

EU HTA Regulation and EU Harmonised Assessment for Digital Medical Devices (including AI)

Reflection paper by a community of Digital Health and
Artificial Intelligence experts



Highlights

- Despite the promise of digital medical devices (DMDs) to transform healthcare, their adoption in clinical practice is very limited, their regulatory environment is still developing, and coverage decisions are lacking or incomplete.
- To support appropriate access pathways for DMDs and increase their adoption, the full value proposition of these technologies and their impact on healthcare systems must be understood. Few frameworks exist to evaluate DMDs and inform reimbursement and the scope of these current frameworks remains too restrictive to provide a solution for all DMDs.
- This reflection paper highlights the need for comprehensive and adaptive evaluation frameworks for DMDs and reflects on ongoing country-specific initiatives and on approaches for EU-level harmonisation. If applied, the evaluation of DMDs should secure timely and appropriate funding and reimbursement of these technologies, as well as stimulate access.

Executive summary

Despite the promise of digital health technologies to transform healthcare, (whereby continued work is ongoing to exactly define these technologies and develop a taxonomy), their adoption in clinical practice is very limited, their regulatory environment is still developing and coverage decisions are lacking or incomplete^{1,2}. The focus of this reflection paper is on a subset of digital health technologies, referred to as digital medical devices (DMD), for which CE-marking according to requirements of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) is a mandatory step to gain marketing authorisation in the EU^{3,4}. To increase the adoption of DMDs in various care settings, their full value and impact must be understood. However, at the moment there are no standardised evaluation methods or common language to help address the uncertainty around investing in digital health technologies. While a few frameworks exist to evaluate DMDs and inform reimbursement, the scope of such frameworks remains too restrictive to provide a solution for all DMDs. For example, there is a lack of AI focus and DMDs intended for use by healthcare professionals are generally not in scope.

In the last few years, we observed some changes on the horizon:

1. National initiatives proposing evaluation frameworks and digital innovation access pathways which are linked to reimbursement processes,
2. a drive towards pan-European harmonised evaluation.

The aim of this paper is two-fold: to provide an overview of existing evaluation frameworks for DMDs, with a focus on frameworks informing funding and reimbursement decisions and adoption in Europe and to reflect on limitations and opportunities offered by these frameworks in view of challenges encountered by DMDs along their life cycle. Regarding this second objective, our analysis of existing evaluation frameworks across Europe revealed several limitations:

- Limited and different scope across countries.
- Assessment timelines not accounting for short DMDs life cycles.
- Lack of focus on artificial intelligence.
- Lack of transparency and predictability on evidence generation requirements for regulatory approval and funding/ reimbursement decision-making.
- Current evidence generation methods are still mainly limited to randomised clinical trials, while the incorporation of methods that adapt to the specificities and fast-evolving nature of DMDs (e.g. incorporation of real-world evidence generation methods) remains mostly a theory.
- Lack of focus on comprehensive evaluations incorporating value elements beyond clinical and economic outcomes.

Setting up comprehensive and adaptive evaluation frameworks for DMDs is crucial and ongoing. However, challenges and limitations of currently existing health technology assessment frameworks and innovation access pathways must be recognised and addressed properly to ensure timely access to DMDs.

Moving towards a more comprehensive and fit-for-purpose evaluation of DMDs will require acknowledging the rapidly evolving nature of these technologies and their specificities (e.g. shorter life cycle than other technologies). Further, it requires a strategic change, from incorporating only conventional clinical outcomes to considering broader value elements for stakeholders in healthcare (e.g. operational efficiency, personalised care, patient and care provider empowerment, etc.). It is to be highlighted that the design of DMDs can minimise the workload of healthcare professionals, as the use in practice of these technologies should not entail more data processing. Infrastructural changes and educational initiatives are needed, as well as improvements in digital literacy to further contribute to the acceptance and use of DMDs in daily clinical practice. This is expected to foster a positive transformation of healthcare systems, by reducing waste and inefficiencies and the total cost of care.

1. Introduction

1.1. Leveraging digital health technologies to transform healthcare

Digital health transformation provides many opportunities to improve the resilience, efficiency and quality of healthcare services. It can help decrease healthcare costs, reduce the burden on healthcare professionals and enable patients to receive more personalised care and become more empowered, consequently increasing their quality of life. In the longer term, digital health can drive a more proactive approach towards healthcare, enabling the shift from "sick care" to "health care" and prevention. Finally, it can also help to rethink and reorganise the current care delivery towards more effective, efficient, sustainable and future-proof ways.

There is a rapid evolution in the field of digital health and in the development of technologies referred to as digital medical devices (DMDs). DMDs cover a multitude of solutions that enable diagnosis, monitoring, treatment and follow-up of patients. For these technologies, obtaining CE-marking according to requirements of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) is a mandatory step to gain marketing authorisation in the EU^{3,4}. Despite their promise to improve care delivery, the adoption of DMDs by public healthcare systems in Europe has faced challenges and remains limited. There are several reasons for that, for example:

- DMDs transform existing healthcare systems and the current standard of care, forcing all stakeholders involved, from clinicians to patients, to have a certain degree of digital literacy and to apply new tools/ information to guide decision-making.
- The successful adoption of DMDs requires new investments, e.g. into a digital infrastructure in hospitals or alternative care settings (e.g. patients' homes) and new incentive schemes. Currently, there are only a few evaluation frameworks and no standardised evaluation methods to guide healthcare systems in addressing the uncertainty of investing in digital technologies. This makes it challenging to support payment for digital innovation.

1.2. DMDs: Towards harmonised assessment procedures and dedicated innovation access pathways

As the availability of DMDs in Europe is expected to significantly increase, European regulatory bodies are recognising that existing regulatory frameworks (covered by the MDR and the IVDR) require new methodological approaches and guidance to ensure a conformity assessment along the life cycle of DMDs^{3,4}. The AI Act will play a critical role in the digital transformation in line with EU's 2030 digital objectives^{5,6,7}. The European Health Data Space (EHDS) aims (along with other digital initiatives and if well implemented) to give both healthcare systems and developers of DMDs an opportunity to evaluate the impact of introducing DMDs in real-world settings. EHDS can also enable better access to data needed by DMD developers to train AI algorithms⁸.

Further, EU initiatives such as the development of Testing and Experimenting facilities (TEF-Health) and the Innovative Health Initiative (IHI), as well as national initiatives proposing to build out living labs (e.g. in Luxembourg) aim to provide a supportive infrastructure to apply DMDs in care pathways^{9,10,11}. The crucial element that is currently being worked on, both at the European and Member State level, is the design of evaluation frameworks that account for the specificities of DMDs. Such frameworks would ideally help secure timely and appropriate financing for DMDs (through reimbursement or other financial agreements) and stimulate access to these technologies.

Currently, there is a clear interest in adopting digital innovation access pathways incorporating Health Technology Assessment (HTA) methodologies. Some authorities created first guidelines in support of the introduction and reimbursement of DMDs and AI into clinical pathways, e.g. The National Institute for Health and Care Excellence (NICE) together with York Health Economics Consortium (YHEC) in the UK. In Germany and France, innovative access pathways with specific evaluation frameworks for DMDs are directly informing reimbursement decisions taken by national health insurances^{12,13}. However, the uptake of DMDs is progressing slowly in Europe and market access strategies and timeframes vary greatly across member states due to differing: 1) interest to introduce digital innovation, 2) willingness to structurally transform healthcare (i.e. to advance towards an data-information driven value-based healthcare), and 3) pricing and reimbursement models for selected digital health technologies¹⁴.

Recent developments also indicate a drive towards pan-European harmonisation of methodologies to evaluate DMDs and have highlighted the need for dedicated innovation access pathways.

- In January 2022, the Regulation on HTA (HTAR) entered into force, aiming to establish a joint framework for HTA, based on common methodology and approach for Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs). Highly innovative medical devices that incorporate AI (Class III and IIb drug delivery) are in scope of the HTAR and can be selected for JCAs. Further discussions are also planned in a few years regarding voluntary cooperation by HTA agencies to assess DMDs¹⁵.
- In April 2022, under the French presidency, the European Taskforce for Harmonised Evaluation of Digital Medical Devices was launched with secretarial support of EIT Health². The taskforce seeks voluntary engagement of countries in an exercise to harmonise nomenclature and taxonomy of DMDs and to define future evidence requirements to demonstrate their added value. It also aims to advise the Member State Coordination Group, national responsible authorities and agencies, innovators, and policy makers, to come to the development of a joint DMDs assessment framework and common assessment procedures².
- In January 2024, two European projects were launched focusing on harmonisation of terminology and methodologies in the digital health space: 1) the European Digital Health Technology Assessment framework (EDiHTA), and 2) Assess-DHT - a project which aims to boost the adoption of trustworthy and effective digital health technologies across Europe by developing and harmonising assessment methodologies^{16,17}. A primary task of EDiHTA is, by means of a Delphi methodology, to define and identify a taxonomy of Digital Health Technologies.

2. Objectives and scope

The focus of this reflection paper is on a subset of digital health technologies, which are referred to as digital medical devices and for which CE-marking according to MDR/ IVDR requirements is a mandatory step to gain marketing authorisation in the EU^{3,4}.

The aim of this paper is two-fold: to provide an overview of existing value assessment frameworks for DMDs, with a focus on frameworks informing funding/ reimbursement decisions and adoption in Europe and to reflect on limitations and opportunities offered by these frameworks in view of challenges encountered by DMDs along their life cycle.

3. Overview of existing value assessment frameworks for DMDs

To foster the adoption of DMDs in clinical practice, some countries have implemented digital innovation access pathways that incorporate HTA as one of several tools for value assessment¹⁸. An analysis of eight HTA frameworks that address DMDs directly (e.g. PECAN in France)¹² or indirectly (e.g. NICE in the UK) identified a total of 12 assessment dimensions – nine domains as defined within the EUnetHTA Core Domain Model¹⁹, and three additional domains, namely “Usability”, “Data Security” and “Interoperability”. All HTA frameworks include domains such as “Health Problem and Description of the Application”, “Safety”, “Clinical effectiveness” and “Patient and social aspects”. As indicated in **Figure 1**, more digitally technical domains like “Usability”, “Data security” and “Interoperability” are included in six out of the eight frameworks described.

Figure 1. Domains covered by HTA frameworks for DMDs

	Germany	UK / Wales	France	France	EU	Australia	Finland	Denmark
Domains	DiGA	NICE ESF	Clinical evaluation of CMD	PECAN	MAST	MSAC technical guidelines for HTA	Digi-HTA	MAS-AI
Economic		●	●	●	●	●	●	●
Safety	●	●	●	●	●	●	●	●
Clinical effectiveness	●	●	●	●	●	●	●	●
Patient and social aspects	●	●	●	●	●	●	●	●
Legal	●	●	●	●	●	●		●
Ethical		●	●	●	●	●		●
Organizational	●		●	●	●	●	●	●
Technical aspects and stability	●	●	●	●		●	●	●
Health problem and description of the	●	●	●	●	●	●	●	●
Usability	●	●	●	●		●	●	
Data security	●	●	●	●		●	●	
Interoperability	●	●	●	●		●	●	

Source: MedTech Europe internal analysis

3.1. German DiGA as a digital innovation access pathway – Paving the way?

In 2019, the German Digital Healthcare Act (Digitale-Versorgung-Gesetz/ DVG) introduced a new approach to market access – a uniform framework for Digital Health Applications (DiGA), commonly referred to as an “app on prescription”¹³. At that time, the evaluation process for DMDs already existed in other European countries, e.g. Belgium and the UK, but DiGA was (and still is) considered one of the most applied. The DiGA Fast-Track pathway established market access for certain categories of DMDs that meet the definition of lower-risk medical devices and are primarily used by patients rather than physicians. Those DMDs are eligible for subsequent entry into a DiGA Directory maintained by the German Federal Institute for Drugs and Medical Devices (BfArM). The positive care effects of the DMD being evaluated need to be demonstrated through evidence (e.g. RCTs). When all the criteria are met, the digital solution enters the healthcare system and can be reimbursed by all statutory health insurers in Germany. If evidence is still under development at the time of submission, a temporary listing decision can be made for 12 months, after which the new evidence is assessed and a decision for permanent listing is made.

In recent years, DiGA-like initiatives started proliferating across Europe proposing the use of HTA as part of digital innovation access pathways to inform reimbursement decisions, e.g., France introduced the PECAN (Prise En Charge Anticipée Numérique Numerique) fast-track market innovation access pathway system¹². The limitations of these initiatives are described in sections below.

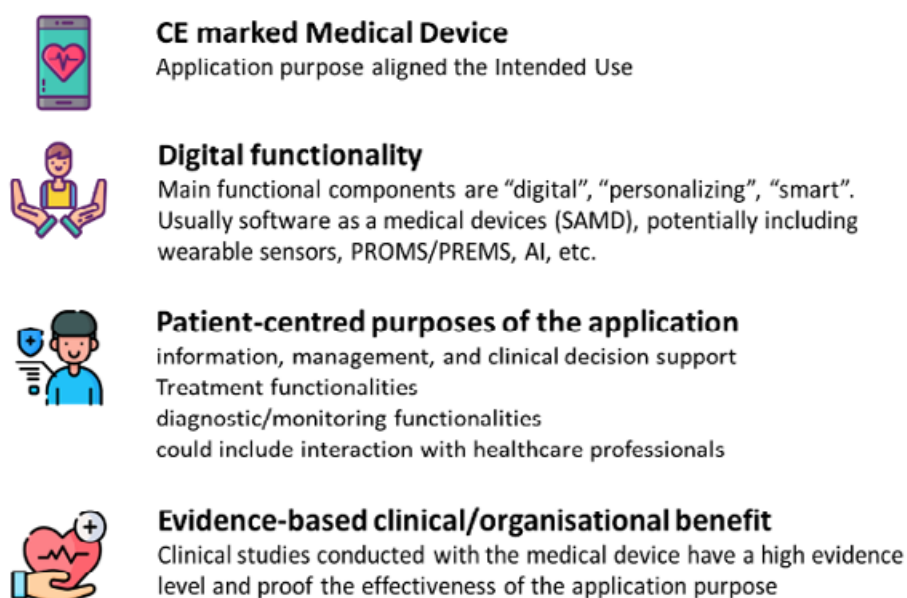
4. Reflection on evaluation frameworks for DMDs: limitations and opportunities

While frameworks to evaluate DMDs and to inform reimbursement are set up in some European countries, the technologies in scope for evaluation remain heterogeneous and limited and there is little consideration of AI features. For example:

- The DiGA includes EU MDR Class I, IIa and IIb medical devices achieving their medical purpose through core digital functions and used either by patients alone or patients and healthcare professionals for the diagnosis, monitoring, treatment or alleviation of diseases or disabilities. This still will be too restrictive to provide a solution for all DMDs²⁰. More particularly, DMDs for use by healthcare professionals should also be in scope.
- In France, the focus is on “innovative” digital therapeutics (PECAN), digital diagnosis (Prise en charge transitoire; PECT) intended for registration on the list of reimbursable services and products (LPPR) and remote monitoring devices intended for registration on the list of medical remote monitoring activities (LATM). There is no limitation related to the MDR risk classes, yet not all DMDs will match the criteria described on these reimbursement lists¹².

EU harmonised evaluation frameworks (e.g. those being developed by the European Taskforce for Harmonised Evaluation of DMDs) are focusing on “medical devices” i.e. DMDs (standalone or part of solutions/ combinations) defined by the MDR/ IVDR^{3,4,15,2}. This Taskforce has advanced the field by proposing a harmonised nomenclature and categorisation of DMDs, based on their intended purpose:² inform, diagnose, manage, monitor and treat. The classification is also based on an analysis of intended beneficiaries of the DMDs, as well as their estimated clinical, organisational, and societal impact. For each of these categories, the aim is to define appropriate and proportionate evidence requirements.

Figure 2. Main characteristics of DMDs



Source: European Taskforce for Harmonised Evaluation of DMDs ⁹

4.1. CE-marking requirements and early assessments of medical technologies

While CE-marking is a mandatory step to gain marketing authorisation for DMDs and officially launch products, not all digital health technologies are medical devices. Although these technologies can bring benefits to healthcare systems (e.g. ward management systems) few assessment frameworks have considered them (e.g. NICE Evidence Standards Framework for Digital Health Technologies in the UK)²¹. It is worth noting that in Germany, alongside DiGA apps, there is a distinct category of digital technologies designed exclusively for care and nursing purposes, known as DiPAs (class I or IIa). DiPAs that are not classified as medical devices and are thus exempt from the regulatory requirements of the MDR, are eligible for reimbursement but must also prove that they fulfil the requirements for safety and functional suitability²⁰.

Conducting early assessments for DMDs can provide valuable insights to manufacturers. One identified example of this is NICE's Medtech Early Technical Assessment (META) Tool - a platform that can be used at any stage of the development of products to help developers understand evidence requirements and make a convincing case for payers/ commissioners. Recently, a dedicated tool has also been made available for AI²².

4.2. Transparency over DMD EU regulatory processes and national requirements

Various EU regulatory frameworks, for example the MDR and the AI Act, ensure patient safety and efficacy and together with the Data Act, the Data Governance Act and the EHDS^{5,6,8} are collectively shaping a comprehensive ecosystem to govern the use of digital technologies in Europe. The EU regulatory framework is getting more and more stringent (which is a direct response to the fast-changing nature and vast marketplace of digital health). Furthermore, our analysis pointed out that additional regulatory requirements exist at the national level for DMDs (e.g. ANS Conformity Assessment in France) and need to be fulfilled before reimbursement application.

In the UK, NICE has been collaborating with the Medicines and Healthcare Products Regulatory Agency to create a streamlined regulatory pathway for digital health technologies. The aim is to ensure that effective and cost-effective digital health technologies can be accessed by patients in the NHS in a timely manner²³. There are numerous organisations in the UK that provide support, advice, and information for each stage of the development life cycle of digital health technologies. Standard practices are already in place and there are several routes to market for companies interested in supplying innovative digital goods and services to the NHS. For instance, the Digital Health London organisation facilitates collaboration between clinicians, healthcare providers, entrepreneurs and industry stakeholders to accelerate the adoption of digital health technologies in clinical practice. This organisation also provides clear pathways to the market for entrepreneurs. Other examples of enabling organisations are the health innovation networks facilitating technology introduction into the NHS²⁴.

4.3. Reimbursement of DMDs

While funding/ reimbursement decisions for health technologies are a national competency in Europe, the development of common methodologies could incentivise member states and regions to consider the value of DMDs more systematically and to learn/ share good practises for DMDs adoption.

At the national/ regional level, evaluations conducted for DMDs should be linked to adequate reimbursement/ funding (i.e. linked to the value-driven/ improved provision of care) and incentivise the adoption of DMDs that have demonstrated benefits for patients and the healthcare system. However, there are only few HTA frameworks linked directly to any type of reimbursement or recommendation to support healthcare decision-makers. As described in **Table 1**, evaluation frameworks linked to innovation access pathways in Europe differ in terms of the scope of technologies considered, the focus of the assessment and the focus on defining quality standards versus opening paths to reimbursement.

Table 1. Examples of reimbursement pathways for DMDs in leading European countries

Dedicated framework on national level					Key stakeholders	Requirements to achieve reimbursement	Timeframe
Country	Scope	Evaluation	Reimbursement	Reimbursement pathways			
Germany	Digital Therapeutics (DTx) Class I, IIa, IIb	●	●	DiGA	-BfArM -Statutory health insurance funds (GKV-Spitzenverband)	-CE Mark -Data on safety, functionality, quality, data protection, data security, interoperability -Data on medical benefits, and/or structural and procedural improvements	-Initial price is the manufacturers price -Negotiate final price after 12 months
France	DTx or telemonitoring activities Class I, IIa, IIb, III	●	●	PECAN platform	-CNEDiMTS/ HAS -Social Security Department of the Ministry of Health -CEPS when there is a transition from PECAN to LPPR and/or LATM registration	-CE Mark -ANS conformity assessment -Clinical dossier -Organizational impact analysis including economics	-Predefined fixed compensation -Negotiate final price after 12 months (only for DTx) -Telemonitoring prices are predefined (no negotiation)
UK	Digital Health Technologies	●	●	-Dedicated NICE Evidence Standards Framework for digital health technologies -MedTech Funding Mandate policy, that can potentially gain national reimbursement for DHTs -DHTs are generally reimbursed a system level through Integrated Care Systems [Integrated Care Systems payor and Integrated Care Board]	-UK CE Mark -Meeting DTAC (digital technology assessment criteria): clinical safety, data protection, technical assurance, interoperability, usability and accessibility	-Varies depending on the path/ region	

Source: IQVIA, MedTech Europe internal analysis, HAS, BfArM, NICE

4.3.1. Varying level of complexity of economic evidence requirements in HTAs

An analysis of HTA frameworks focusing solely on the economic domain of the evaluation revealed a big gap in the level of complexity of the economic evidence required (see Table 2). Interestingly, those frameworks that require heavy and medium-weight economic evidence are not always linked to reimbursement, e.g. in Denmark and in Finland. To follow the Danish Model for Assessment of Artificial Intelligence (MAS-AI), the manufacturer must perform an economic evaluation of the societal impact, provide the business case and explain the use of health services. This process is not linked to reimbursement and currently resembles a checklist for best practices in Denmark²⁵. For the assessment by the Finnish Coordinating Centre for Health Technology Assessment (FINCCHTA), manufacturers must outline the costs for the customer and the healthcare system, including the costs for the setup and the maintenance²⁶. In case the DMD is offered for free, the manufacturer must lay out the sources of funding or income. Moreover, the projected frequency of software updates and device renewals needs to be outlined. All this information must be contextualised with the remaining uncertainty around the cost estimations.

Table 2. Economic evidence requirements and link to reimbursement

Country	Process	Link to reimbursement	Economic endpoints included	Economic evidence requirements	Details
European Union	MAST (27)	No	Yes	Light	-Cost to system pre/post -Business case -Budget impact
Belgium	RIZIV (28)	Yes	Yes	Heavy	-Pricing -Budget impact
Australia	MSAC (29)	No	Yes	Light	-Price -Cost of system (when applicable)
UK	ESF (21)	No	Yes	Unclear	-Economic analysis tied to tier and financial risk (not defined)
France	HAS/ PECAN (12)	Yes	Yes	Medium	-Not mandatory to include -Dependent on data availability
Finland	FINCCHTA (26)	No	Yes	Medium	-Cost for consumer -Cost for healthcare system -Uncertainty of cost
Denmark	MAS-AI (25)	No	Yes	Medium/ Heavy	-Societal economic evaluation -Business case -Use of health service

Source: MedTech Europe internal analysis. Relevant terms: ESF - Evidence Standards Framework for Digital Health Technologies, FINCCHTA - Finnish Coordinating Centre for Health Technology Assessment, HAS - French National Authority for Health, MAS-AI - Model for Assessment of Artificial Intelligence, MAST - framework for the assessment of telemedicine applications, MSAC – Medical Services Advisory Committee, RIZIV - National Institute for Health and Disability Insurance.

*In the section on the UK included in Table 2, we refer specifically to the Evidence Standards Framework for Digital Health Technologies (ESF). Please note that in the UK, the level of economic evidence requirements is determined by the type of NICE evaluation.

4.4. Fast-track toward reimbursement and new methods of evidence generation

Current HTA frameworks, which serve as a blueprint for the evaluation DMDs, are not equipped to address unique, dynamic value considerations of those technologies, especially given the ever-changing field of AI development. In DMDs assessment, the timing and accessibility for patients and healthcare professionals is crucial to generate the best care experience and outcomes, fostering the economic sustainability of healthcare systems. We should strive to maximize access to DMDs while managing uncertainty, setting high quality standards and considering adaptive approaches.

4.4.1. The DiGA fast-track process in Germany

Within the DiGA fast-track process, lower risk DMDs can enter a directory of reimbursable DiGAs maintained by BfArM. This provides an opportunity to conduct evidence-based price negotiations after the first year of the product's marketing and to help drive coverage³⁰. DMDs can be included in the BfArM directory either permanently or provisionally, depending on the availability of evidence. In theory, the DiGA process accepts the generation of real-world evidence (RWE) as one of the ways to create evidence supporting reimbursement. Given the short life cycle of DMDs and the lengthy nature of randomised controlled trials (RCTs), it is clear that RWE should be utilised more. However, from the total of 186 applications submitted for inclusion in the directory³¹, only 24 DiGAs were listed permanently and all of them provided RCTs (as of Sep 2023). This seems to indicate that RCTs are crucial for permanent listing and securing reimbursement under DiGA^{32,33,34}.

4.4.2. UK's early value assessment (EVA) process

Another example of overcoming lengthy evidence-generation processes for DMDs is the UK's early value assessment (EVA) process. It aims to provide recommendations for technology use while evidence continues to be gathered, especially when multiple promising technologies with similar applications are under consideration. The EVA process specifically evaluates technologies that address unmet medical needs, in line with NHS long term plan focused on embracing innovation by integrating real-world data (RWD) and speeding up patients' access to new and effective technologies^{34,35}. For example, the latest assessment conducted in the field of COPD included an evidence gap analysis outlining avenues to address these gaps through RWE. However, the EVA process also applies restrictive reimbursement schemes.

4.4.3. Accelerated coverage pathways for innovation

Some countries in Europe have implemented accelerated coverage pathways for innovation (ACPIs)³⁶. These pathways aim to verify truly innovative technologies in a short period of time (e.g. after one/two year(s)), whereby RWD are gathered and analysed between programme launch and the point of verification. If the key outcomes of the assessment are in line with the value assumptions initially made, the value of the technology will be confirmed, fostering its adoption in clinical practise. In the case of promising and potentially truly innovative digital health technologies, ACPIs might be an impactful instrument for both payers and manufacturers³⁷. However, the existence of these pathways does not automatically guarantee improved adoption of digital health technologies, as success is linked to an appropriate design and implementation³⁸.

4.4.4. Patient access schemes

The implementation of patient access schemes that allow data collection in real-life settings could be a way to accelerate access to DMDs. In some forms, patient access schemes are known as 'risk sharing' or 'rebate' schemes. They can also be referred to as managed entry agreements, as they enable arrangements between companies and healthcare payers/ providers that allow for coverage/ payment of new health technologies while managing uncertainty around their financial impact or performance. Even though financial agreements are the most used, some countries rely on performance-based agreements, which makes companies conditional on product performance³⁹.

4.5. Adoption of DMDs in clinical practice

Looking at the evolving landscape of digital health technologies in Europe, the importance of social acceptance cannot be overstated. A sustainable model for DMDs assessment, along with continued multi-stakeholder engagement, sets the foundation for a framework that prioritises their adoption and retention. It is thus crucial that usability and social acceptance are placed at the centre of the design process to ensure retention and greater patient benefits.

Usability, encompassing ease of use, awareness, incentivisation and integration into existing workflows, is key for the engagement of both healthcare professionals and patients. The trajectory of DiGA prescriptions since its inception and the limited number of prescribers/ early adopters, seems to indicate a "failed" approach to the adoption and retention of DMDs⁴⁰. Physician surveys on DiGA usage in 2020 (i.e. first year of application) reported that only

2% of physicians had issued a DiGA prescription, while 24% indicated that they will issue a DiGA prescription in the future, 10% did not know what DiGA was and 28% answered that they would explicitly not issue a DiGA prescription. In 2021, the number of physicians issuing a DiGA prescription rose to 4%, with a total of 44,000 prescriptions⁴¹. In 2022, the number of DiGA prescriptions almost tripled, which indicates that the initial hesitancy among prescribers and unawareness among patients began to subside⁴². Still, DiGA 2023 uptake numbers have not lived up to expectation. Since 2022, the number of monthly unlocked codes has remained virtually unchanged between 10,000 and 12,000 DiGA. In line with these observations, the German Association of Statutory Health Insurers has highlighted the importance of integrating digital health technologies into care pathways to increase trust and acceptance among doctors and patients.

The UK has also adopted approaches to increase social acceptance for digital health technologies. For example, Digital Technology Assessment Criteria (DTAC) have been identified to reassure stakeholders that all digital health technologies employed within the NHS adhere to national standards. These criteria are established in regulations and industry best practises, covering five essential data categories: clinical safety, data protection, technical security, interoperability and usability & accessibility²¹. The overarching goal is to establish robust and proportional evaluation frameworks for digital health technologies that align with NHS's key objectives and priorities⁴³.

5. Conclusion

Despite the promise of DMDs to transform healthcare, their adoption in clinical practice is very limited, their regulatory environment is still developing and coverage decisions are lacking or incomplete. To increase the adoption of DMDs in various care settings, their full value and impact must be understood. However, at the moment there are no standardised evaluation methods or common language to help address the uncertainty around investing in digital health technologies. While a few frameworks exist to evaluate DMDs and inform reimbursement, the scope of such frameworks remains too restrictive to provide a solution for all DMDs. For example, there is a lack of AI focus and DMDs intended for use by healthcare professionals are generally not in scope.

Setting up comprehensive and adaptive evaluation frameworks for DMDs is crucial and ongoing. An analysis of several existing HTA frameworks and innovation access pathways for DMDs revealed that many of them face several challenges, e.g. limited and different scope across countries; lack of AI focus; assessment timelines not accounting for short DMDs life cycles; evidence generation methods mainly limited to RCTs; and low acceptability of DMDs in clinical care pathways. Those challenges must be recognised and addressed properly to ensure timely access to these technologies.

Advancing towards a more comprehensive and fit-for-purpose evaluation frameworks for DMDs will require acknowledging the rapidly evolving nature of these technologies and their specificities (e.g. shorter life cycle than other technologies). Further, it requires a strategic change, from incorporating only conventional clinical outcomes to considering broader value elements for stakeholders in healthcare (e.g. operational efficiency, personalised care, patient and care provider empowerment, etc.). This is expected to benefit healthcare systems, by reducing waste and inefficiencies. Finally, it requires multi-stakeholder education and engagement, investment into building capacity and specific value assessment expertise, and must be accompanied by changes in the policy environment.

6. References

1. EDiHTA . The first European Digital Health Technology Assessment framework co-created by all stakeholders in the European Health Ecosystem. <https://edihta-project.eu/?playlist=03c706c&video=e6841ee>
2. EIT Health. European Taskforce for Harmonised Evaluations of Digital Medical Devices (DMDs). <https://eithealth.eu/external-collaborations/european-taskforce-for-harmonised-evaluations-of-digital-medical-devices-dmds/>
3. EUR-Lex. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE. 2017. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>
4. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU . 2017. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746>
5. Proposal for a Regulation of the European Parliament and of The Council on harmonised rules on fair access to and use of data (Data Act). 2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN>
6. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence. 2024. <https://eur-lex.europa.eu/eli/req/2024/1689/oj>
7. European Commission (EC). Shaping Europe's digital future. Europe's Digital Decade. 2024. <https://digital-strategy.ec.europa.eu/en/policies/europes-digital-decade>
8. European Commission. European Health Data Space. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
9. ISPOR Spotlight Session. Recommendations for a Harmonized Health Technology Assessment for Digital Medical Devices (DMDs) Across Europe: A Multi-Stakeholder Discussion. ISPOR Europe 2022. <https://www.ispor.org/conferences-education/conferences/past-conferences/isporeurope-2022/program/spotlight-sessions/>
10. TEF-Health Consortium. Testing and Experimentation Facility for Health AI and Robotics. 2024. <https://tefhealth.eu/home>
11. (IHI)., Innovative Health Initiative. 2024. <https://www.ih.europa.eu/>
12. HAS. Guide. Prise en charge anticipée d'un dispositif médical numérique (Art. L.162-1-23 du CSS). 2024. https://has-sante.fr/upload/docs/application/pdf/2023-03/pecan_guide_de_depot_de_dossier.pdf
13. (BfArM)., Federal Institute for Drugs and Medical Devices. The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V: A Guide for Manufacturers, Service Providers and Users. 2020. https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.html
14. Petracca F, Ciani O, Cucciniello M, Tarricone R. Harnessing digital health technologies during and after the COVID-19 pandemic: Context matters. J Med Internet Res. 2020. 22(12). doi: 10.2196/21815.
15. EUR-Lex. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. 2021. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282>
16. European Digital Health Technology Assessment (EDiHTA). <https://edihta-project.eu/>
17. ASSESS-DHT. <https://assess-dht.eu/>
18. KCE. Evaluation of digital medical technologies. https://kce.fgov.be/sites/default/files/2023-01/KCE_362_Evaluation_Digital_Medical_Technologies_Report.pdf.
19. EUnetHTA. A methodological framework for collaborative production and sharing of HTA information. HTA Core Model. 2021. <https://www.eunetha.eu/hta-core-model/>
20. (BfArM)., Federal Institute for Drugs and Medical Devices. DiPA. Digitale Pflegeanwendungen. 2023. https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiPA/_node.html;jsessionid=0C1228A14E41A15BA634B5A5E1796E1B.intranet231
21. (NICE)., National Institute for Health and Care Excellence. NICE Evidence standards framework (ESF) for digital health technologies. 2018. <https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies>
22. Medtech Early Technical Assessment (META) Tool. . 2024. <https://meta.nice.org.uk/>

23. IQVIA. Panel Discussion - A Deep Dive Into The Future of Digital Health Reimbursement Pathways in Europe. 2022
24. DigitalHealth.London. Transforming health and care through digital innovation. 2024. <https://digitalhealth.london/>
25. CIMT. MAS-AI: Model for ASsessment of Artificial Intelligence. 2022-2022. <https://cimt.dk/en/projects/research-and-assessment-projects/mas-ai-model>
26. OYS. FINCCHTA. Kansallinen HTA-koordinaatioyksikkö. <https://oys.fi/fincchta/>
27. CIMT. MAST (Model for Assessment of Telemedicine). 2015. <https://cimt.dk/en/assessment/mast>
28. RIZIV . Campagne 'Digital-In-Health': oproep aan zorgverleners om mee op de kar te springen van digitaal ondersteunde zorg. 2024. Campagne 'Digital-In-Health': oproep aan zorgverleners om mee op de kar te springen van digitaal ondersteunde zorg
29. MSAC. Australia Government HTA Process 2024. <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Factsheet-02>
30. Stern AD, Brönneke J, Debatin JF, Hagen J, Matthies H, Patel S, Clay I, Eskofier B, Herr A, Hoeller K, Jaksa A, Kramer DB, Kyhlstedt M, Lofgren KT, Mahendraratnam N, Muehlan H, Reif S, Riedemann L, Goldsack JC. Advancing digital health applications: priorities for innovation in real-world evidence generation. 2022. 4(3). doi:[https://doi.org/10.1016/S2589-7500\(21\)00292-2](https://doi.org/10.1016/S2589-7500(21)00292-2) : Lancet Digit Health.
31. GKV-Spitzenverband. Fokus: Digitale Gesundheitsanwendungen (DiGA). [https://www.gkv-spitzenverband.de/gkv-spitzenverband/presse/fokus/fokus_diga.jsp#:~:text=Derzeit%20sind%2055%20DiGAs%20gelistet,Antr%C3%A4ge%20zur%20dauerhaften%20Aufnahme\)%20gestellt](https://www.gkv-spitzenverband.de/gkv-spitzenverband/presse/fokus/fokus_diga.jsp#:~:text=Derzeit%20sind%2055%20DiGAs%20gelistet,Antr%C3%A4ge%20zur%20dauerhaften%20Aufnahme)%20gestellt)
32. Chalmers M, Hughes J, Rai D, Saini R. Digital Health Applications (DIGA) in Germany - an Observation of Clinical Evidence Submissions. Value in Health. 2023. 26(12). doi:<https://doi.org/10.1016/j.jval.2023.09.2286> : EYGM Limited.
33. ISPOR Poster. Digital Health Applications (DIGA) in Germany- an Observation of Clinical Evidence Submissions. 2023.
34. (NICE), National Institute for Health and Care Excellence. NICE strategy 2021 to 2026. 2021. <https://www.nice.org.uk/Media/Default/Get-involved/Meetings-In-Public/Public-board-meetings/Mar-24-pbm-NICE-strategy-2021-2026.pdf>
35. (NICE), National Institute for Health and Care Excellence. Early Value Assessment (EVA) for medtech. 2024. <https://www.nice.org.uk/about/what-we-do/eva-for-medtech>
36. MedTech Europe, Taxonomy of Value-Based Access Programmes. Guidance document. . 2020. https://www.medtecheurope.org/wp-content/uploads/2019/06/2020_MTE_Taxonomy-of-Value-Based-Access-Programs-Guidance-Doc.pdf
37. L., Annemans. Access to Medical Technology Innovations: A Proposal for a Value of Innovation and Partnership Model. 2021. <https://www.medtecheurope.org/wp-content/uploads/2021/03/access-to-medical-technology-innovations-a-proposal-for-a-value-of-innovation-and-partnership-model.pdf>.
38. MedTech Reimbursement Consulting. Mapping the pathways enabling market access to innovative medical procedures and technologies. 2022
39. (YHEC)., York Health Economics Consortium. Patient Access Scheme. 2016. <https://yhec.co.uk/glossary/patient-access-scheme/>
40. Statista. Ärzteumfrage: Werden Sie künftig digitale Gesundheitsanwendungen (DiGA) verordnen bzw. haben Sie dies bereits getan? 2020. <https://de.statista.com/statistik/daten/studie/1201096/umfrage/aerzteumfrage-in-deutschland-zur-verordnung-digitaler-gesundheitsanwendungen/>
- 41.(TK),TechnikerKrankenkasse.DiGA-Report2022.<https://www.tk.de/resource/blob/2125136/dd3d3dbafcfcaef0984dcf8576b1d7713/tk-diga-report-2022-data.pdf>.
42. Pharmazeutische Zeitung. Gesundheits-Apps werden öfter verschrieben. 2022. <https://www.pharmazeutische-zeitung.de/gesundheits-apps-werden-oefter-verschrieben-136910/>
43. Unsworth H, Dillon B, Collinson L, Powell H, Salmon M, Oladapo T, Ayiku L, Shield G, Holden J, Patel N, Campbell M, Greaves F, Joshi I, Powell J, Tonnel A. The NICE Evidence Standards Framework for digital health and care technologies - Developing and maintaining an innovative evidence framework with global impact. Digit Health. 2021. 27(7). doi: 10.1177/20552076211018617

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

www.medtecheurope.org

For more information, please contact:

Teresa Barcina Lacosta

Manager Health Technology Assessment

t.barcina@medtecheurope.org



MedTech Europe
from diagnosis to cure