expanding the Healthcare Basket (last updated 2024): Public Committee to Expand the Healthcare Services Basket | Ministry of Health
  - Inclusion of new non-pharmaceutical medical technologies in the healthcare basket – issues and challenges (2016): Inclusion of new non-pharmaceutical medical technologies in the healthcare basket - Issues and challenges
- Digital Health Technology Evaluation for Health Organisations (Ministry of Health, 2021[43]): Evaluation of Digital Health Technologies - A Framework for Examining Technologies in the R&D Stages of Health Organizations at the Ministry of Health
- Guide to Economic Evaluation for Digital Health Services (Ministry of Health, 2024[44]): https://www.gov.il/he/pages/guide-economic-evaluation-digital-health-services

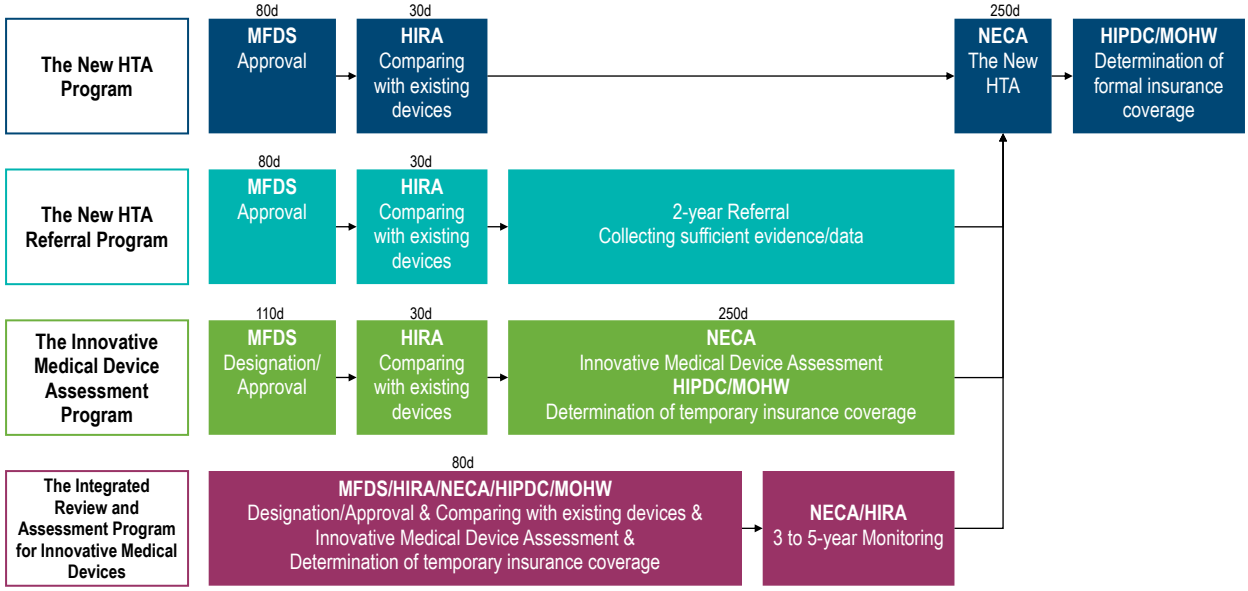
Korea

Table A B.4. Snapshot overview: Korea

Area of interest	Notes
Regulatory	**Approach:** approval based on safety and effectiveness **Institution:** Ministry of Food and Drug Safety (MFDS)
General HTA context of medical devices	**HTA approach:** all new medical devices must undergo HTA if it is determined to be a device different from existing ones, regardless of whether they will be registered as reimbursed or non-reimbursed. **HTA scope:** mainly clinical. Cost-effectiveness is conducted separately after HTA **HTA remit**: advisory. The results of the HTA serve as an important reference for the Committee and Ministry of Health and Welfare (MOHW) when deciding on health insurance coverage, but they are not the sole determining factor **Evaluation:** specific criteria or indices for safety and effectiveness vary by device. The main criteria used in the assessment of digital technologies include addressing the characteristics of the targeted diseases (such as mortality, morbidity, and overall impact), improving patients' quality of life, and enhancing clinical outcomes, which are mainly medical aspects **Institutions:** NECA (National Evidence-based healthcare Collaborating Agency) for evaluation, HIRA (Health Insurance Review and Assessment) for coverage
HTA approach and methodology specific to digital medical devices	**Technology scope:** AI-related technologies and digital medical devices fall under the Advanced Technology category, which has 10 subcategories. Digital therapeutics would fall under the 'Digital and wearable technology' category, and include e.g. IoT/biosensor-based wearable devices, digital therapeutic products, medical apps, etc **Evaluation:** largely similar to that of other new medical devices (create different indices for each device) but more streamlined process. There are ten specific criteria for evaluating the potential of digital medical devices, involving assessing market potential, impact on health and patient outcomes, and the degree of compatibility with existing medical practices. **Institutions:** NECA (evaluation), HIRA (coverage), Korean Health Industry Development Institute - KHIDI (market potential)
Assessment approach	**Assessment level:** product based **Prioritisation for assessment:** those designated as innovative medical devices by the MFDS are given higher priority for assessment. **Re-assessment:** if the level of change is deemed to affect the safety or effectiveness of the technology, a re-evaluation must be conducted.
Coverage/ reimbursement listing pathways	*See Figure A B.3.* **Traditional pathway:** All products, regardless of reimbursement status, must be registered on the MOHW list. Companies choose whether to seek temporary reimbursement during the three-year market entry period, during which field data is collected. NECA then conducts a formal HTA, and HIRA, the Health Insurance Policy Deliberation Committee (HIPDC), and MOHW make the final decision on insurance coverage registration. **Fast-track:** Digital devices eligible for fast-track assessment under the Integrated Review and Assessment Program for Innovative Medical Devices program, whereby the processes of designation as an Innovative Medical Device (by the regulator, the Ministry of Drug and Food Safety), provisional insurance listing (by HIRA), and assessment of innovative medical technology in terms of potential safety and effectiveness in clinical settings (by NECA) are integrated into a single process, which takes a total of 80 days (rather than the usual 250 days total)
Pricing and reimbursement	**Institution:** HIPDC, HIRA, MOHW **Pricing:** The developer proposes a price, which is reviewed by HIRA and finalised by the HIPDC. If a device is temporarily reimbursed, the fee is officially announced. For non-reimbursed devices, a proper fee is set, and the company can add. **Reimbursement:** A device can be temporarily reimbursed at 10% for three years.

Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

Figure A B.3. The New HTA Framework and its categories in Korea



Notes: MFDS Ministry of Food and Drug Safety; HIRA Health Insurance Review and Assessment; NECA National Evidence-based healthcare Collaborating Agency; MOHW Ministry of Health and Welfare; HIPDC Health Insurance Policy Deliberation Committee. "d" refers to number of days.
The Integrated Review and Assessment Program for Innovative Medical Devices is the most applicable for digital medical devices in scope of this paper.
Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

For additional information:

- A Simple Guide to New Health Technology Assessment: A to Z: (Ministry of Drug and Food Safety, 2020[39])
- Introduction to Integrated Review and Assessment Program for Innovative Medical Devices: (Kim, 2023[41])
- Regulations on the Evaluation and Implementation of Innovative Medical Technologies, Ministry of Health and Welfare Notice No. 2023-260: (Ministry of Health and Welfare, 2023[67])
- Guideline for digital therapeutic devices to be listed in health insurance (published in August 2023): Digital Therapeutic Devices Health Insurance Registration Guidelines
  - Operational Guidelines for Temporary Registration of Digital Therapeutic Devices in Health Insurance (published in December 2023): Innovative Medical Technology (Digital Therapeutic Device, Artificial Intelligence) Temporary Registration of Health Insurance Pilot Project Operation Guidelines
- Guideline for the listing evaluation framework of medical technology using artificial intelligence (published in August 2023): Evaluating Guidelines for Eligibility of Medical Care Benefits for Innovative Medical Technology – AI-based innovative Medical Technology
  - Operation guideline preliminary listing evaluation framework of medical technology using artificial intelligence (published in December 2023): Guidelines for Provisional Registration of AI-based Innovative Medical Technology in Health Insurance

Spain

Table A B.5. Snapshot overview: Spain

Areas of interest	Notes
Regulatory	**Approach:** review of safety and performance/efficacy **Institution:** CE-marking through EU Notified Body that operate within the Agency of Medicines and Medical Devices (Spanish regulator) but are independent
General HTA context of medical devices	**HTA approach:** medical devices undergo HTA evaluation to be included in the national Common Benefit Package (and also for inclusion in complementary benefit package – at regional level – and hospital benefit packages – at hospital level) **HTA scope:** systematic, clinical and economic evaluation **HTA remit:** advisory **Institutions:** Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS), a network of eight regional agencies that develop reports following the same methodology and in collaboration with each other.
HTA approach and methodology specific to digital medical devices	**Technology scope:** all digital health technologies commissioned in the Spanish National System for medical, health or wellness or system for efficiency purposes. Applies to medical therapeutic and diagnostic technologies, including in vitro diagnostics and screening technologies, and including software as a medical device. Excludes software *in* a medical device. **Evaluation:** digital-specific HTA evaluation framework with 13 domains, 41 dimensions and 9 subdimensions possible, including those most relevant to AI such as ethical, legal and regulatory, and technical
Assessment approach	**Assessment level:** technology-based **Prioritisation for assessment:** PriTec web tool is a multi-criteria analysis tool that prioritises all health technologies (not just medical devices) that should undergo HTA evaluation in a given year. **Re-assessment:** in the event of a change to the intended purpose or evidence, otherwise only notification
Coverage/ reimbursement listing pathways	**Traditional pathway:** national Common Benefit Package **Fast-track / alternative pathway:** None

Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

For additional information:

- HTA evaluation framework adapted to digital health technologies (framework and user guide) (AQuAS, 2023[18]): Methodological framework for the evaluation of digital health technologies. Agency for Health Quality and Assessment of Catalonia (AQuAS) (gencat.cat)
  - Published version of methodological framework scoping review and thematic analysis (Segur-Ferrer et al., 2024[32]): Methodological Frameworks and Dimensions to Be Considered in Digital Health Technology Assessment: Scoping Review and Thematic Analysis - PubMed (nih.gov)

United Kingdom

Table A B.6. Snapshot overview: United Kingdom (England)

Areas of interest	Notes
Regulatory	**Approach:** Responsible for regulating the UK medical devices market **Institution:** UK conformity assessment bodies, Medicines and Healthcare products Regulatory Agency (including transitional measures from previously CE-marked devices)
General HTA context of medical devices[1]	**HTA approach:** used in some circumstances, when companies apply; medical devices with enough clinical evidence can undergo HTA evaluation by the National Institute for Health and Care Excellence (NICE). A positive assessment does not directly lead to coverage by the National Health Service (NHS). Sub-national or local NHS organisations decide on pricing and reimbursement. NICE evaluates medical devices through several evaluation pathways including technology appraisals guidance (mostly pharmaceuticals), highly specialised technologies guidance (mostly pharmaceuticals), medical technologies guidance, and diagnostics guidance. The programme used depends on the technology and its expected impact on health and social care spend – The Office for Digital Health can advise about the programmes. NICE, however, is currently consulting on its methods and processes for health technologies with the aim of unifying the health technologies evaluation programme. **HTA scope:** clinical and economic evaluation **HTA remit:** advisory **Evaluation:** evidence of effectiveness relevant to the intended use of the technology and evidence of economic impact (according to guidance in PMG36) **Institutions:** NICE is responsible for the HTA and appraisal
HTA approach and methodology specific to digital medical devices	**Technology scope:** no specific taxonomy used, although a guidance for developers outlines a taxonomy for digital health technologies that classifies them according to their intended purpose and function using tiers **Evaluation:** depends on the pathway. For a full NICE evaluation, same criteria as other medical devices, informed by some elements from the Evidence Standards Framework (ESF). For Early Value Assessment (EVA), there is no structured framework or methodology, and is adapted to the evidence base available. **Additional requirements:** digital medical devices should have undertaken a national Digital Technology Assessment Criteria (DTAC) – clinical safety, data protection, technical security, interoperability, usability and accessibility – assessment by NICE or the NHS organisation procuring the technology
Assessment approach	**Assessment level:** EVA – multiple technology appraisals; other guidance can be singular appraisals **Prioritisation for assessment:** no direct prioritisation; however there are topics (i.e. disease areas) selected by NICE as priority areas for inclusion in e.g. the EVA **Re-assessment:** assessment is made on a certain version of the technology. A significant change would require reassessment by the regulatory authority
Coverage/ reimbursement listing pathways	**Traditional pathway:** see above, for technologies with robust clinical evidence **Fast-track pathway:** Early value assessment, for promising technologies in certain topic areas that have not yet generated sufficient evidence
Pricing and reimbursement	**Institution: I**ntegrated care boards (replacement of clinical commissioning groups) **Pricing:** NICE provides a recommendation on cost-effectiveness but price negotiations occur individually with the integrated care boards. Pricing negotiations can also happen nationally and through procurement.

Note: Additional details regarding the Scottish system are described below. 1. Most digital health technologies are procured directly by NHS Trusts which do their own HTA. The proportion of technologies assessed by NICE is increasing, but it cannot yet be positioned as the standard assessment pathway.
Source: Authors' compilation based on desk research and semi-structured interviews, 2024.

NICE is not responsible for the HTA of medical technologies in Scotland. Instead, the Scottish Health Technologies Group (SHTG), part of Healthcare Improvement Scotland, oversees the HTA of medical devices, including digital medical devices. HTA provides evidence, support and advice to NHS Scotland on the use of existing and new health technologies and supports planning and decision-making process of NHS boards. HTA outputs range from in-depth assessments to rapid reviews and innovative medical technology overviews. Evaluation criteria for digital medical devices are the same as for other medical devices, following the Evidence Standards Framework for Health Technology Assessment as a high-level guide, with additional requirements for DTAC (as in England). A positive SHTG assessment does not directly lead to funding by the NHS as sub-national or local NHS organisations decide on procurement, pricing and reimbursement.

For additional information:

England

- NICE health technology evaluations: the manual PMG36((2022[68]), last updated October 2023): Overview | NICE health technology evaluations: the manual | Guidance | NICE
  - A new manual is in development to unify the methods and processes for health technologies with the aim of unifying the health technologies evaluation programme (February 2025): Methods / process manual consultation | Project documents | NICE HealthTech programme manual | Guidance | NICE
- NICE website dedicated to digital health: Digital health | What we do | About | NICE
- Links to NICE products in digital health, including guidance and quality standards: Digital health | Topic | NICE
- Early Value Assessment pathway: Early Value Assessment (EVA) for medtech | What we do | About | NICE
- NICE-wide topic prioritisation: the manual (2024[45]): Overview | NICE-wide topic prioritisation: the manual | Guidance | NICE
- Evidence standards framework for digital health technologies (NICE, 2018[17]), published December 2018 and updated August 2022 Overview | Evidence standards framework for digital health technologies | Guidance | NICE
- Digital Technology Assessment Criteria for Health and Social Care (DTAC) (NHS England, n.d.[69]): Digital Technology Assessment Criteria (DTAC) - Key tools and information - NHS Transformation Directorate (england.nhs.uk)
- Proposal for a new integrated rules-based pathway for medtech (NICE/NHSE/DHSC, 2024[19]): NHS England » Building an integrated, rules-based medical technology (medtech) pathway: engagement on proposals

Scotland

- Evidence Standards Framework developed by the Scottish Health Technologies Group (SHTG, 2023[70]): Evidence Framework (shtg.scot)

Annex C. Evaluation documents

Table A C.1. Relevant frameworks or documents describing evaluation criteria or domains applicable to digital medical devices

Country	Relevant framework, regulatory text, or guiding principles for evaluation	Purpose of the document	Applicable product scope	Domains
France	Assessment principles established by CNEDiMTS (of HAS) to determine reimbursement eligibility of medical devices for individual use, (HAS, 2019[62])	Assessment principles established by CNEDiMTS (of HAS) to determine reimbursement eligibility of medical devices for individual use	Medical devices for individual use eligible for reimbursement via LPPR	**Actual clinical benefit** (as sufficient or insufficient): based on individual benefit of the device, and collective public health benefit **Added clinical value** (as absent, minor, moderate, important, major): in comparison to appropriate comparator
France	Decree 2022-1767 30 December (French Parliament, 2022[63])	Decree outlining the regulatory criteria for HAS to evaluate remote telemonitoring devices for coverage and reimbursement	Remote telemonitoring devices for reimbursement via LATM	**Interest** compared to existing alternatives – in terms of clinical improvement (individually), gain in organisation of care, and public health interest
France	Decree 2023-232 30 March (French Parliament, 2023[64])	Decree outlining early coverage of digital medical devices for therapeutic purposes and remote medical monitoring activities	Digital medical devices for therapeutic purposes and remote medical monitoring activities (non-invasive) for reimbursement via PECAN	**Pre-requisites for PECAN:** Presumed to be innovative, in terms of clinical benefit or progress in organisation of care, according to first available data and taking relevant comparators into account; compliance with rules on protection of personal data and interoperability and security standards; CE-marking; shall make it possible to export processes data in interoperable, appropriate formats etc *Need to submit application on LPPR within 6 months or LATM within 9 months from decision on advanced coverage*
Germany	Digital Health Applications (DiGA) Guide, (BfArM, 2023[65])), according to DiGAV - Ordinance on the Procedure and Requirements for Testing the	Requirements for reimbursement of Digital Health Applications in Statutory Health Insurance	Medical device of risk class I or IIa (now also IIb), main function is based on digital technologies and has to be used by the patient or the patient and the healthcare	**Technical requirements**: security, functionality, quality, data protection, data security, interoperability **Positive care effects:** either medical benefit or patient-

Country	Relevant framework, regulatory text, or guiding principles for evaluation	Purpose of the document	Applicable product scope	Domains
	Reimbursement of Digital Health Applications in Statutory Health Insurance, (Federal Office of Justice, 2020[66]), updated March 2024		provider (e.g. digital health applications)	relevant structural and procedural improvements in care
Israel	Digital Health Technology Evaluation for Health Organizations: an evaluation framework for early-stage technologies, (Ministry of Health, 2021[43])	Evaluation framework to help innovation promoters in healthcare organisations to examine value and feasibility of implementing digital health technologies, as well as the feasibility of collaborating with industry for a pilot R&D project. Adapted versions of this framework are used by the Ministry of Health when reviewing various grant programmes.	Early-stage technologies (i.e. during research and development, in the pre-market stage)	**Assessment categories:** health value and feasibility; organisational benefits and suitability; economic value and feasibility; usability and social considerations; company capabilities
Israel	Guide to Economic Evaluation for Digital Health Services, (Ministry of Health, 2024[44])	Guide that outlines a standarised process for developing an economic model for the evaluation of a service based on digital health technologies	Services based on digital health technologies	The model includes five steps, from creating the framework of the economic model (defining the problem, characterisation of the target population, quantification of costs of illness and definition of the clinical objectives of the programme), to evaluating clinical impact, cost of intervention, impact on cost structure, and finally calculating the cost-effectiveness of the intervention.
Korea	Guidelines on Procedures, Methods, and Criteria for Designation of Innovative Medical Devices, (Ministry of Drug and Food Safety, 2020[39])	Regulations on assessment criteria of the Innovative Medical Device Assessment Programme	Medical devices that significantly improve or are expected to improve the safety and effectiveness compared to existing devices or treatments through the application of advanced technologies, such as information communications technology (ICT), biotechnology, or robotics. The devices fall into four categories: Advanced Technology, Medical Innovation, Technological Innovation, and Public Health.	Innovativeness of technology; improvement in safety and effectiveness; industrial value and benefit. **10 specific criteria to assess the potential of devices**, covering market potential; impact on health and patient outcomes; compatibility with existing medical practices
Spain	Methodological framework for the evaluation of digital health technologies, (AQuAS, 2023[18]).	Health Technology Assessment Framework adapted for digital health technology assessment. Intended to support evaluation of all DHT	Applicable to medical therapeutic and diagnostic technologies, including IVDs and screening technologies. E.g. smartphone apps; stand-alone software	**13 Domains; 41 dimensions; 9 subdimensions** **Domains:** description of the health problem; description of the technology; content; safety; clinical efficiency and

Country	Relevant framework, regulatory text, or guiding principles for evaluation	Purpose of the document	Applicable product scope	Domains
		commissioned in the Spanish National Health System for medical, health or wellness or system efficiency purposes.	(e.g. SaMD); online tools for treating or diagnosing conditions, preventing ill health, or for improving system efficiency; programmes that can be used to analyse data from medical devices such as scanners, sensors and monitors	effectiveness; economic aspects; human and sociocultural aspects; ethical aspects; legal and regulatory aspects; organisational aspects; technical aspects; environmental aspects; post-deployment monitoring
United Kingdom (England)	NICE health technology evaluations: the manual PMG36 January (2022[68]), last updated October 2023 *A new manual is in development to unify the methods and processes for health technologies.*	Guide to describe methods and processes carried by NICE in health technology evaluations	Technologies that would be assessed through the various NICE programmes: Diagnostics Assessment Programme; Medical Technologies Evaluation Programme; Highly Specialised Technologies Evaluation Programme; and Technology Appraisal Program. These include medicines, medical devices, diagnostics, digital products, procedures, systems of care and screening tools etc	**Scope** (provides the framework for the evaluation): information on disease or health condition; information about the technology; target population; relevant comparators; care/treatment pathway; clinical outcomes; cost measurement; any other relevant issues e.g. health inequalities
United Kingdom (England)	Evidence standards framework for digital health technologies, NICE published in December (2018[17]) and updated August 2022	Guide to help evaluators, decision makers and purchasers to make more informed and consistent decisions when commissioning or buying digital health technologies. Intended to evaluate of digital health technologies likely to be commissioned in the UK health and social care system for medical, health or wellness, or system efficiency purposes. Not directly used by NICE in its own HTA evaluations.	Applicable to medical therapeutic and diagnostic technologies including IVDs and screen technologies. e.g. smartphone apps; standalone software; online tools for treating or diagnosing conditions; preventing ill health or improving system efficiencies; programmes that can analyse data from medical devices like scanners, sensors and monitors	**5 groups of evidence standards relating to different aspects of the product lifecycle**: design factors; describing value; demonstrating performance; delivering value; deployment considerations
United Kingdom (England)	Digital Technology Assessment Criteria for Health and Social Care (DTAC), (NHS England, n.d.[69])	The Digital Technology Assessment Criteria (DTAC) tool sets the national standards for digital technology use within the NHS and social care. All digital medical tools within NHS system should comply with DTAC.	All new digital health technologies (e.g. staff facing and patient facing digital health technologies; health apps; medtech and devices with an associated app; systems; web based portals etc.) – "a product used to provide electronic information for health or social care purposes where the product may include hardware, software or a combination of	**Technical questions:** clinical safety; data protection; technical security; interoperability criteria **Key principles for success:** usability; accessibility

Country	Relevant framework, regulatory text, or guiding principles for evaluation	Purpose of the document	Applicable product scope	Domains
			both”	
United Kingdom (Scotland)	Evidence Standards Framework, (SHTG, 2023[70])	Evidence standards framework to help evaluators, technology developers, and decision makers better understand what information is required for us to be able to identify technologies of value to service users and the health and care system. This is a high-level guide and not the exact HTA methodology used by Scottish Health Technologies Group in their HTA evaluations.	A ‘health technology’ is an intervention, product or service developed to prevent, diagnose or treat medical conditions; promte health; provide rehabilitation; or organise healthcare delivery. **Included**: tests, devices, procedures, talking therapies, digital healthcare, programmes or systems **Excluded:** medicines	**Domains for all health technologies**: the technology and its value; safety, acceptability and credibility; performance of the technology; cost and value for money **Additional domains for digital health technologies (as per the NHS England Digital Technology Assessment Criteria (DTAC)):** clinical safety; data protection; technical assurance; interoperability; and usability and accessibility

Note: See list of acronyms and abbreviations. Acronyms are explained in Section 2 of the main text. This list may not be exhaustive.
Sources: As cited in second column.

Table A C.2. Spanish HTA framework for digital health technologies

Domains	Dimensions	Subdimensions
1. Description of the health problem[1]		
2. Description of the technology	Credibility and reputation	
	Scientific basis	
	Technical evaluation and validation	
	Adoption (use and integration)	
	Intended use	
	Information management	
	Novelty	
3. Content	Adequacy of the information	
	Adequacy of the intervention	
4. Safety[1]	Clinical safety	
	Technical safety	
5. Clinical efficiency and effectiveness[1]		
6. Economic aspects[1]	Costs	
	Efficacy: economic evaluation	
	Resource use and efficiency	
7. Human and sociocultural aspects	User experience	
	Accessibility	
	Acceptability	
	Engagement	
	Perceived benefit	
8. Ethical aspects[1]	Equity and fairness	
	Control, user autonomy and accountability[2]	
	Responsibility[2]	
	Minimal intervention	
	Transparency, explainability and interpretability[2]	
9. Legal and regulatory aspects[1]	Privacy[2]	
	Transparency[2]	
	Responsibility	
10. Organisational aspects		
11. Technical aspects	Usability	
	Standardisation and re-use of data	
	Adaptability[2]	Interoperability[2]
		Scalability[2]
		Data integration[2]
		Transferability[2]
	Quality	
	Design	Persuasive design
	Technical stability	
	Aesthetics	
	Ease of use	
	Accessibility	
	Technical effectiveness and performance[2]	Reliability[2]
		Validity[2]
		Accuracy[2]
		Sensitivity[2]

Domains	Dimensions	Subdimensions
	Feasibility	
	Generalisability and reproducibility[2]	
	Interpretability and explainability[2]	
	Customisation	
12. Environmental aspects		
13. Post-deployment monitoring		

Note: 1. Corresponds to HTA Core Model® Version 3.0. 2. Recommendation that these areas be given special consideration in the assessment of artificial intelligence-based technologies.
Source: Adapted from (AQuAS, 2023[18]).

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