COCIR
Advancing Healthcare

MARKET ACCESS PATHWAYS
for
DIGITAL HEALTH SOLUTIONS

November 2020

COCIR, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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INTRODUCTION

In a society that is becoming increasingly digital, the use of digital health solutions in healthcare is often less common or available than we might expect.

This may come as a surprise, as there are numerous use cases where innovative digital health solutions have led to better health outcomes. This is particularly relevant at a time where public health systems are under heavy strain, and more needs to be done with less resources.

Patients have become accustomed to connectivity and to the availability and accessibility of technology within the reach. This is raising the level of expectation when it comes to what matters most to them - their health.

This has not gone unnoticed; the current ecosystem of digital health is changing with new market entrants from the technology or insurance sectors. However, as with many of the incumbents, they are facing difficulties in bringing their solutions to the market.

As national authorities search for new and better ways to assess innovative technologies, overall coordination is often lacking and can lead to a heavily fragmented European market. Inconsistencies in market access requirements are increasing the time and costs of bringing digital health solutions to market.

The absence of clear links between market authorisation and reimbursement policies is placing further strain on the financial sustainability of innovative companies.

The gap between market authorisation requirements and reimbursement policies is large for conventional health technologies; it is even greater when it comes to digital health technologies, as the authorities' requirements for digital healthcare may differ and there is no single clear guideline.

The European Commission acknowledges that the landscape of digital health services remains fragmented, particularly in case of cross-border care. In its "European Strategy for Data[1]", the European Commission has announced it will tackle barriers to the provision of digital health services and products.

The COVID-19 crisis has further highlighted the value of digital health solutions, for example in diagnosing COVID-19 patients or in supporting continuity of care in a safe and remote way. It has also stressed the need for a clear and swift process for bringing innovative products to the market. While in some Member States the health crisis has led to new or temporary measures in this area, it is important to create a long-term, sustainable framework.

1. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "A European strategy for data" (19 February 2020)*

EXECUTIVE SUMMARY

In a society that is becoming increasingly digital, the use of digital health solutions in healthcare is often less common or available than we might expect.

As national authorities search for new and better ways to assess innovative technologies, overall coordination is often lacking and can lead to a heavily fragmented European market. Inconsistencies in market access requirements are increasing the time and costs of bringing digital health solutions to market and to the patient.

This report is about market access of digital health solutions that already obtained market authorisation or CE-marking, or expect to obtain it in the near future.

We can detect a number of challenges for digital health solutions. Some can be attributed to the competences and responsibilities that EU Member States hold in the area of health. Others are linked to the slow or ineffective adaptation of health systems and market access protocols to changing circumstances and innovative health solutions. At the same time, there are promising developments and initiatives that will facilitate a new approach to evaluating and implementing digital health solutions.

COCIR is aware of the changing dynamic regarding market access for digital health technologies. This document serves as a preliminary analysis of some of the market access approaches that have been initiated at the national level.

As reported through our National Trade Associations members, we took stock of the current situation of market access for digital health solutions in a number of Member States and explored how outcomes are being considered.

It is crucial that Member States learn from each other, evaluate and share best practices, and - in collaboration with industry - construct clear and efficient pathways for digital health solutions, in order to provide patients timely access to the best available care.

Based upon the learnings from the case studies, COCIR would like to open the discussion with all involved stakeholders. To this end, we offer an initial set of recommendations that should establish a more accommodating environment for allowing digital health solutions to reach and benefit all European citizens and patients.

COCIR RECOMMENDS TO THE EUROPEAN COMMISSION TO:

1. **PERFORM** a baseline measurement on market access conditions for digital health solutions as a first step for a coordinated action plan.
2. **FACILITATE** discussions between Member States on the use of clinical evidence and information exchange, including on cost drivers.
3. **ESTABLISH** a fitting data governance framework and structure as part of a European Health Data Space in order to accommodate access to qualitative health data for innovation.
4. **PROMOTE** consistency between and alignment on market authorisation and evidence requirements for reimbursement.
5. **CREATE** guidelines that establish harmonised rules for public procurement by building upon existing European or international frameworks and standards.

COCIR RECOMMENDS TO THE MEMBER STATES TO:

1. **ENSURE** that market access processes are fit for digital health solutions.
2. **CONSTRUCT** a clear pathway from market authorisation to reimbursement.
3. **PROVIDE** conditional reimbursement to digital health solutions based on real world evidence, with the possibility of revoking reimbursement in the absence of demonstrable benefits.
4. **LEVERAGE** market access as a tool to guide investment towards solutions that provide more efficient and effective outcomes.
5. **PROVIDE** clear guidelines on evidence requirements for reimbursement of digital health solutions.

1. MARKET ACCESS FOR DIGITAL HEALTH SOLUTIONS

Digital health solutions have been recognised as providing benefits for all healthcare stakeholders:

- patients and society
- healthcare professionals
- healthcare providers

DIGITAL HEALTH PRODUCTS AND SOLUTIONS ARE
medical technologies and related services which utilise information and communication technologies (ICTs) across the whole range of functions that affect the health sector, that can improve prevention, diagnosis, treatment, monitoring, prediction, prognosis and management of health [2]

There are, however, varying levels of availability and use of digital health solutions throughout the different regions and countries in Europe.

Digital health solutions with a medical purpose will be covered by the Medical Device Regulation, which will come into force on 26 May 2021.

As well as adherence to the general performance and safety requirements for regulatory approval of medical devices, EU Member States may have additional and country-specific procedures in place. These are designed to ensure digital health solutions introduced into their national market are able to meet specific requirements relating to, for example:

- interoperability
- data protection
- cybersecurity
- clinical benefit
- economic impact

Such additional criteria can determine whether, or to which extent, digital health solutions will be reimbursed. Neither these criteria, nor the ways in which to provide evidence in these areas, are harmonised.

Each country has defined, or is in the process of defining, digital health solutions in a different way, with taxonomies being based on different aspects such as risk classification or intended use. On a country level, the definition of digital health solutions from a market access perspective can encompass a wide range of applications (such as telemedicine), be more application-specific (such as teleconsultation), and may include AI-based applications.

Regardless of this, many countries are yet to support the reimbursement of digital health solutions. In its final report on "Shaping the digital transformation in Europe",[3] the European Commission identified that targeted actions to digitise healthcare (extrapolated to EU level) would result in efficiency gains of about 120 billion Euro, out of which 25 billion - around 20% - could be realised by supporting teleconsultation and telemonitoring. These figures underline the urgent need to accelerate the uptake of digital health solutions.

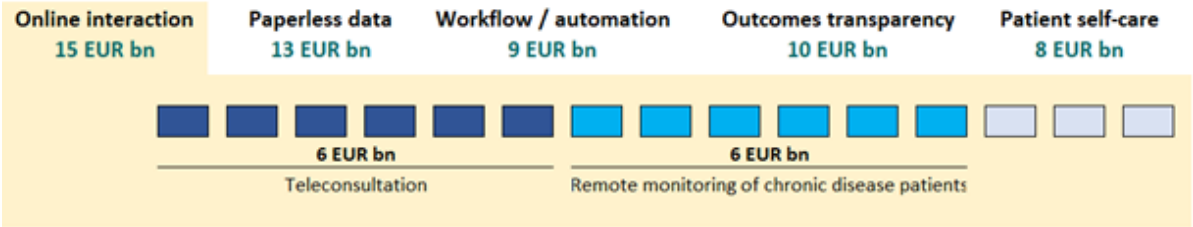


Figure 1 *Benefit potential of digital health solutions for France and Germany (2017-2018) for 26 use cases across five digital domains, capturing reductions in the cost of delivery and/or direct decreases in activity.*[4]

2. *eHealth Stakeholder Group report, Proposed guiding principles for reimbursement of digital health products and solutions (February 2019)*
3. *https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=69479*
4. *Source: German Federal Ministry of the Interior, German Federal Statistical Bureau; French Ministry of Social Affairs and Health (based on 2017 data)*

2. CHALLENGES AND OPPORTUNITIES

With regard to market access for digital health solutions, we can detect a number of challenges. Some of these can be attributed to the competences and responsibilities EU Member States have in the area of health. Others are linked to the slow or ineffective adaptation of health systems and market access protocols to changing circumstances and innovative health solutions.

At the same time, there are promising developments and initiatives that will facilitate a new approach to evaluating and implementing digital health solutions.

CHALLENGES

DECISION-MAKING BY PAYERS FOLLOWS DIFFERENT METHODOLOGIES AT COUNTRY LEVEL

There are four cost management systems that represent different cost management philosophies:

1. Therapeutic referencing – these systems limit pricing and reimbursement relative to a reference therapy
2. Health economic driven – these systems primarily use cost-effectiveness
3. Competitive insurance – these systems favour a free market approach to private health insurance whereby payers compete based on their offering
4. Emerging cash - these systems mostly lack health coverage, and most payments are made out-of-pocket by the patient.

In Europe, the therapeutic referencing and health economic-driven systems are the most commonly used. Differences in cost management systems do, however, determine to a large extent if and how digital health solutions are being reimbursed as well as what type of evidence is required.

CLARITY AND FEASIBILITY ON PROVIDING (CLINICAL AND ECONOMIC) EVIDENCE

The exponential growth in data and availability of technology and computing power is fuelling innovation in the digital health sphere. The speed of innovation in digital healthcare is, however, not always matched by existing market access protocols.

This may result in procedures that are not fit for, or adapted to, the latest technologies. As a consequence, the evidence requested may be costly to produce and/or irrelevant or ineffective in demonstrating the value of the digital health solution in question. Competent authorities may also lack the resources or expertise to make the correct judgment.

In addition, timelines for producing clinical and economic evidence may be counter-productive to the iterative development cycles of digital health solutions, which aim to further improve the health outcomes.

LACK OF RESOURCES WITHIN COMPANIES

Fragmentation of market access requirements in EU Member States can multiply work and costs. This increase in the administrative burden is putting a strain on companies' available resources.

Companies may need to invest heavily in specialised profiles to address these challenges, or decide to only focus on one or a few national markets. This is not limited to SMEs, but may particularly impact them, a fact acknowledged in the European Commission's report on critical industrial applications of artificial intelligence.[5]

These constraints to scaling up digital health solutions also affect the patient. Availability of digital health solutions may be limited in some countries, undermining the principle of equitable access to the best care possible for all EU citizens.

5. *European Commission (DG GROW/EASME) study "Critical industrial applications: report on market analysis of prioritised value chains, the most critical AI applications the conditions for AI rollout"*

NO ALIGNMENT BETWEEN MARKET AUTHORISATION AND REIMBURSEMENT PROCEDURES

Digital health solutions are being developed to address unmet health needs. Proving clinical benefits should also consider the use of real world evidence (RWE) as an evidence generation strategy and for the purpose of a post-market study. This is a different perspective from relying solely on strict clinical studies in a controlled environment, as is the case with clinical studies using a randomised control trial design.

The viability of digital health solutions may be highly dependent on the applicable payment model. The time between initial market authorisation and the actual reimbursement, which may be lengthened due to the period required to generate and evaluate (new) evidence on the benefits of the technology, should therefore be kept as short as is practically possible, in order to ensure financial security and stability.

ABSENCE OF A VALUE-DRIVEN INTEGRATED CARE APPROACH

Many health systems lack a value-driven integrated care approach. The compartmentalisation of care leads to multiple inefficiencies:

- Different payment mechanisms may apply, based on the type of care or the location where the care has been provided (e.g. in-patient vs out-patient) or may require administrative adjustments that complicate the process (e.g. coding or DRG[6] updates).
- Process-related outcomes may not be taken into consideration for reimbursement, even where they can lead to improved patient benefits (e.g. triaging pulmonary embolism or stroke patients in radiology reading workflows can lead to patients receiving critical care in time, thus reducing mortality rates).
- Health outcomes may be compounded by other decisions within the care pathway, for instance based on the choice of treatment by the healthcare professional. In addition, measuring and perceiving the impact on certain health outcomes requires real-world data in clinical settings.
- There are no incentives to optimise those processes or structures where another actor benefits (e.g. efficiency and savings in hospitals through AI may be less relevant for a payer).

OPPORTUNITIES

NEW DYNAMICS THROUGH NATIONAL INITIATIVES

In order to realise the digital transformation of health and care, countries are establishing their own national eHealth strategies. These are essential in progressing new ways of evaluating and integrating digital health solutions. At the same time, countries can learn from each other's approach and experiences.

Germany is the most recent example of a Member State trying to lead in the area of digital health solutions and quality of care, by enacting the Digital Healthcare Act.[7]

INCREASED EXPECTATIONS FROM STAKEHOLDERS AND STRONG PUSH AT EU LEVEL TO LEVERAGE BENEFIT OF DIGITAL TRANSFORMATION OF HEALTH AND CARE

Patients and citizens are increasingly making more use of digital and connected technology. Their personal use, understanding and acceptance of technology is increasing their expectations of, and relationship with, the health system.

A person-centred approach in the digital transformation of health and care[8] should further empower patients and citizens by making their health data available to themselves - and others they wish to share it with - in a secure and digital manner. Data portability and data sharing options will create new possibilities for digital health technologies to interact with patients and provide the possibility for direct input and feedback.

6. *DRG – Diagnosis Related Group: a classification system that identifies the products or services that a patient has received*
7. *The Act to Improve Healthcare provision through Digitalisation and Innovation (Digital Healthcare Act)*
8. *European Commission Communication on Digital Transformation of Health and Care in the Digital Single Market*

INNOVATIVE PAYMENT MODELS

Some countries have now started to establish innovative payment models. These provide a fast-track process for innovative technologies for early market access. In practice, this creates a temporary framework that allows innovative technologies to be funded in anticipation of a permanent long-term recognition for reimbursement, as is the case with existing market access protocols.

STRATEGIC DISCUSSIONS ON THE USE OF HEALTH DATA

Data is considered a valuable resource, one that will help drive new insights and innovative technologies in a number of different sectors. To capture that potential, the European Commission in its European Strategy for Data[9] has announced the creation of common European data spaces.

A European Health Data Space will facilitate the large-scale availability and accessibility of health data for research and other purposes. It may also have a catalysing effect on the uptake of trust-enhancing technologies, which currently lack strong incentives.

By defining clear requirements on data quality and provenance, the availability of real world data in such a system would be critical to evaluate real world outcomes and to demonstrate the benefit and value of the digital health solutions.

COVID-19

The COVID-19 crisis has accelerated the uptake and acceptance of digital health solutions, on both the side of the healthcare providers and professionals, as well as on the side of patients.

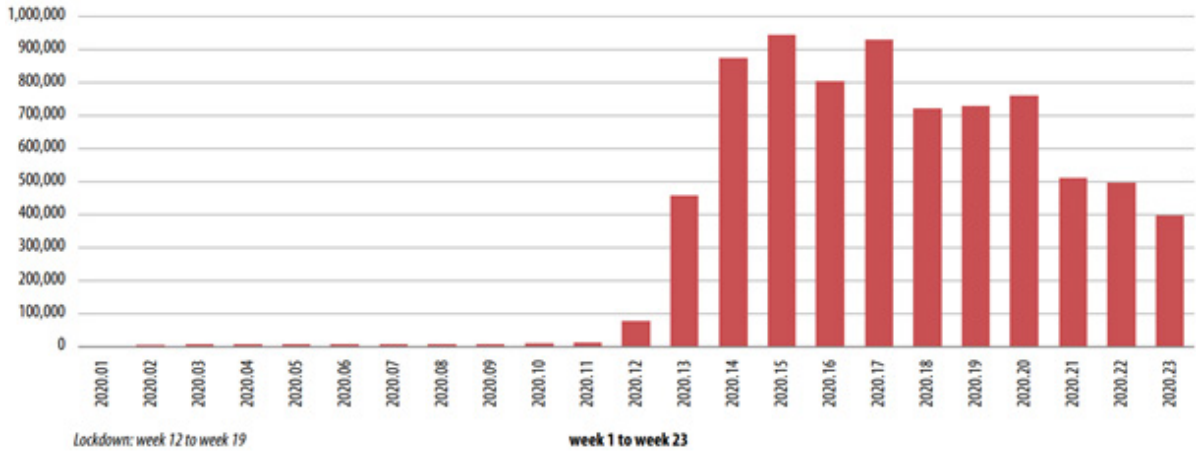


Figure 2 *Number of teleconsultations in France, 2020 (Week 1 to Week 23)[10], source: CNAM*

There has, for example, been a substantial increase in the use of telemedicine. This is because it has provided a safe option for pre-triaging potential patients or for accommodating remote supervision to ensure continuity of care for patients, whether affected by COVID-19 or not.

While the use of digital health solutions may decrease again as the situation normalises, there may be a lasting effect.

9. https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy
10. *EuroHealth 2020; 26(2) – Keeping what works: Remote consultations during the COVID-19 pandemic -* https://apps.who.int/iris/bitstream/handle/10665/336301/Eurohealth-26-2-73-76-eng.pdf

3. EXPERIENCE FROM MEMBER STATES

In Europe, there are varying levels of digital health integration across countries and regions. There are many underlying reasons (e.g. historical, political, structural, cultural) explaining some of these differences; however, when it comes to business models and incentives to innovate, the applicable market access processes play an important role.

COCIR is aware of the dynamic environment of market access for digital health solutions. The overview of countries covered within this chapter only provide a limited and preliminary analysis of some of the current market access approaches initiated at the national level.

BELGIUM

mHEALTH

Belgium has a specific process in place for mobile health solutions, which consists of three levels; the so-called 'validation pyramid'. Only applications that are classified as a medical device are being considered.

Figure 3 *mHealth Belgium validation pyramid*[11]

Level 3 apps can be reimbursed by RIZIV/INAMI (the National Institute for Health and Disability Insurance - NIHDI) if the social-economic added value has been demonstrated.

The criteria for reimbursement of Level 3 apps still need to be defined.[12] However, this is in its final stages. The criteria and the process are expected to be available by the end of 2020.

Level 3 apps must also meet the criteria for Level 1 and Level 2. This includes classification as a medical device, compliance with data protection rules and an independently validated risk assessment on the interoperability and connectivity with the local eHealth services, including security aspects.

In anticipation of reimbursement by the NIHDI, a private health insurance company is already reimbursing all listed apps to its clients.

TELEHEALTH

Teleconsultations are being reimbursed during the crisis where these are being used to support the triage of possible COVID-19 patients or to provide continuity of care to existing patients[13].

11. *https://mhealthbelgium.be/validation-pyramid*
12. *The NIHDI has initiated a pilot project in which for the very first time a mobile health app will be reimbursed to participants in a clinical trial*
13. *https://www.agoria.be/nl/Coronavirus-leidt-tot-artsenvergoeding-voor-teleconsultaties*

The use of teleconsultation comes at no cost to the user and the healthcare professional is directly being reimbursed by the NIHDI for the amount of € 20.

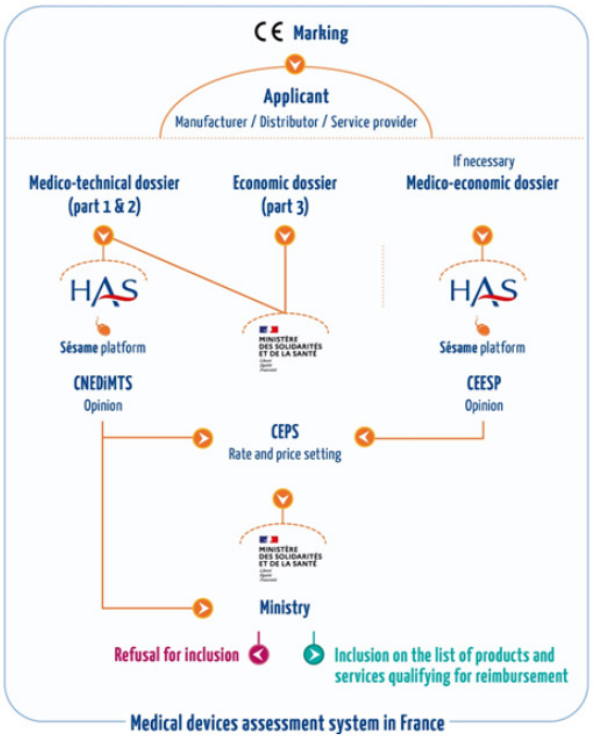
The conditions for reimbursement require the teleconsultation platform to offer:

- synchronous communication
- both parties being able to hear (and preferable see) each other
- both parties being able to identify themselves and verify the other person's identity.

FRANCE

CONNECTED MEDICAL DEVICES (CMD)

For connected medical devices used by individuals, the reimbursement process is based on a registry of the list of procedures and services (the so-called 'LPP').[14] In order to be listed on the LPP, the CMD must be assessed by the Haute Autorité de Santé (HAS) and priced by the French Healthcare Products Pricing Committee (CEPS[15])



The Medical Device and Health Technology Evaluation Committee (CNEDiMTS) evaluates only CMDs that meet the following criteria:

- They are intended for use for medical purposes (CE-marked)
- They are for individual use
- They have a telecommunication function
- The company has submitted an application for reimbursement.

14. *Liste des produits et prestations remboursables*
15. *Comité économique des produits de santé*

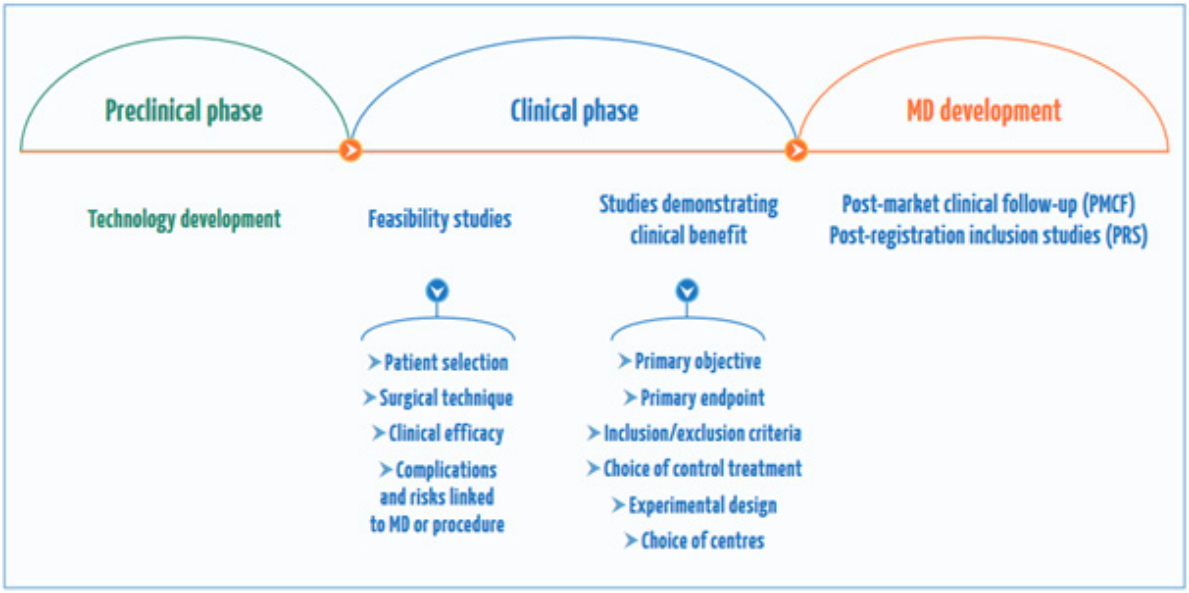
The CNEDiMTS has developed a guide to the specific features of clinical evaluation of a CMD in view of its application for reimbursement.[16]

The CNEDiMTS evaluation is complementary to that of CE marking, and aims to evaluate the usefulness of the medical device for the patient and for public health.

Compliance with the General Data Protection Regulation is a prerequisite, but is not evaluated by the CNEDiMTS.

The CNEDiMTS is also not responsible for evaluating the algorithmic functioning of the model, even although information needs to be provided on both on the way in which the algorithm was created and on monitoring of the relevance of the algorithm.

The CNEDiMTS evaluates the actual clinical benefit and clinical added value. The actual clinical benefit is evaluated at patient level and population level. The clinical added value has an impact on the tariff negotiated by the French Healthcare Products Pricing Committee. Listing for reimbursement is granted for a maximum of five years.



For as long as technology is evolving, the CNEDiMTS can request that post-registration studies be set up. In particular, these studies are used to confirm the benefit of the CMD in a real-world use scenario.

The CNEDiMTS has recently updated its guidance documents on how to apply, including specific requirements for AI-based systems [17] [18].

When a CMD is used through a procedure by a healthcare professional, this procedure must be registered on the Common Classification of Medical Acts (CCAM).[19] In this event, the price of the CMD is included in the Act. To be listed on the CCAM, the first step in this process is to be assessed by the HAS.

The application for including the procedure in the HAS, copying in the UNCAM (National union of health Insurance funds), is completed by the professional body representing professionals that are concerned by the performance of the procedure. The CNEDiMTS may also act on its own initiative.

The HAS recommendation is then sent to the UNCAM, which will structure and position the procedure among all the others and find an agreement with healthcare professionals to price it.

16. *Guide to the specific features of clinical evaluation of connected medical device (CMD) in view of its application for reimbursement*
17. *https://www.has-sante.fr/upload/docs/application/pdf/2016-01/guide_fabricant_2016_01_11_cnedimts_vd.pdf#page=51*
18. *https://www.has-sante.fr/upload/docs/application/pdf/2020-10/fi_guide_de_depot__2020_10_01.pdf#page=41*
19. *Classification Commune des Actes Médicaux*

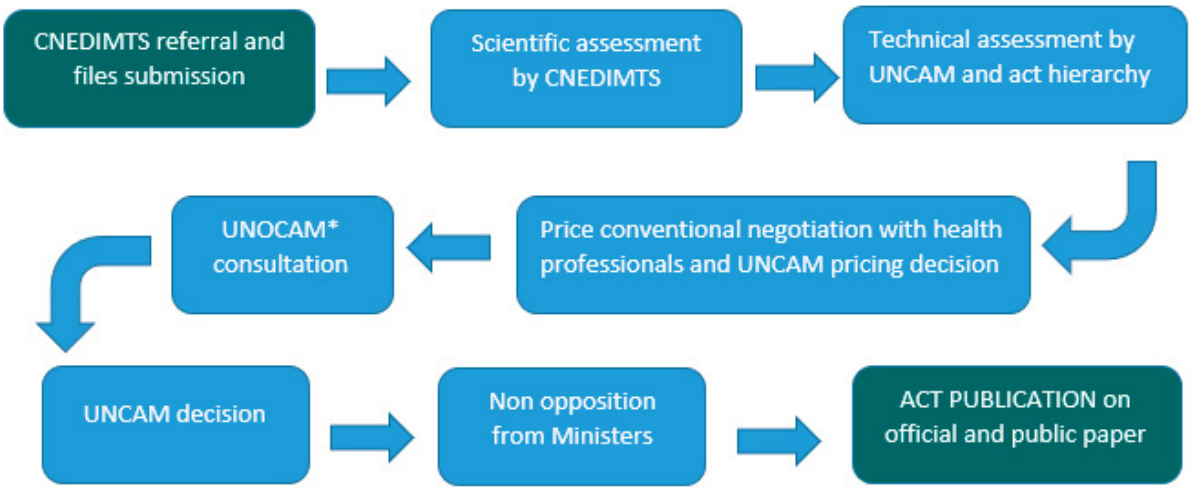


Figure 4 *Act assessment and reimbursement process*

This procedure is relatively unclear and very long.

- The average time to be processed by the HAS is about 500 days.
- The UNCAM average file review time was 581 days.[20]
- Files that are still being processed have been so for, on average, 955 days.
- The average time to have an Act published is 1000 days.

In addition, for various reasons the HAS / CNEDIMTS does not assess all requests, for example the low quality of a file. For example, out of 30 requests for assessment submitted by learned societies in 2015, only two were accepted for assessment in 2016.

There is also no opportunity for industry to be involved in this process.

Some changes have been introduced in this procedure by the French social security financing bill for 2020, but the implementation decree has not been published as yet.

TELEMEDICINE

French legislation defines five disciplines of telemedicine[21] :

1. TELECONSULTATION (TLC) - TLC allows a medical health professional to provide a consultation remotely via information and communication technologies. It is a medical act and a synchronous action (patient and doctor talk to each other). It allows the medical health professional to undertake an overall assessment of the patient, in order to define the action to be taken following this teleconsultation.

2. TELESURVEILLANCE (REMOTE MONITORING - TLS) - TLS allows a medical professional to remotely interpret data collected from the patient's home.

3. TELE-EXPERTISE (TLX) - TLX enables a medical professional to solicit the advice of one or more medical professional colleagues remotely through information and communication technologies. First of all, it is a medical act and an asynchronous action (patient and doctor do not speak to each other). This concerns two doctors during, or at a distance from, the initial consultation. This share was not remunerated until now.

4. TELEASSISTANCE (TLA) - TLA allows a medical professional to remotely assist another health professional colleague while performing an act.

5. MEDICAL REGULATION - Medical regulation is the medical response provided as part of the activity of the centres for emergencies (Phone number 15 in France)

20. https://www.vie-publique.fr/sites/default/files/rapport/pdf/124000579.pdf (page 73)
21. https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/telemedecine/article/la-telemedecine

The current status of reimbursement is as follows

TLC	In France, each patient can make use of teleconsultations. This process has been reimbursed since 1 August 2018. The medical doctor in charge evaluates whether the patient needs a teleconsultation or if they need a visit *in situ*.
TLX	Tele-expertise between two healthcare professionals is also reimbursed since 2018, through the TLX act.
TLS	This telemedicine discipline has been under review in France since 2018 and the French Ministry of Health has decided to renew experimentation for a further four years, until 2022. TLS Acts should be created by the end of 2021 to remunerate each actor of a telesurveillance act (MD, technical solutions/industrial, paramedic). The goal of these experiments is to create Acts and Acts pricing for specific pathologies. For that purpose, the health ministry has published five technical specifications in 2016 for: • cardiac insufficiency • respiratory insufficiency • renal insufficiency • diabetes • implantable cardiac prosthesis

Teleassistance and medical regulation responses are more focused on organisational measures and do not include the patient. These are therefore not subject to specific market access procedures.

RECENT DEVELOPMENTS

As from this year, the health ministry has decided to include a new 'tele-discipline', to allow pharmacists and paramedical professionals to provide remote care : TELECARE (or *Télésoin* in French)

This offers the possibility for pharmacists and paramedics to organise patient care using digital communication technologies.

GERMANY

Regarding reimbursement, Digital Health Applications are considered in the same way as other health procedures and methods. There is a defined pathway to reimbursement for new procedures or methods. In-patient and out-patient health services are subject to different reimbursement systems.

In addition to this normal pathway, which is complex and requires considerable efforts, the Digital Healthcare Act (Digitale-Versorgungs-Gesetz, DVG)[22] of 19 December 2019 now stipulates reimbursement criteria for patient-oriented digital health applications (DiGAs) that are Medical Devices of low risk.

DiGAs typically take the form of apps on a patient's smartphone. Given the definition, DiGA cover just a small part of possible digital health applications as they are primarily intended to be used by patients or in adherence with patients, not by physicians.

22. *https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl119s2562.pdf*

Digital health applications are considered as those classified as Class I and Class IIa under the Medical Devices Regulation. Other applications that fall into Class IIb and III (high-risk) are not regarded as DiGAs. Digital health applications that are not DiGAs have to follow the usual pathway for reimbursement by statutory health insurance.[23]

As a matter of principle, DiGAs can be prescribed by healthcare providers and reimbursed by the statutory health insurance if they are:

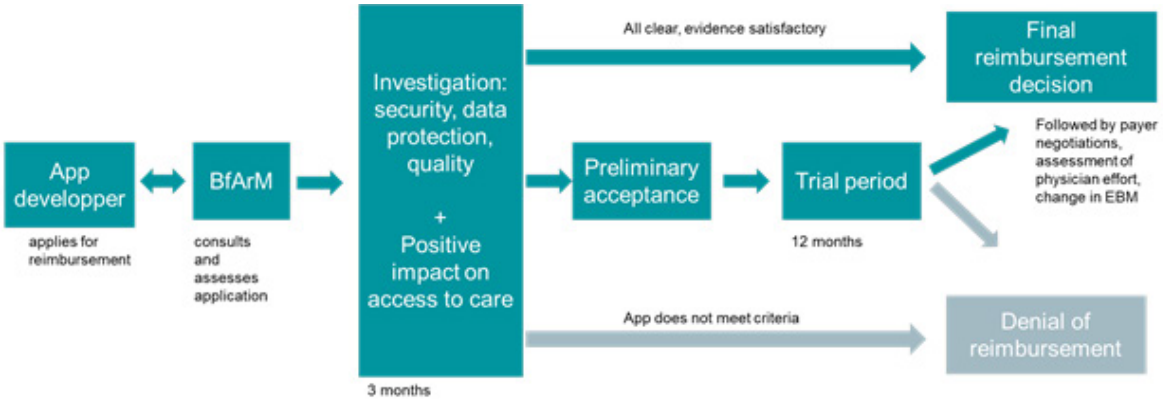
- listed in the DiGA catalogue[24] of the Federal Institute for Drugs and Medical Devices (BfArM) based on § 139e SGB V;
- prescribed by either the treating physician or applied following the payer's approval.

To be listed in the DiGA catalogue, the manufacturer submits an application to BfArM. This application starts a so-called fast-track procedure, which should take no longer than three months.. BfArM will assess the application based on a range of criteria that are laid out in the Digital Health App Regulation (Digitale Gesundheitsanwendungen-Verordnung, DiGAV[25]). These criteria include:

- safety, functionality and quality of the application
- interoperability with the existing health IT infrastructure
- data protection and data safety
- positive effects on care, divided into two groups of equally accepted value:
  - medical benefits (for example improvement of the state of health, reduction of the duration of a disease, prolongation of survival)
  - patient-relevant improvement of structure and processes (for example coordination of treatment processes, facilitating access to care, health literacy, patient autonomy)

If a manufacturer is not yet able to provide evidence on the positive effects on care, BfArM can agree to a testing phase of up to 12 months (and a further extension of maximum 12 months), while the application is listed in the BfArM catalogue. During this time, the app will be reimbursed up to the cost indicated by the manufacturer.

Following the testing phase and a subsequent positive assessment by BfArM, the manufacturer will enter into negotiations with the statutory health insurance. It is important to note that the general physicians' fee schedule (EBM catalogue) will then also cover additional time spent by physicians in relation to the DiGA prescription/management. However, the manufacturer of the DiGA should define the required physician services in relation to its use, so that they may be reimbursed.



By 1 November 2020, there were five digital health apps listed in the DiGA catalogue.

23. *The process for digital health applications that are not DiGA follows that defined in IQWIG's General Methods document. See also: https://www.iqwig.de/en/methods/methods-paper.3020.html*
24. *https://diga.bfarm.de/de/verzeichnis*
25. *http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl120s0768.pdf*

SPAIN

In Spain, health is largely decentralised, with the 17 regional Autonomous Communities managing their own public health services.

A recent study by Fenin, the Spanish Federation of Healthcare Technology Companies, on the maturity level of digital health in Spain[26] has shown the different degrees of development of digital health infrastructures among these Autonomous Communities. Existing infrastructures are only able to support a limited number of services and there are problems equipping them to incorporate information into the Spanish National Health System.

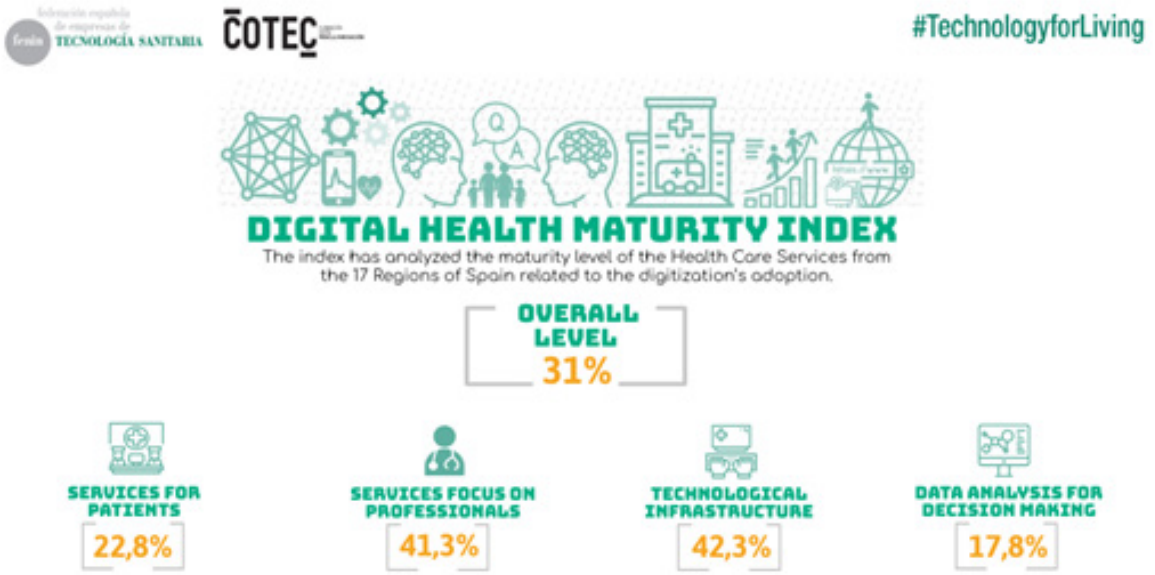


Figure 5 *Availability of digital health solutions within Spain*

The situation of digital health in Spain, which now under debate, is pending a significant economic investment that will take time to be addressed effectively.

In July 2020, the national government announced the Digitalisation Plan "Digital Spain 2025".[27] This plans to invest in the digital transformation of the health sector as a strategic sector, and takes into account the possibilities it could offer in the context of a pandemic crisis.

At the moment, there is no reimbursement for digital health solutions by the public health system. All health services are provided to the patient without reimbursement, with exception of some single-use medical products that are provided through pharmacies.

There is no regulation in place addressing the payment for services provided by private parties to the public health system when it comes to digital health solutions.

In the private health sector - depending on the insurer - there is the possibility of making use of teleconsultation services. However, these services come at additional cost, as they are not covered by basic health insurance plans.

26. https://www.fenin.es/resources/estudios/708
27. https://www.lamoncloa.gob.es/presidente/actividades/Documents/2020/230720-Espa%C3%B1aDigital_2025.pdf

SWEDEN

Healthcare within Sweden is mainly tax-financed and has a decentralised organisation. Health policy and guidelines are developed at a national level, while the 21 regions enjoy a high level of autonomy. In addition, 290 municipalities are responsible for certain types of care, including the elderly and support for people with physical disabilities or psychological disorders. In practice, this leads to situations where responsibilities are shared or overlap.

In addition, budgets and procedures are fragmented across the patient journey, and success for a digital health technology company will depend heavily on the customer's level of care or care setting (i.e. primary care, hospital, out-patient, home care, etc). As a consequence, savings and efficiency gains are being missed, as there are little or no incentives for one level of care setting to invest to reduce the cost at another.

A few private players were the first to offer digital healthcare services on a larger scale in Sweden. Via subcontracting agreements with private health centres a few years back, they gained access to public funding.

Currently, SALAR[28] has a national recommendation to the regions for the pricing of digital care, along with a minimum patient fee. Through this, digital visits to the different healthcare providers is reimbursed as long as they are connected to the Swedish national healthcare insurance system, regardless of whether they are private or public providers.

The Swedish Government and SALAR agreed, in 2016, on a joint vision for eHealth, stating that that Sweden should be best in the world at utilising the opportunities of the digitisation by 2025. Today, Sweden is in the top-tier in Europe in digital maturity. Despite this - and even as a country with a very advanced digital health system – it is still slipping when it comes to implementation and actual use.

There are many ongoing initiatives in the effort to realise this vision, one example being the initiative *Coordinated Implementation of Digital Products and Services* with the objective of facilitating the implementation of digital tools. The implementation model, which is still under development, includes a proposal for national prioritisation of possible treatments as well as one for establishing a common library of requirements of, for example, technical safety, usability, health economic aspects as well as clinical effects.

UNITED KINGDOM (ENGLAND)

In the UK, the National Institute for Health and Care Excellence (NICE) has worked with NHS England, Public Health England, MEDCITY and Digital Health London to develop a trusted and respected set of standards on what evidence to produce for different types of digital health technologies. This 'Evidence Standards Framework for Digital Health Technologies' (DHTs) enables the innovators to understand the level of evidence they will need to produce. This makes evidence generation plans faster and more cost-effective for them, allowing the NHS to commission, deploy and scale clinically and cost-effective digital health tools that meet demand.[29]

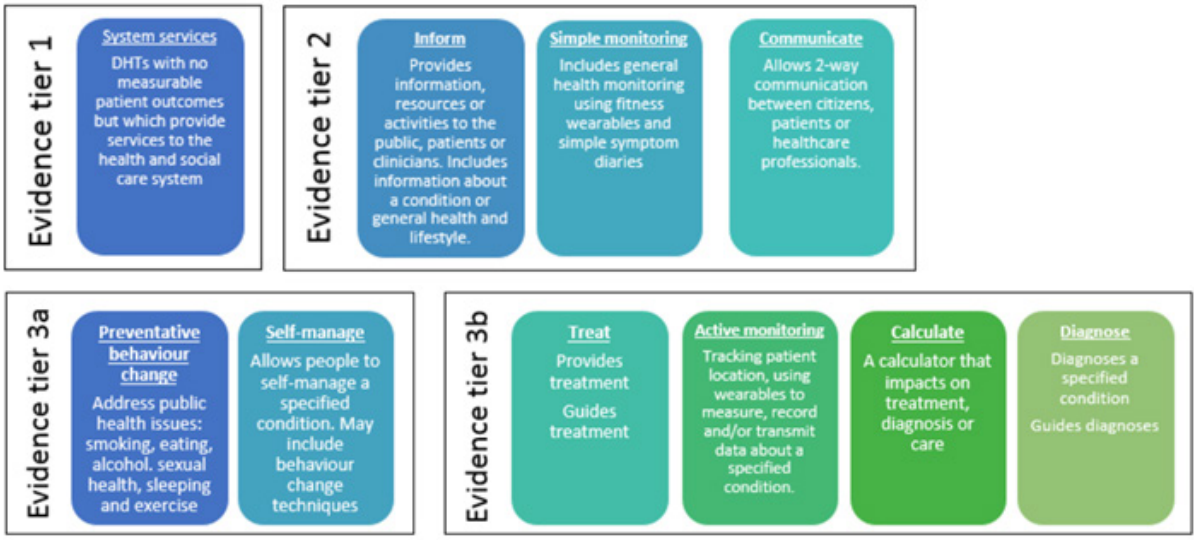
28. *The Swedish Association of Local Authorities and Regions (SALAR) is an employers' organisation that also represents and advocates local government in Sweden. All municipalities and regions are members of SALAR.*

29. *https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf*

The framework describes standards for the evidence that should be available, or developed, for DHTs to demonstrate their value to the UK healthcare system. This includes evidence of effectiveness relevant to the intended use(s) of the technology and evidence of the economic impact relative to the financial risk. The evidence standards framework is intended to be used by technology developers to inform their evidence-development plans, and by decision makers who are considering whether to commission a DHT.

There are two main sections to evaluating DHT. Section A comprises evidence for effectiveness standards; section B comprises evidence for economic impact standards. The evidence standards framework is not suitable for all DHTs, as the framework has been designed for DHTs that are commissioned in the UK healthcare system, it is therefore less relevant to DHTs that are downloaded or purchased directly by users (such as through app stores).

The framework defines a functional classification of digital health technologies. This classification determines the evidence requirements, while the contextual questions further determine what depth of evidence is required.



Standards cover multiple types of evidence linked to different evidence categories.

The evidence tiers are cumulative, meaning the digital health technology should also meet the standards in the previous tiers.

The framework defines both minimum evidence standards as well as a best practice evidence standards for each evidence category.

Best practice evidence standards should be used for technologies that present a potential high risk.

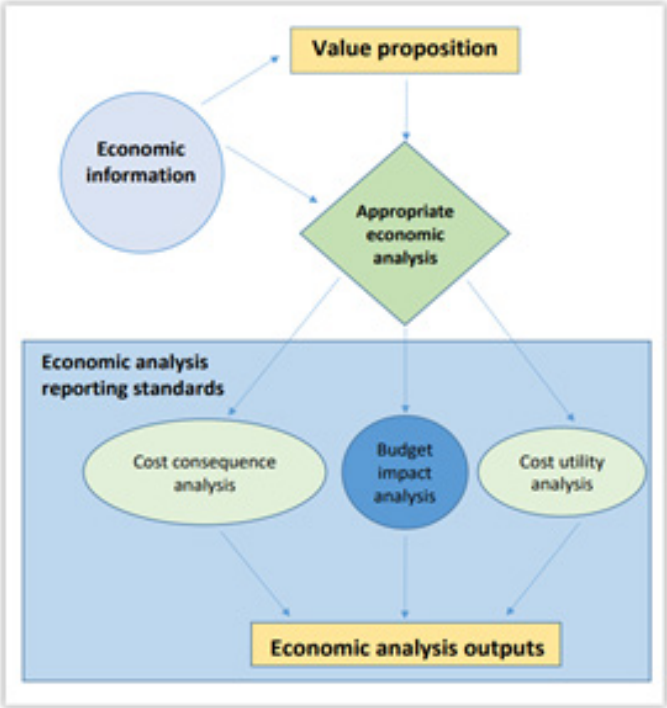
Tier	Evidence category
1	Credibility with UK health and social care professionals Relevance to current care pathways Acceptability with users Equalities considerations Accurate and reliable measurements Accurate and reliable transmission of data
2	Reliable information content Ongoing data collection to show usage of the DHT Ongoing data collection to show value of the DHT Quality and safeguarding
3a	Use of appropriate behaviour change techniques
3a&b	Demonstrating effectiveness

Contextual questions help to identify higher-risk technologies:

- Are the intended users considered to be in a potentially vulnerable group?
- How serious could the consequences be to the user if the technology failed to perform as described?
- Is the DHT intended to be used with regular support from a suitably qualified and experienced health or social care professional?

- Does the DHT include machine learning algorithms or artificial intelligence?
- Is the financial or organisational risk of the DHT expected to be very high?

Furthermore, the framework also defines evidence for economic impact standards, related to key economic information, appropriate economic analysis (budget-impact, cost-sequence or cost-utility analysis) and economic analysis reporting standards.



The DHT framework covers all digital health and care technologies being commissioned and/or purchased in the NHS and the English social care system. However, the framework excludes technologies with adaptive algorithms and does not assess the regulatory requirements. This is mainly because the manufacturer needs to pass that regulatory threshold in any case, prior to the market access process that examines safety and other regulatory aspects (which do not replace the CE marking process), compliance with data protection and security rules, as well as performing a technical assessment.

NHS APPS LIBRARY

For patient-facing health apps, the NHS Apps Library can be used as a platform to review the quality and to support the adoption of the technology. NHS Apps Library is a tool of NHSX that collects all the health apps that have been assessed against national standards and that are proven to be safe and secure[30]. However, the presence of the app in the NHS Apps Library does not mean funding or reimbursement will be mandated, as this is decided individually by the CCGs/NHS Trusts. NHS Apps Library only facilitates the app commissioning decision to the CCGs/NHS Trusts.

As of October 2020, there were 97 apps in the NHS Apps Library.

Previously, the apps in the NHS Apps library were assessed using the Digital Assessment Questions. Since October 2020, this has changed to assessment through the Digital Technology Assessment Criteria.

For patients-facing apps, it is advisable that health apps developers register them in the NHS Apps library, to support their acceptance and adoption by providers and commissioners. These apps have been assessed against national standards and are proven to be safe and secure. There is a formalised process for apps to gain acceptance into the library, which (as of October 2020) is at a beta-testing phase.[31]

The assessment criteria focus on five core areas:

1. CLINICAL SAFETY assessed to ensure that baseline clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk.
2. DATA PROTECTION assessed to ensure that data protection and privacy is 'by design' and the rights of individuals are protected.
3. TECHNICAL ASSURANCE assessed to ensure that the products are secure and stable.
4. INTEROPERABILITY assessed to ensure that data is communicated accurately and quickly whilst remaining safe and secure.

30. https://digital.nhs.uk/services/nhs-apps-library
31. https://www.nhsx.nhs.uk/key-tools-and-info/designing-and-building-products-and-services/

5. USABILITY AND ACCESSIBILITY products are allocated a conformity rating, having been benchmarked against good practice. Where there are areas for improvement, recommendations will be made accordingly.

There is no national reimbursement framework for health apps in England. It is up to Clinical Commissioning Groups (CCGs) and NHS Trusts to negotiate reimbursement with the developers.

MARKET ACCESS PATHWAYS FOR DHTS

The DHTs framework issued by NICE is intended to be used by app developers and commissioners (CCGs/Trusts), to understand how good levels of evidence for DHTs should look.

Nevertheless, there is no direct connection between the NICE review of DHTs and reimbursement decisions. The same holds valid for the apps listed in the NHS Apps Library. A positive endorsement from NICE can, however, support the acceptance and adoption of the health app by providers and commissioners.

RECENT DEVELOPMENTS

NHSX has recently announced real-world evaluations for a select number of AI-based health solutions.[32]

The evaluation will consist of three types:

1. PROCESS EVALUATION: examining the deployment and operational implications of the AI solution.
2. IMPACT EVALUATION: measuring impact by seeking to attribute an observed operational or clinical improvement to the deployment of the AI solution.
3. ECONOMIC EVALUATION: measuring whether the AI solution is a valuable addition to the healthcare system.

This project will help the NHSX develop new methods and establish best practice for assessing the use of AI in healthcare.

Next to this, NICE has recently launched a public consultation on reviewing its health technology evaluations[33].

32. *NHSX, Evaluating AI in health and care is essential, https://www.nhsx.nhs.uk/blogs/evaluating-ai-health-and-care-essential/*
33. *https://www.nice.org.uk/about/what-we-do/our-programmes/hice-guidance/chte-methods-consultation*

4. OUTCOMES AND FRAMEWORKS

The patient is at the centre of a healthcare system, and improving patient outcomes using the best and most cost-effective available technology is its goal. Digital health solutions offer new opportunities for delivering healthcare, from prevention to diagnosis, treatment and monitoring. As with other services, it is important to evaluate the impact of such digital health solutions.

The nature and consequences of digital health solutions can differ from case to case, and clearly from conventional health technologies, leading to the complexity and time-consuming process of their assessment by healthcare systems.

In addition, every healthcare system has a limited budget, with many health technologies and interventions competing for available funding. HTA provides a foundation to decide which health technologies best benefit the patients. Depending on the setting in question and the evidence available in support of the new health technology, establishing the level of reimbursement can be a complex process; it may take up to three to five years following the collection and analysis of evidence. Unfortunately, there is no guarantee of success and each national healthcare system might arrive at different decisions.

Decisions to adopt, use or reimburse new digital health solutions, taken at different levels of the healthcare system, are ideally based on evidence of their performance in the light of health system goals. In order to evaluate this, a broad perspective should be taken.[34] Achieving the broader health system goals, including quality, accessibility, efficiency and equity, are objectives against which to judge digital health solutions. These goals are unaltered by the process of digitalisation. Evaluations should be designed and tailored in such a way as to capture all relevant changes adequately.

A common pre-requisite for market access of digital health solutions in all healthcare systems is that they must pass the regulatory hurdle and obtain CEmarking, indicating that they perform safely, have an acceptable benefit-risk ratio and are state-of -the-art.

CLINICAL AND PROCESS-RELATED OUTCOMES

For digital health solutions, the following outcomes are considered important in most healthcare systems: ***clinical outcomes*** (as defined by the medical societies), ***patient-reported outcomes*** (by validated questionnaires) and ***process-related outcomes*** relevant for care providers, such as efficiency gains, support in administrative/tedious activities, faster access to information, electronic health records, etc.

The latter is often highly valued by the care providers, as using digital health solutions to support them with tedious administrative work could allow them to have more quality time with patients. They are also the assessors of this outcome, as it can be highly user-specific. A process-related outcome can also eventually benefit the patients. However, the aspect of process improvement is often overlooked when assessing the outcomes, as reimbursement by definition is clinical-procedure or intervention specific, rather than process specific.

This imposes challenges for medical device companies, as often they do not own an end-to-end or full-treatment pathway. Another distinguishing feature specifically for digital health solutions is the cross-setting application of the technology, e.g. from out-patient hospital setting to improving self-management behaviour by patients at home. Reimbursement per definition is setting-specific.

The outcomes will differ for each healthcare system, hence the answer as to whether there is an impact on outcome will depend on whether you ask patients, payers or a government official.

Although the main focus is usually on direct clinical outcomes, process-related and structure-related outcomes are also important and can be measured. These outcomes are explained in the PICOS framework.

34. *https://ec.europa.eu/health/sites/health/files/expert_panel/docs/022_digitaltransformation_en.pdf*

PICOS FRAMEWORK

The validated framework of **PICOS** (Patient, Intervention, Comparator, Outcomes and Settings) is used by HTA bodies, payers and budget holders. For all health technologies, of the countries that include a scoping phase the majority (>90%) of countries include PICOS within their scope.[35]

In general, other information is also included, such as study design, economic analysis/indicators, cost impact, ethical aspects, subgroups and therapeutic value. The latter is adjustable by the specific healthcare systems.

P Relevant **P**atient, Population or Problem	Describe and define the patient target group unmet clinical need; health inequality. • Epidemiology, aetiology, ethnicity, age group (children, adult, elderly), gender • Position in the clinical pathway (do patients need to be diagnosed, do patients need to be treated, etc)
I **I**ntervention	• Type (Screening; diagnostic test; treatment; preventive measure; therapy; monitoring) • Use of the product in the care pathway • Where (setting); who (user); when is it used (e.g. before/after therapeutics); how often and how long is it used? • What is the target condition that the test aims to diagnose or exclude? • Does it replace an existing diagnostic or therapeutic method, or does it add something new? • Does it require behavioural changes (patients; caregivers)?
C **C**omparison / **C**omparator	• What is the main alternative to compare with the intervention (current established practice, standard of care)? • Do you anticipate any new future comparators for your product? • Consider as comparator: devices; drugs; service; disruptive and transformative health tech
O **O**utcome(s) (i) Clinical – Patient benefit (ii) Process (iii) Structure	What outcomes do you want to improve or affect AND measure? • Diagnostics accuracy (test parameters); relevant direct & downstream measures • Clinical patient outcome(s); patient reported outcomes measures (PROMs); patient reported experience (PRE) • Health economic outcomes
S **S**etting in (targeted) Health System or Geography	Impact on health system resources; contextual factors that may impact adoption, acceptance and/or implementation at *meso* (provider) and macro (national) health system level: • Does it require systemic changes (example: Integration of in-patient & ambulatory care)? • Does it change existing process/es; structure; skill sets at provider level (learning curve)? • Relevance for low and middle income countries : how do you create patient access to health intervention (e.g. physical access; financial access,) does it fit in the priorities of the health system?

Outcomes according to PICOS can be evaluated or expressed in terms of

- Structure
- Process
- Clinical or clinico-economic outcomes

35. https://eunethta.eu/wp-content/uploads/2018/02/WP7-Activity-1-Report.pdf

Structure is defined as the environment in which healthcare is provided, *process* is the method by which healthcare is provided, and *outcome* as the consequence of the healthcare provided.

Enhancing process and structure can help improve patient outcomes. Different digital health solutions have been shown to improve structure, process and outcomes and therefore improving quality of care.

This also implies that the evidence required will depend on the outcome one wants to measure or achieve, and the setting where it will be measured. However, PICOS does not specifically provide the level of evidence required for digital health solutions.

MAST FRAMEWORK

Another framework, known as the MAST framework[36] (Model Assessment of Telemedicine), considers several aspects to be measured as outcomes. It provides a guideline on how digital health solutions are assessed, valued, operationalised or stimulated in the different European countries.

Figure 5: MAST framework

Source: Jasehn, 2017

For example, in the earlier national case studies, the UK framework looks at the functionality of DHTs, the German pathway for low -risk apps should contribute to positive care effects. Meanwhile in Belgium, the concept of assessing outcomes in Step 2 could be made more applicable for the different digital health solutions if the care providers' perspective and patient-reported outcomes beyond the clinical outcomes can be included. The deliverables for the different steps are decided by the different healthcare systems.

The MAST framework was developed for the context of evaluating telemedicine.

Broader eHealth technologies originally were not considered when developing the framework.

Hence, the MAST-IC framework was developed to allow evaluation of ICT-supported integrated care. In order to allow broader care aspects to be addressed, the wording in three domains in Step 2 was changed as follows: (1) Health and social situation of the care recipient and characteristics of the service (3) Clinical and care effectiveness and (4) Care recipient perspectives.

This illustrates the possibilities of using the MAST framework in the broadest sense of the word for digital health solutions that are harmonised in Europe.

When economic analysis is required for digital health solutions, there are different requirements and timelines involved depending on the healthcare system. Different types of economic analysis exist, such as cost-effectiveness analysis or cost-utility analysis that takes into account for instance quality-adjusted life years (QALY) or disability-adjusted life years (DALY).

Such economic models are, however, less common in practice when it comes to digital health solutions.

Whichever framework, tools, pathway, etc. is selected for a digital health solution, the market access strategy is aimed at reimbursement. In most healthcare systems, reimbursement is paid for by public funding with or under agreements with health insurance companies with corresponding indication. For reimbursement, it is important to know that there are three reimbursement mechanisms: Coverage criteria, procedure code, and payment rate or tariff. The process of having a digital health solution reimbursed may still involve HTA.

36. https://doi.org/10.1017/S0266462311000638

LEARNED LESSONS AND BEST PRACTICES

NICE was the first HTA body to publish an evidence standards framework for digital health technologies, in 2018, which since then has been regularly revised and updated. The framework describes standards for the evidence that should be available or developed for DHTs to demonstrate their value in the UK health and care system. This includes evidence of effectiveness relevant to the intended use(s) of the technology and evidence of the economic impact relative to the financial risk.

The evidence standards framework is intended to be used by technology developers to inform their evidence development plans, and by decision makers considering whether to commission a DHT.

This framework is perceived as a best practice, as it provides clear description on the clinical and economic evidence required according to the effectiveness and economic impact standards.

A joint effort at European level seems necessary to establish a knowledge management approach for identifying and sharing good practices, evidence and lessons learned on digital health across countries and international communities. In the case of mHealth, there may be a role for the European mHealth hub[37] project.

Such joint efforts should be considered as part of a strategy to understand the potential of digital health solutions. At the same time, it will help indicate the type of evidence that should be generated to demonstrate the solutions' impact on access, cost, quality, and sustainability.

37. https://mhealth-hub.org

5. CONCLUSIONS AND RECOMMENDATIONS

COCIR is aware of the dynamic nature of the environment surrounding market access for digital health technologies. This document serves as a preliminary analysis of a number of market access approaches that have been initiated at the national level.

The market access and reimbursement pathways for digital health solutions discussed in this paper are country-specific, with some included as innovative pathways and some existing outside the HTA procedure (although this may change over time).

It is vital that Member States learn from each other, evaluate and share best practices, and - in collaboration with industry - construct clear and efficient pathways for digital health solutions, in order to provide patients timely access to the best care available.

It would be valuable to find the appropriate balance between the length of the evaluation process and the time needed to demonstrate that the outcome is meaningful for the users in the healthcare systems, be they providers, patients or any other stakeholders involved in measuring them.

Based upon the learnings from these case studies, COCIR would like to open a discussion with all involved stakeholders. Below, it offers a first set of recommendations for creating a more accommodating environment for digital health solutions to reach and benefit all European citizens and patients.

COCIR RECOMMENDS TO THE EUROPEAN COMMISSION TO:

1. **PERFORM** a baseline measurement on market access conditions for digital health solutions as the first step for a coordinated action plan.
2. **FACILITATE** discussions between Member States on the use of clinical evidence and information exchange, including on cost drivers.
3. **ESTABLISH** a fitting data governance framework and structure as part of a European Health Data Space, in order to accommodate access to qualitative health data for innovation.
4. **PROMOTE** consistency between and alignment on market authorisation and evidence requirements for reimbursement.
5. **CREATE** guidelines that establish harmonised rules for public procurement, by building upon existing European or international frameworks and standards.

COCIR RECOMMENDS TO THE MEMBER STATES TO:

1. **ENSURE** that market access processes are fit for digital health solutions.
2. **CREATE** a clear pathway from market authorisation to reimbursement.
3. **PROVIDE** conditional reimbursement for digital health solutions, based on real -world evidence, with the possibility of revoking reimbursement in the absence of demonstrated benefits.
4. **LEVERAGE** market access as a tool to guide investment towards solutions that provide more efficient and effective outcomes.
5. **PROVIDE** clear guidelines on evidence requirements for the reimbursement of digital health solutions.

ANNEX 1
RELEVANT EUROPEAN LEGISLATION

MEDICAL DEVICES REGULATION (REGULATION 2017/745) [38]

The Medical Devices Regulation ensures the safety and performance of medical devices in the EU. It updates the rules on the placing on the market, making available and putting into service of medical devices for human use and their accessories on the EU market.

Software intended to be used for a medical purpose is also considered to be in its scope. The Medical Devices Regulation will replace the Medical Devices Directive as of 26 May 2021.

GENERAL DATA PROTECTION REGULATION (REGULATION 2016/679) [39]

The General Data Protection Regulation (GDPR) provides a single set of EU-wide rules on data protection. It strengthens the rights of citizens in providing greater control over their personal data.

The GDPR defines a set of principles when processing personal data and indicates responsibilities for data controllers and data processors. It includes specific measures on transparency and accountability. Measures on security and international data transfer have been further enhanced.

The General Data Protection Regulation became applicable as of 25 May 2018.

CYBERSECURITY ACT (REGULATION 2019/881) [40]

The Cybersecurity Act aims to achieve a high level of cybersecurity, cyber resilience and trust in the EU. It gives an enhanced and permanent mandate to ENISA, the EU Agency for Cybersecurity.

In addition, the Cybersecurity Act creates a framework for voluntary European cybersecurity certification schemes for ICT products, services and processes. It defines three different risk assurance levels, namely 'basic', 'substantial' and 'high'.

The Cybersecurity Act became applicable as of 27 June 2019. Currently no cybersecurity certification schemes have been established.

38. https://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=celex:32017R0745
39. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679
40. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R0881

ANNEX 2
CLINICAL EVIDENCE FOR DIGITAL HEALTH SOLUTIONS UNDER THE MDR

INTRODUCTION

The MDR has a mature infrastructure for creating clinical evidence, often covering - for a large part - the requirements for reimbursement of digital health solutions. Clinical Evidence based on pharma concepts often do not work well for digital health solutions, however for most issues there are solutions available within the MDR.

Medical device regulations started in 1990 with the Active Implantable Medical Device Directive. This Directive covered implantable devices such as pacemakers. Clinical evidence was based on clinical evaluation, clinical investigation and post market surveillance. In addition, pre-clinical evidence based on the essential requirements checklist had to be created. This checklist covered safety and performance requirements for - amongst others - product development, production, installation, service and traceability of a medical device and its labelling. In addition, a device had to be state-of-the-art and risk management techniques had to be used.

Over 30 years, many improvements have been made. there were new requirements introduced for medical device software, clinical evidence. requirements for cybersecurity, data privacy, interoperability, usability and software life cycle, and other requirements were introduced. The description of the clinical evaluation process became more detailed, and with new requirements such as (PICO) search techniques, the quality of the clinical data and appraisal of the clinical data. Checklists for notified body reviewers were introduced. Assessors from the manufacturer and the reviewing notified body had to have relevant clinical experience and had to provide a financial disclosure. In addition, planning requirements for the follow-up were created. Therefore with the Clinical Evaluation, the following plans have to be created: a Clinical Development Plan, a Post-Market Surveillance Plan and a Post-Market Clinical Follow-Up plan.

New guidance is also developing quickly, and requirements such as - for example - ethical hackers and AI change protocols are coming in the near future.

CLINICAL EVIDENCE FROM CLINICAL EVALUATION

There are a number of different medical devices, this means that there needs to be a flexible but robust process to determine what clinical evidence is needed for each medical device. Acceptance criteria are used for each clinical evidence element, so it can be assessed as to whether the medical device does indeed meet its intended purpose. The scientific process to do this is known as clinical evaluation. The clinical evaluation has a full set of quality requirements to obtain a sufficient level of scientifically valid clinical evidence for market access. A risk classification of the medical device determines how strict the clinical evaluation requirements are. The following figure outlines the three main steps of the clinical evaluation process:

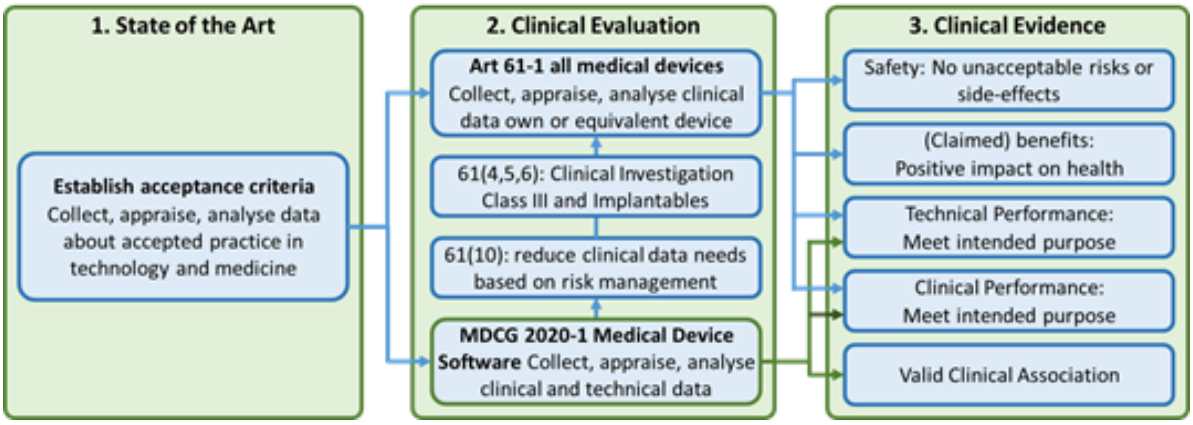


Figure 6 *- Relation between State-of-the-Art, Clinical Evaluation and Clinical Evidence*

1. STATE OF THE ART

The state-of-the-art acceptance criteria are based on the accepted practice in technology and medicine. The consequence is that new medical devices have to be able to deliver similar or greater safety, performance and benefits than current alternative treatment options. The State-of-the-Art has to be maintained, therefore innovations that advance the State-of-the-Art from alternative treatment options are a reason that the existing device also has to be improved. Safety issues uncovered with similar devices also have to be resolved using risk management techniques. For nearly every aspect of a Medical Device, there are standards with requirements which have to be met.

The information of the State-of-the-Art has to be collected via a literature study. During the development process, this literature study has to be performed and later regularly repeated during the lifetime of the device. The search protocol of the literature study needs to guarantee that the collected data is complete. The data needs to be appraised, to guarantee the data quality and applicability. During the development process, the acceptance criteria are translated into product requirements, user requirements and test requirements. Then the data is analysed to obtain acceptance criteria for indirect or direct clinical outcomes for the medical device being analysed.

2. CLINICAL EVALUATION

2A MDR ART 61.1 CLINICAL EVALUATION OF ALL MEDICAL DEVICES

For all Medical Devices, a Clinical Evaluation has to be performed based on clinical data to create clinical evidence. The State-of-the-Art acceptance criteria and the General Safety and Performance Requirements (GSPR) are used to determine which clinical evidence is needed.

The GSPR is analysed to determine what requires clinical evidence and what is covered by Pre-Clinical Evidence. Safety, undesirable side-effects, performance and benefits always need clinal evidence. In addition, the clinical evidence is already available from clinical investigations, post market clinical follow-up studies and post market surveillance is reviewed. Clinical data from equivalent devices may be used, for which the equivalency is analysed based on technical, biological and clinical characteristics.

A literature search is planned to find clinical data from the own device and equivalent devices. The literature search uses a PICO-search protocol (Patient / Problem / Population; Intervention; Comparison / Control; Outcome(s)) to find all applicable clinical data. This data comes from clinical investigations and other clinical experience that has been published or peer reviewed. The search covers, at minimum, the major databases such as PubMed. The publications identified are appraised on the full text articles and duplicates are removed. The articles are read and analysed.

2B MDR ART. 61.4-6 CLINICAL INVESTIGATION

An MDR Art 61.4 Clinical Investigation according to ISO 14155 is required for all Class III devices and implantables, with a few exceptions (MDR Art. 61.5-6). When the level of clinical evidence is insufficient under 2a, then a clinical investigation or a post market clinical follow-up study also has to be performed to generate new clinical data.

2C MDR ART. 61.10 PRECLINICAL DATA

For Class I, IIa and IIb, pre-clinical data may be used to reduce the amount of clinical data needed when justified using risk management.

2D MDCG 2020-1 CLINICAL EVALUATION OF MEDICAL DEVICE SOFTWARE

For all medical device software, a clinical evaluation has to be performed that meets the requirements of an MDR Art. 61.1 clinical evaluation. In addition, a MDCG 2020-1 clinical evaluation of medical device software has to be performed. This guidance anticipates the characteristics of software, which often deviate significantly from hardware.

Medical device software technical performance has to be accurate and reliable. Accuracy for algorithms with a clinical effect have to be proven, for example by validating the sensitivity, specificity and other applicable parameters for diagnostic software. The reliability of the software also has to be proven, mainly based on the requirements in standards, such as for software life-cycle development, standards for cybersecurity and data protection and other applicable standards.

The clinical performance of medical device software has to be validated. The medical software should generate clinically relevant output or benefits when used as intended. For this, pseudonymised or real world clinical data may be used.

Software does have an intended purpose, but not always indications, clinical performance or clinical benefits. Therefore, when justified there is no clinical evidence needed for clinical performance or clinical benefits.

Software can contain algorithms which have clinical benefits. For those types of software, clinical evidence is needed for a valid clinical association between the indication and the benefit. This evidence can come from clinical investigations, literature studies, scientific publications, etc.

3. CLINICAL EVIDENCE

When the clinical evaluation is completed, the clinical evidence is assessed by a clinically qualified assessor, for which a financial disclosure is provided. The accessor reviews whether there is sufficient clinical evidence for the acceptance criteria set during the investigation of the State-of-the-Art under 1.

Where applicable, clinical evidence should be created for safety, including no unacceptable risk or undesirable side-effects, technical and clinical performance, a valid clinical association, claimed benefits and a positive risk / benefit ratio where the device is used as intended.

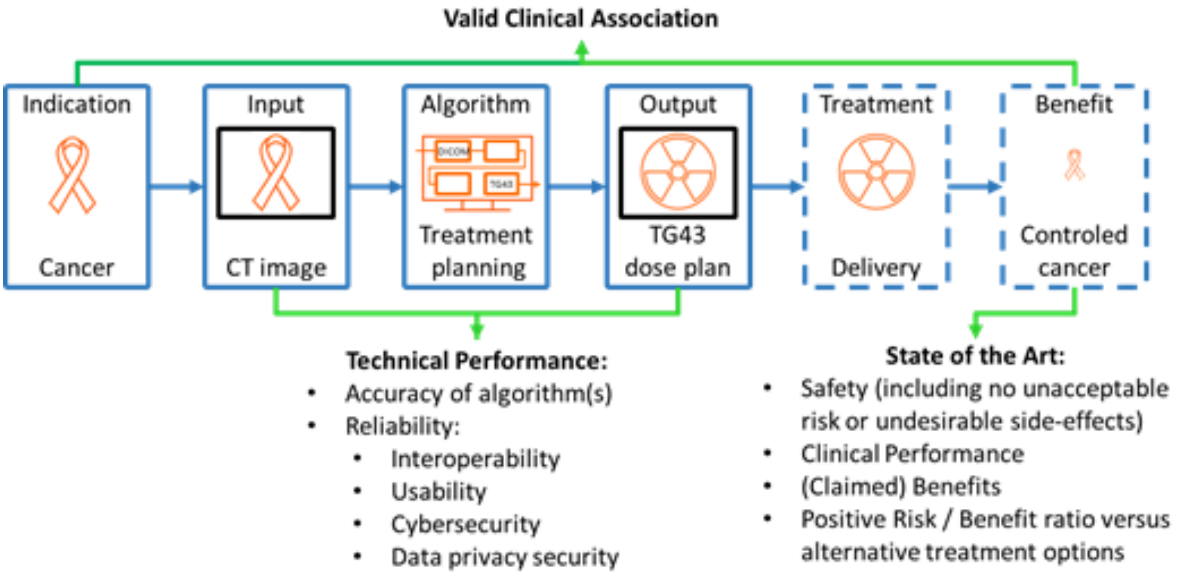


***Figure 7** - Clinical Evidence sources*

When the clinical evaluation is ready and has been assessed, there needs to be plans for how to address gaps in the clinical evidence, if any. A clinical development plan, a post-market surveillance plan and a post-market clinical follow-up plan have to be created in order to disclose how new clinical evidence will be gathered during the life cycle of the device. When the clinical evaluation is ready, the notified body also reviews the clinical evidence with its own assessor. For certain devices, there is also an additional scrutiny procedure.

ANNEX 3
REFERENCES

AGORIA / Coronavirus leidt tot artsenvergoeding voor teleconsultaties

BUNDESGESETZBLATT / Digitale-Gesundheitsanwendungen-Verordnung

BUNDESGESETZBLATT / Digitale-Versorgungs-Gesetz

BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE (BfArM) / DiGA catalogue

BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE (BfArM) / The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139z SGB V: A Guide for Manufacturers, Service Providers and Users

BUNDESMINISTERIUM FÜR GESUNDHEIT / Driving the digital transformation of Germany's healthcare system for the good of patients

CENTRE D'ANALYSE STRATÉGIQUE / Le dispositif médical innovant

eHEALTH STAKEHOLDER GROUP / Proposed guiding principles for reimbursement of digital health products and solutions

EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES / EuroHealth 2020, 26(2) - Keeping what works: Remote consultations during the COVID-19 pandemic

EUROPEAN COMMISSION / A European Strategy for Data

EUROPEAN COMMISSION / Critical industrial applications: report on market analysis of prioritised value chains, the most critical AI applications, the conditions for AI rollout

EUROPEAN COMMISSION / Communication on Digital Transformation of Health and Care in the Digital Single Market

EUROPEAN COMMISSION / Shaping the digital transformation in Europe

EUROPEAN MHEALTH HUB / Final report health app assessment frameworks

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT (EUnetHTA) / An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH (EXPH) / Assessing the impact of digital transformation of health services

FENIN / Estudio Fenin de Índice de madurez Digital en Salud (Fenin study on Digital health maturity index)

GOBIERNO DE ESPAÑA / Plan España Digital 2025

HAUTE AUTORITÉ DE SANTÉ - Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use

HAUTE AUTORITÉ DE SANTÉ - Guide to the specific features of clinical evaluation of connected medical device (CMD) in view of its application for reimbursement

HAUTE AUTORITÉ DE SANTÉ / Guide LPPR : Dépôt d'un dossier auprès de la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé

HAUTE AUTORITÉ DE SANTÉ / Guide Forfait innovation : dépôt de dossier de demande de prise en charge dérogatoire pour un produit innovant

INTERNATIONAL JOURNAL OF TECHNOLOGY ASSESSMENT IN HEALTH CARE / A Model for Assessment of Telemedicine Applications: MAST

IQWIG / General Methods (benefit assessment)

mHEALTH BELGIUM / mHealth Belgium validation pyramid

MINISTÈRE DES SOLIDARITÉS ET DE LA SANTÉ / La télémédecine

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) / Evidence standards framework for digital health technologies

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) / Reviewing our methods for health technology evaluation: consultation

NHS DIGITAL / NHS Apps Library

NHSX / Designing and assessing digital health services

NHSX / Evaluating AI in health and care is essential

OFFICIAL JOURNAL OF THE EUROPEAN UNION / Cybersecurity Act

OFFICIAL JOURNAL OF THE EUROPEAN UNION / General Data Protection Regulation

OFFICIAL JOURNAL OF THE EUROPEAN UNION / Medical Devices Regulation

SWEDISH ASSOCIATION OF LOCAL AUTHORITIES AND REGIONS (SALAR) / About SALAR

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