White Paper

Regulations and Reimbursement for Software as a Medical Device in Europe

Part 3 — Reimbursement of SaMD in Europe

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Introduction

The abundance and speed of software development have brought new challenges and opportunities to healthcare. It is hard to imagine modern healthcare without software in different forms — in digital devices as well as standalone software, known as Software as a Medical Device or SaMD.

While the unique features of SaMD make it difficult to define such medical devices, to assess their safety as well as to set up the rules for reimbursement, these steps are necessary to give patients access to these modern technologies.

In Europe, only a few countries are currently advanced in terms of setting up reimbursement policies for SaMD. Germany and Belgium are the pioneers in this space: Germany with its Digital Healthcare Act Fast Track platform, and Belgium with its mHealthBELGIUM platform. France and the UK are also among the leaders, with France having a PECAN fast-track market access pathway system similar to the German one, and the UK system being de-centralized, with local developed solutions for reimbursement. Other European countries are also taking steps towards reimbursement of digital healthcare and working to adopt innovations in the reimbursement domain developed by the leaders.

Reimbursement opportunities for digital health applications and services are expected to improve significantly over the next few years in Europe as regulatory bodies recognize that the old paradigm of evaluating medical products will not suffice in a market with increasingly fast-paced innovation. These bodies have been working to create regulatory frameworks for medical devices and medical device software that prioritizes both patient safety and healthcare innovation.

In parts 1 and 2 of this series, we covered the definition, regulatory landscape, regulatory challenges of SaMD, the ways regulators try to address them, as well as the expected development of regulations related to artificial intelligence and machine learning (AI/ML) in SaMD.

In this third part, we cover both the current reimbursement pathways for SaMD in Europe (by looking into the pioneering countries with systematic pathways for reimbursement of digital health solutions such as DiGA in Germany), as well as explore the expected development in the reimbursement of digital healthcare in Europe in the coming years (by taking a look at the various national initiatives and governments' efforts in countries such as France and the UK, that only recently became the leaders).

Reimbursement opportunities for digital health applications and services are expected to improve significantly over the next few years in Europe

SaMD reimbursement pathways in Europe

Healthcare systems in Europe are grappling with the mounting challenges of demographic changes such as an aging population, the prevalence of chronic diseases, and a scarcity of resources and healthcare professionals. In response, there has been a notable increase in the implementation of digital healthcare solutions (DHS) throughout Europe. These solutions are being adopted as a means to enhance prevention and treatment protocols, improve access to care, and deliver safer and more efficient healthcare services.

However, significant barriers to the widespread adoption of DHS persist: the lack of appropriate funding and reimbursement mechanisms. Despite some countries taking significant strides in this area, reimbursement of DHS in Europe remains fragmented and lacks harmonization across nations.

Nevertheless, certain countries established dedicated reimbursement pathways several years ago, such as the digital health applications or DiGA law in Germany. This legislation enables digital health developers to charge national and private health insurers for prescriptions (see Table 1).

Table 1: Examples of the reimbursement pathways for DHS in leading European countries

	DEDICATED FRAMEWORK ON NATIONAL LEVEL			KEY STAKEHOLDERS	REQUIREMENTS TO ACHIEVE REIMBURSEMENT	TIME FRAME
	EVALUATION	REIMBURSE-MENT	REIMBURSEMENT PATHWAYS			
GERMANY	✓	✓	DiGA	• BfArM • Statutory health insurance funds (GKV-Spitzenverban)	• CE Mark • Data on safety, functionality, quality, data protection, data security, interoperability • Data on medical benefits, and/or structural and procedural improvements	• Preliminary admission after 3 month • Permanent admission after 12 month
BELGIUM	✓	✓	Mhealth BELGIUM platform	• NIHDI • E-Health • FAMHP	• CE Mark • Compliance with GDPR • Connectivity and interoberability with eHealth platform • Submission of socioeconomic, clinical, budgetary impact evidence	
FRANCE	✓	✓	PECAN platform	• CNEDiMTS / HAS • CEPS • ANSM • CNAM	• CE Mark • Compliance with GDPR • Clinical dossier • Organizational impact analysis including economics	• Preliminary admission after 3 mo for 1 year • Permanent admission: » after 6 month for products and services » after 9 month for telemonitoring solutions
UK	✓	✗	Reimbursement system not centralized. While evaluation is done by the central body (MHRA), DTx are reimbursed at the regional or local levels via different initiatives (e.g., institutions funding programs for digital innovations)		• UKCE Mark • Meeting DTAC (digital technology assessment criteria): clinical safety, data protection, technical assurance, interoperability, usability and accessibility	• Varies depending on the path / region

Source: Internal IQVIA materials, interviews with experts.

But while some countries have well-established systems for defining regulations surrounding SaMD, including compliance with GDPR, and have implemented reimbursement policies, others are still in the process of developing these guidelines or do not have them in place at all.

Reimbursement maturity within European markets

In recent times, particularly since the onset of the COVID-19 pandemic, the acceptance and demand for digital health products in Europe have experienced a significant surge. Consequently, countries in the region are now reevaluating their frameworks for reimbursing SaMD, although the level of progress varies among nations.

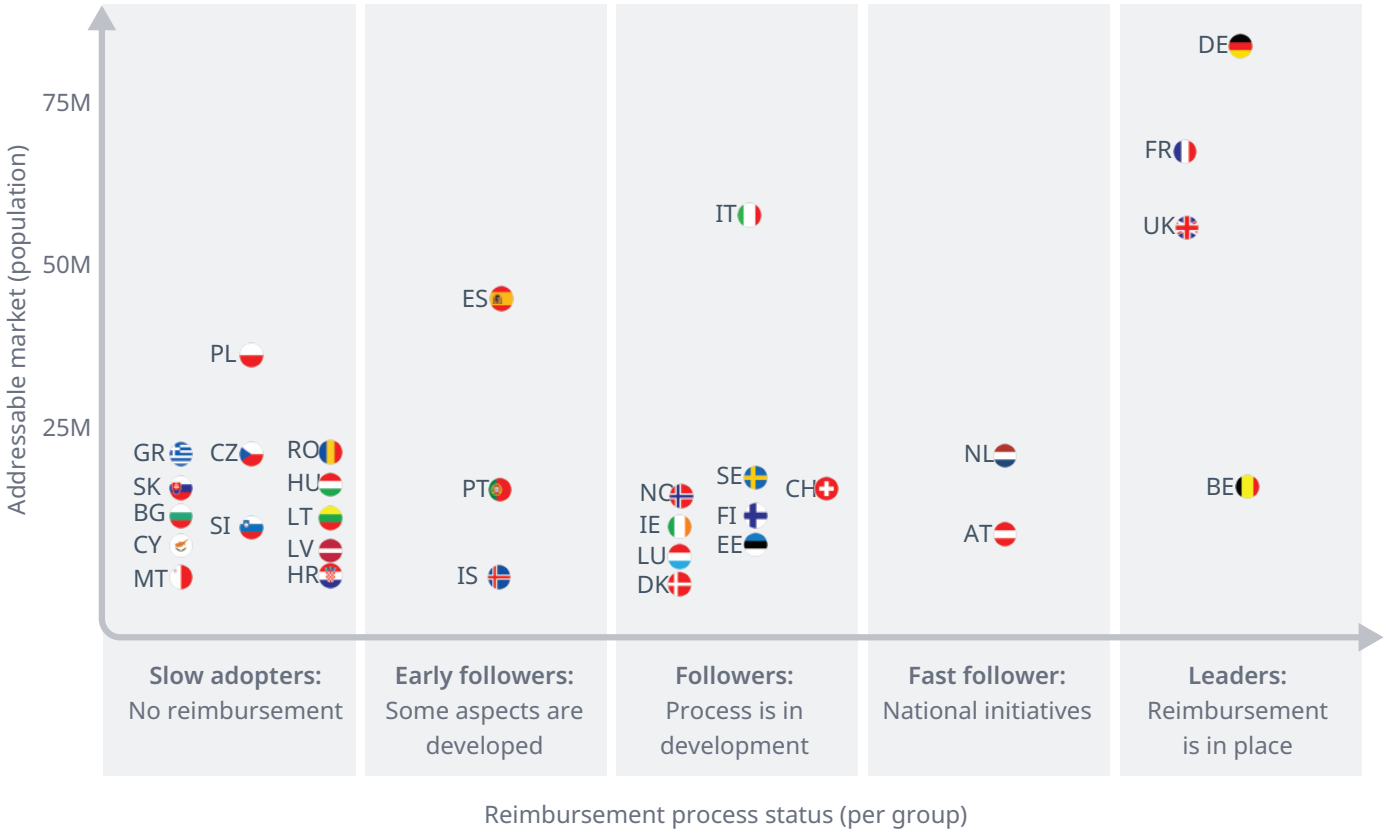
To evaluate the maturity of reimbursement processes for digital health solutions in Europe, we have classified countries into five distinct groups (Figure 1). This classification is based on the current development status of reimbursement processes for digital health solutions.

I. LEADERS: REIMBURSEMENT IS IN PLACE

Germany, Belgium, France and the UK are at the forefront of the reimbursement process for DHS in Europe, with established dedicated pathways for the national reimbursement of DHS.

In Germany, the "Digitale Gesundheitsanwendung" or DiGA provides a framework for the reimbursement of digital health apps. Currently, 54 digital health apps are covered by national health insurance (Appendix A), supporting various therapeutic areas such as cancer, weight management, diabetes, and mental health.[1]

Figure 1: European countries archetypes based on the development status of dedicated reimbursement process for Digital Health



Source: Internal IQVIA resources, interviews with experts, Research2Guidance; Digital Therapeutics Alliance.

In the first year of reimbursement, DiGA manufacturers set their own prices. Starting from the 13th month, the price is determined through negotiations between the DiGA manufacturer and the GKV-SV. Following this negotiation process, manufacturers are required to reimburse the difference between their initial pricing and the negotiated price for all prescriptions sold beyond the initial year.[2]

DiGA focuses solely on the patient. Other types of DHS exist, for example, SaMD apps used only by HCPs, which are reimbursed by the HCPs or by the hospitals or organizations that finance HCPs (e.g., Health Insurance covering medical procedures, including equipment). Neither statutory health insurances nor private insurance companies are obliged to reimburse the DHS and the contract has to be negotiated with each of them (currently there are 103 statutory and 47 private insurers in Germany).[3]

In Germany, there is also a well-defined pathway for DHS that do not fall under DiGA. For technologies that can be categorized using existing EBM codes (Einheitlicher Bewertungsmaßstab), there is an expedited process. The initial reimbursement is obtained through established EBM codes. In cases where there is no suitable EBM code for a specific technology, a standard process is followed. This entails an assessment by G-BA/IQWIG, as per §135 SGB V, culminating in a decision by G-BA regarding reimbursement and the assignment of an EBM code.

It is worth noting that alongside DiGA apps, there is a distinct category of digital technologies designed exclusively for care and nursing purposes, known as DiPAs. DiPAs are not classified as medical devices and are thus exempt from the regulatory requirements of the MDR. However, in Germany, such apps are eligible for reimbursement. The determination of patient eligibility for reimbursement is made by the long-term care insurance fund and follows a pricing cap model. Currently, BfArM (the Federal Institute for Drugs and Medical Devices) is actively developing an inclusion list for DiPAs to streamline the reimbursement process in the future. Additionally, this body has already released a set of rules pertaining to the application process.[4]

Belgium has implemented its own system, the mHealth Validation Pyramid, that evaluates the quality and effectiveness of digital health applications. The mHealth Validation Pyramid consists of three levels (M1, M2, M3) that assess the suitability of health apps to be reimbursed by the Social Health Insurance (SHI). Currently, 39 healthcare apps are undergoing evaluation through the mHealth Validation Pyramid based on factors such as patient risk, interoperability, and clinical evidence.[5] Among these apps, 26 are at the earliest stage (M1), 12 are at M2, and one has reached M3 (Appendix B). The speed of acceptance is slow: though the platform was formed one year earlier than DiGA, in 2018, only one app has been reimbursed in Belgium, compared with the 54 apps currently reimbursed in Germany. Recently, to increase an accessibility of digitally supported healthcare, the NIHDI has revised the reimbursement procedure for medical mobile applications. This will be appied starting on 1 October 2023.[6]

In France, the government has initiated several programs to define digital health ethics and promote uniformity in the digital health market within the European Union. There are also efforts to enable healthcare professionals to prescribe digital health apps and simplify market access for digital health solution providers seeking reimbursement in France. Notably, in October 2021, President Macron announced plans to introduce a “fast track” reimbursement mechanism, inspired by Germany’s DiGA mechanism. This pathway aims to expedite reimbursement for digital health providers in France. PECAN created by article 58 of LFSS 2022, is a system for an early access to reimbursement for digital devices, allowing six to nine months of special coverage by the French health care system for sufficiently mature solutions.[7] The opinion of the first device TECHCARE assessed by HAS for a PECAN has been published very recently and now this app has entered price negotiation phase.[8]

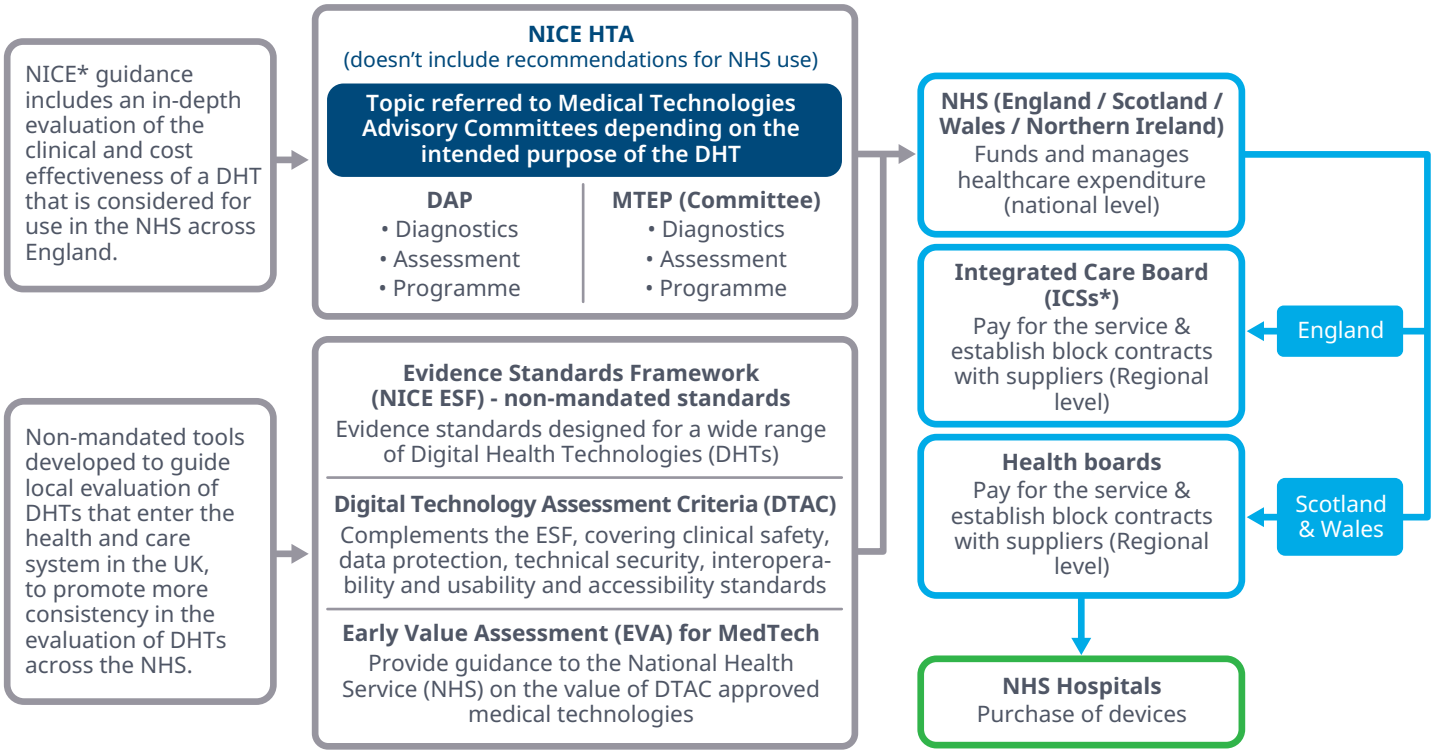
Similarly, the UK stands out as a frontrunner in medical device software reimbursement, thanks to its well-developed reimbursement pathways. The primary distinction between the UK and other leader countries, Germany, Belgium, and France, lies in the decentralization of reimbursement decisions. While technology evaluation is conducted at the national level by the Medicines and Healthcare products Regulatory Agency (MHRA), reimbursement decisions are made independently at the regional level by the respective entities within the National Health Service (NHS), including England, Scotland, Wales, and Northern Ireland.

The UK government has made significant progress in establishing regulatory pathways for digital health. Both the National Institute for Health and Care Excellence (NICE) and MHRA have been working on a streamlined regulatory pathway. The goal is to ensure that effective and cost-effective digital technologies reach patients in the NHS in a timely manner.

Furthermore, NICE and the NHS have joined forces to create assessment tools aimed at guiding local evaluations of DHTs integrated into the UK's health and care system. This collaborative effort aims to foster greater consistency in DHT evaluations across the NHS. These assessment tools encompass non-mandated standards, addressing critical facets such as clinical safety, data protection, technical security, interoperability, and usability. They adhere to accessibility standards, including the Evidence Standards Framework (ESF) and the Digital Technology Assessment Criteria (DTAC), ensuring a comprehensive approach to technology assessment and implementation.[9]

For reimbursement purposes, local NHS organizations have a prominent role in DHS funding. The key decision-makers are the 43 Integrated Care Systems (ICSs) that took over the roles of the previous 200+ Local Clinical Commissioning Groups (CCGs).[10]

Figure 2: Evaluation and reimbursement of DHTs in the UK



*NICE (England) / SMC (Scotland)/AWMCDSG (Wales) / HSC (Northern Ireland) : Assess clinical and cost-effectiveness through various types of HTAs.
Source: IQVIA materials, IQVIA UK Market experts

As the country healthcare funding system operates via the ICS, it is unlikely that the reimbursement decisions for SaMD will be taken at the national level; rather funding decisions will continue to be done at the local level, via third-party partnerships.

In addition, numerous organizations in the UK provide support, advice, and information for each stage of the development life cycle of digital healthcare products. 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 DigitalHealth.London organization[11] facilitates collaboration between clinicians, healthcare providers, entrepreneurs, and industry stakeholders to accelerate the adoption and commercialization of digital health technologies. This organization also provides clear pathways to market for entrepreneurs. Other examples of enabling organizations are the 15 Academic Health Science Networks (AHSNs) facilitating technology introduction into the NHS.[12]

II. FAST FOLLOWERS — NATIONAL INITIATIVES

The Netherlands and Austria have already started developing recommendations based on existing DiGA-like frameworks regarding classification, certification, and reimbursement of digital healthcare products.[13] Within one to two years, the first digital health apps are expected to gain access to funding through the statutory health plans in these countries.

In the Netherlands, the most common route for health apps to enter the market is through individual insurance companies. These companies assess the use of digital technology based on the needs of stakeholders within their ecosystem, including patients, care providers, and authorities responsible for monitoring and evaluating the quality of care. Manufacturers seeking insurance coverage need to engage with individual health insurance companies, which primarily focus on improving care processes, patient outcomes, and reducing healthcare costs. Typically, engagement begins with one insurance company and one or several providers, and gradually expands to the regional level as more insurers adopt the technology.

Simultaneously, the Dutch government supports the development of a framework for assessing the quality and reliability of health and wellness apps by the European Committee for Standardization (CEN). This framework considers specific needs of health apps and settings in which they will be used, such as community/home care settings or specialist care settings. According to guidance from the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa), digital health technologies connected to hospital specialist care are generally reimbursed by the Diagnosis Related Group (DRG). In contrast, devices intended for use in community or home settings are reimbursed based on individual decisions made by insurance companies.[14]

Healthcare systems in Europe are grappling with the mounting challenges of demographic changes such as an aging population, the prevalence of chronic diseases, and a scarcity of resources and healthcare professionals. In response, there has been a notable increase in the implementation of digital healthcare solutions (DHS) throughout Europe.

Since 2021, there has been is an opportunity for financing digital care in specialist medical care in the Netherlands known as “De facultatieve prestatie” or “Optional achievement.” This initiative allows health insurers and care providers to collaborate and propose new initiatives that are challenging to finance through regular DRG mechanisms. Healthcare providers and insurers can jointly apply to the NZa for an optional service that is not covered by the DRG. If approved, the optional service can be utilized by healthcare providers willing to provide that specific type of care, provided they have a contract with the healthcare insurer.[15]

III. FOLLOWERS — PROCESS IS IN DEVELOPMENT

Several countries, including Finland, Norway, Ireland, Luxembourg, Sweden, Denmark, Switzerland, Estonia and Italy, are in the process of standardizing the recognition of software as a medical device. Governmental healthcare bodies in these follower countries have shown interest in implementing practices similar to Germany’s DiGA system.

In Finland, the government is in the process of collecting the information necessary for the implementation of digital health technology assessments. In August 2022, the Finnish Coordinating Center for Health Technology Assessment (FinCCHTA) published an article discussing the implementation of a new Digi-HTA process for digital health technologies.[16]

In Norway, there is a national initiative aiming to establish safer use of health apps that includes evaluation and inclusion of the approved applications in public health services (central registry helsenorge.no), available by prescription.[17]

In Italy, while not yet included in legislation, there is an emerging movement to study and adapt the German legal framework. This effort aims to develop an agreement for bridging the current gap. The Italian Medicine Agency (AIFA) has also taken steps towards regulating digital technologies.[18,19]

An intra-parliamentary initiative was launched in May 2023, aiming to establish formal recognition, assessment, pricing and reimbursement criteria for DHS with the help of a technical scientific committee.[20] One possible outcome is that after being rigorously evaluated via HTA process, DHS may be included in specialized care pathways.

Currently, there is no centralized government framework in these follower countries to assess the application and adoption of health apps. However, the governments closely monitor the development and adoption of health apps while allowing the market to largely drive the evaluation process.

IV. EARLY FOLLOWERS — SOME ASPECTS ARE DEVELOPED

Spain, Portugal and Iceland are among the European countries that are embracing digital health at an early stage. Their focus is primarily on creating certification frameworks for digital health applications, with the establishment of a reimbursement process still pending. While certain apps may receive quality marks, there is no assurance of their being prescribed or having a clearly defined path for reimbursement. App developers in these countries may explore reimbursement options through Social Health Insurance (SHI) or other avenues, but the details are currently uncertain. Although progress is being made, there is still a need for a standardized reimbursement processes to facilitate wider adoption of digital health solutions.

V. SLOW ADOPTERS — NO REIMBURSEMENT

The remaining EU countries, which include Bulgaria, the Czech Republic, Croatia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, the Republic of Cyprus, Romania, and Slovakia, currently show no signs of intending to implement frameworks for recognizing and reimbursing SaMD in the near future. These countries have yet to launch any initiatives or efforts to establish a structured reimbursement process for digital health solutions.

The future of digital health reimbursement pathways in Europe

Inspired by Germany's innovative DiGA Fast Track process established in 2020, several European countries have embarked on their own transformations to adopt frameworks for evaluating digital health apps. While some countries are progressing rapidly as fast followers, the majority still lag behind in providing direct access for medical device manufacturers to the public reimbursement system through the health insurance system.

Recognizing the challenges posed by advancing digital health technology, countries like France and the UK have taken significant steps in developing their regulations for medical devices and recently joined Germany and Belgium as the leaders.

Here, we examine the evolution of the digital health reimbursement pathways in France and the UK with the goal of predicting what the future might hold for SaMD reimbursement in other countries.

The development of SaMD regulations and reimbursement pathways in France

During its presidency of the Council of the European Union, starting in January 2022, France prioritized digital health developments. It aimed to establish a foundation for European industrial data-sharing, foster innovation, champion eHealth initiatives, launch the European Health Data Space, and enhance data security in the digital age.

Before 2022, France did not have a specific framework for national reimbursement of DHS. Instead, these solutions followed the standard market access route for medical devices, allowing for individual funding opportunities for DHS (see Figure 4).

FRENCH NATIONAL PORTAL FOR EHEALTH INNOVATION – G_NIUS

France has established a national gateway called G_NIUS, which serves as a support platform for European digital health entrepreneurs.[21] This aims to facilitate navigation within the digital health ecosystem and accelerate market access in the EU.

G_NIUS is an integral part of France's Digital Health Acceleration Strategy for 2021–2025, with a goal of fostering collaboration with other European countries. This single gateway helps digital health entrepreneurs to save time and expedite the EU market entry of their solutions (Figure 3).

G_NIUS operates at the EU level and will soon offer information on markets including Sweden, Germany, Spain, the Nordic countries, and on bilateral partnerships between G_NIUS and similar structures.

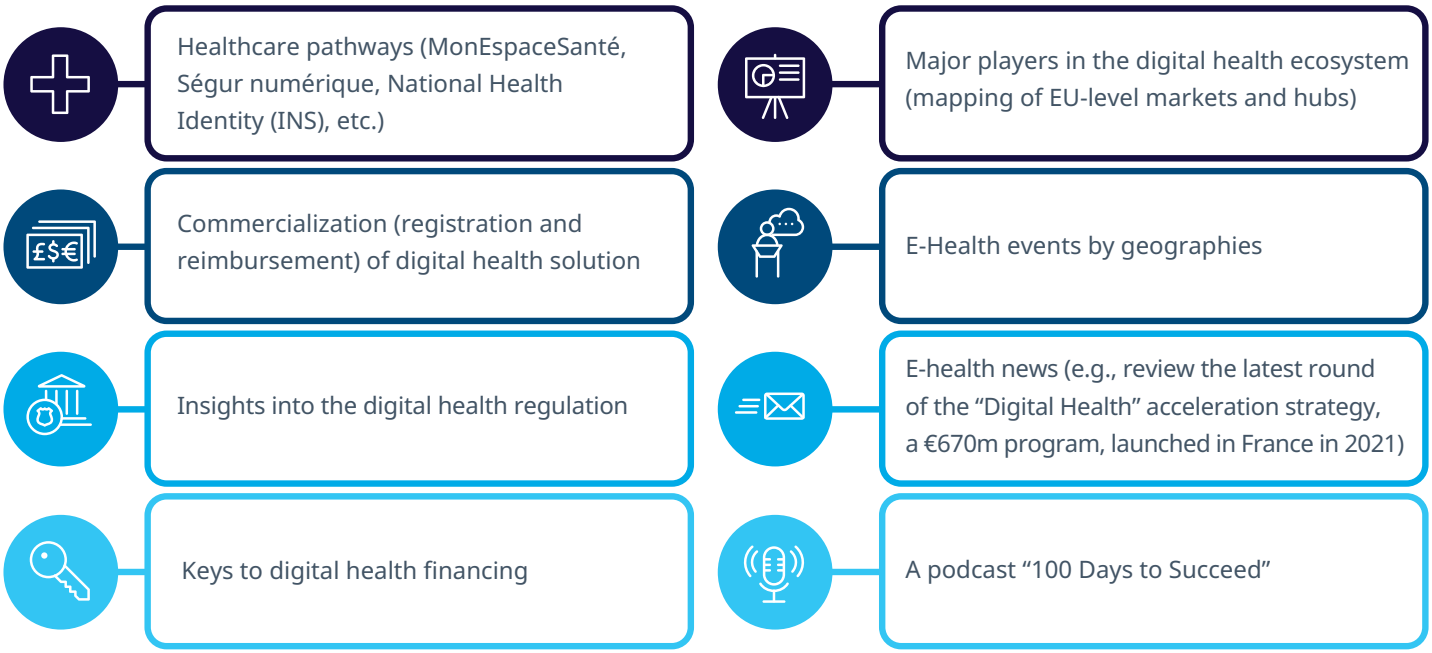
G_NIUS aims to facilitate navigation within the digital health ecosystem and accelerate market access in the European Union (EU).

Prior to development of the specific reimbursement pathways for DHS, a social security funding law in France (LOI n° 2020–1576 du 14 décembre 2020 de financement de la sécurité sociale pour 2021 or "LFSS 2021") [22] has enabled early access to innovative medicines, including digital health solutions. This system went beyond the German DiGA model and encompassed various healthcare technologies, including a broader range of classes, as well as drugs (see Figure 2).[23]

For an early access authorization there are two scenarios, depending on whether the submission is made before or after market authorization:

- **Before the CE mark, innovation funding ("forfait innovation"), created by the French Social Security Financing Act (LFSS) in 2009[24]:** This path is for facilitation of a collaborative funding of research initiatives between public authorities and industry, advancing early access to groundbreaking technologies in clinical and medico-economic domains.

Figure 3: Main G_NIUS platform services



Source: G_NIUS website

HAS (Haute Autorité de Santé) assess the eligibility of the device for innovation funding based on two criteria: the device must be innovative and the clinical or medico-economic study project must be considered relevant. If a favorable opinion is issued by HAS, the Ministry of Health makes an estimation of the study budget and overall associated healthcare costs. The Ministry of Health then takes a positive or negative decision. If a positive opinion is issued, there is an official publication in the *Journal Officiel* and the innovation funding can start.

- **After the CE mark, "prise en charge transitoire", created by LFSS 2020[25]:** This process enables the reimbursement of innovative healthcare products with a therapeutic or disability-supporting purpose for one year, while awaiting conventional reimbursement via the LPPR (the List of Reimbursable Products and Services). To apply for this process, three conditions must be met: the device must be CE marked, it must not already be funded, and the manufacturer must have submitted, or undertake to submit, an application for registration of the medical device on the LPPR within 12 months of the application for "prise en charge transitoire. HAS assesses the eligibility of the device based on five criteria. If a favorable opinion is issued by HAS, then price negotiations with the French Ministry of Health can begin.

The early access pathways discussed above preceded a dedicated pathway for digital solutions, PECAN, a fast-track process for reimbursement of DHS for individual use outside of the hospital that was launched in France in December 2022.

Early access authorizations have a limited duration, and are renewable as set by decree (for three years maximum).[26]

FRENCH NATIONAL INVESTMENTS OF €650 MILLION PLANNED (PART OF HEALTH INNOVATION 2030 PLAN)

In October 2021, the French Minister of Health announced a €650 million investment plan as part of the Health Innovation 2030 plan, aimed at accelerating the national digital health strategy. The investment is divided into five main areas of research and development.[27]

Some €202 million is dedicated to advancing French leadership in research and innovation in areas such as prevention, telehealth, and AI-based medical devices. €168 million is allocated for experimental programs to test digital health innovations in medical facilities. Another €81 million is devoted to training medical professionals and patients to adapt to the digitalization of the healthcare sector. A total of €60 million will support a scientific innovation program focused on exploratory research programs and equipment (PEPR). €35 million is dedicated to monitoring digital health innovations in France and elsewhere. Additionally, around €100 million will be allocated to "Sante Numerique," a project supporting the digital transformation of the health system in France.

This investment plan covers the entire process of supporting digital health entrepreneurs, starting from the early stages of innovation, transitioning from prototype design to a proven product in real conditions, and undertaking the necessary clinical evaluations to obtain certifications such as the CE marking, which demonstrates compliance with European safety, health, and environmental requirements.

DEDICATED REIMBURSEMENT PATHWAYS FOR DIGITAL SOLUTIONS IN FRANCE DHS TYPE OF USE

In France, the reimbursement pathway for digital healthcare solutions depends on the type of use:

1) **Individual use in hospitals**: Digital healthcare devices within this category are reimbursed via GHS (Groupement Hospitalier de Territoire), covering costs related to hospital facilities, staff, common medications, technical and medical equipment. Implantable and certain high-cost medical devices may also be covered.
2) **Individual use outside of the hospital**: Devices that are reimbursed within this category (plus implantable and certain high-cost medical devices) have to be included on the LPPR. The price can be defined based on an existing product with similar characteristics and price or as a new brand with its own price (file must be approved by HAS)
3) **Collective use**: A DHS that can be used several times, like common equipment, is reimbursed as amortization via each medical procedure. If the procedure does not exist, it has to be created separately.

PECAN

PECAN is a fast-track process for reimbursement of digital solutions for individual use outside of the hospital that was launched in France in December 2022.[7]

Once the ANS (Agence du numérique en santé) certifies DHS compliance with interoperability and safety standards and National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the Haute Autorité de Santé (HAS) provides a health technology assessment (HTA) showing positive expected benefit, an application for the fast-track reimbursement (PECAN) can be made.[28]

The reimbursement covers a one-year period and is conditional on a sustainable reimbursement dossier submission within six months of the start of the PECAN for digital therapeutic devices (intended to be included on the LPPR[24]) and within nine months for remote monitoring solutions (intended to be registered on the new list of medical telemonitoring activities, LATM)[29] before a more permanent listing (Figure 2). The social security fund Caisse Nationale d'Assurance Maladie (CNAM) or local representative Caisse Primaire d'Assurance Maladie (CPAM) is responsible for funding but is not involved in initial decision for reimbursement.[17]

In October 2021, the French Minister of Health announced a €650 million investment plan as part of the Health Innovation 2030 plan, aimed at accelerating the national digital health strategy.

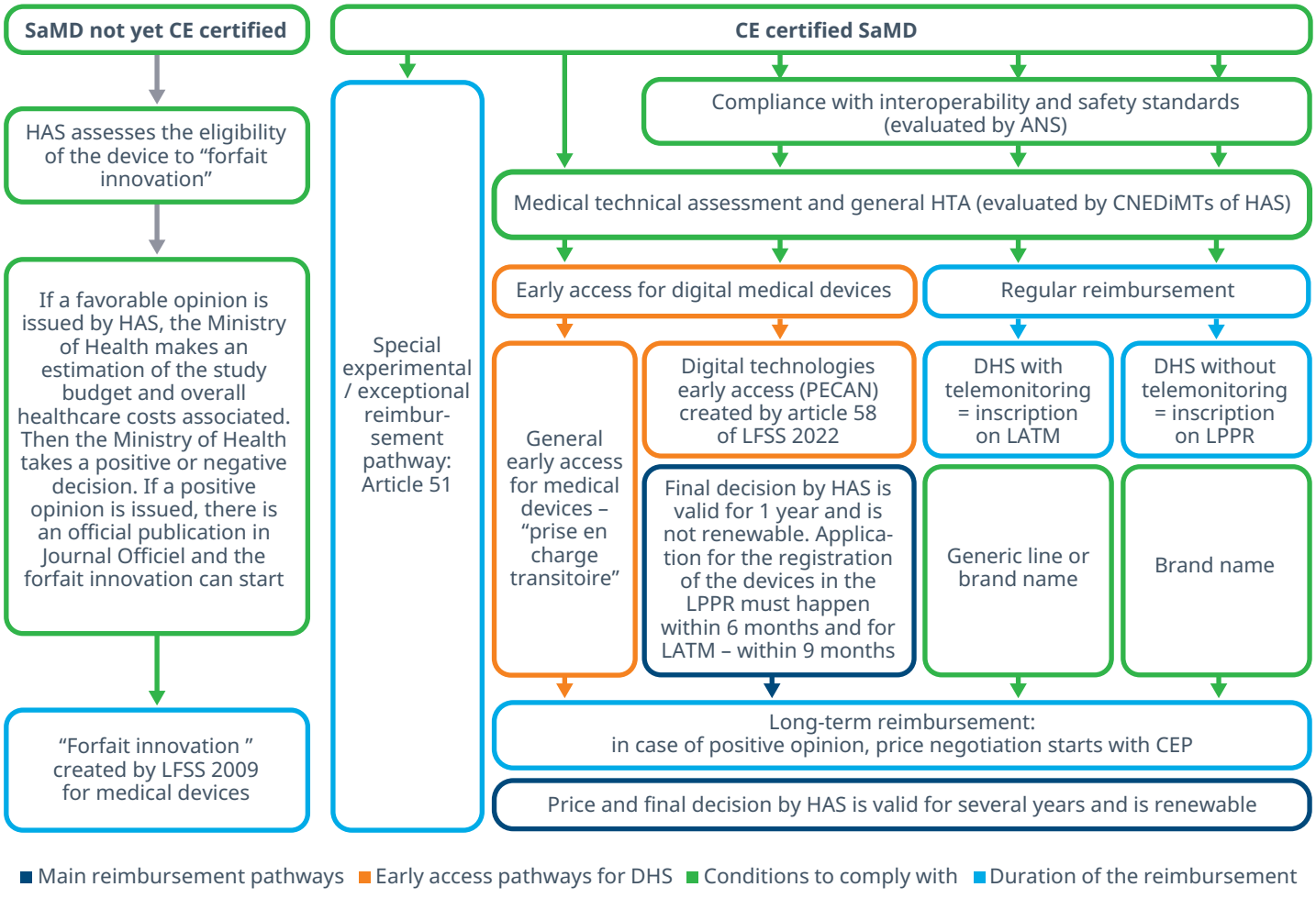
Digital devices must comply with a list of conditions to be eligible to apply for PECAN.[30,31] The device must:

- Be a healthcare digital therapeutic or telemonitoring solution
- Have a CE mark
- Be evaluated as "innovative" by CNEDiMTS
- Demonstrate the clinical and/or organizational benefits
- Produce exportable processed data
- Comply with GDPR
- Not have any other financial support
- Not have any relevant comparator

SPECIAL EXPERIMENTAL/EXCEPTIONAL REIMBURSEMENT PATHWAYS FOR DHS

Two experimental early access reimbursement pathways are applicable to DHS in France. "Forfeit innovation" has already been described above; this is applied before market authorization is obtained. The other reimbursement pathway, applied to the CE-authorized DHS, is called Article 51. This type funding is for experimental technologies and deployment of innovative DHS within healthcare systems. It is designed for organizations, improving the patient journey, increasing the efficiency of the health system, contributing to access to care, and other applications (Figure 4).

Figure 4: A framework for national reimbursement of digital health solutions in France



Abbreviations: CNEDiMTS - Medical Device and Health Technology Evaluation Committee, HAS - Haute Autorité de Santé (French National Authority for Health); HTA – health technology assessment; ANS - Agence du Numérique en Santé (Digital Health Agency); CEPS Economic Committee for Health Products; PECAN - Prise en Charge Anticipée Numerique des Dispositifs Médicaux (Early Access to Reimbursement for Digital Medical Devices).

Sources: IQVIA materials, online sources: [7,32,33]

The development of SaMD regulations and reimbursement pathways in the UK

The current framework for medical devices in the UK is based on the Medical Devices Regulation 2002 and has not yet incorporated the updated EU regime (Medical Devices Regulations 2017/745). However, the Medicines and Healthcare products Regulatory Agency (MHRA) has expressed its intention to establish a new regulatory regime, initially by July 2023 and recently postponed to July 2025. While the UKCA mark requirements are not updated, the UK relies on EU CE Mark regulations. The new regime will align with the requirements of the EU Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR), as well as international definitions and guidance from the IMDRF (the International Medical Device Regulators Forum).[34]
The MHRA has introduced the "Software and AI as a Medical Device Change Programme"[35], to establish clear regulatory requirements for software and AI technologies and ensure the protection of patients. This program is an extension of broader reforms pertaining to medical devices in general, as outlined in the Government's response to the consultation on the future regulation of medical devices in the United Kingdom.[36]

In addition, the UK government has already taken steps to develop regulatory pathways for digital health. NICE has been collaborating with the MHRA to create a streamlined regulatory pathway for digital health technologies in England. The aim is to ensure that effective and cost-effective digital technologies can be accessed by patients in the NHS in a timely manner.[37]

NICE DIGITAL HEALTH TECHNOLOGIES PILOT

In March 2019, NICE introduced the Evidence Standards Framework (ESF) for digital health technologies. These standards outline the levels of evidence required to demonstrate clinical effectiveness and economic value, striking a balance between innovation and ensuring confidence in the healthcare system.[38]

While not mandatory, the ESF can be used by NHS evaluators and innovation teams when evaluating DHT for commissioning or purchasing decisions.[38]
In 2020, NICE conducted its first assessment using the ESF, focusing on the Zio XT service, which detects abnormal heart rhythms in patients.[38] After the successful pilot, NICE continued to assess additional digital health technologies.

The ESF is utilized both locally and nationally by various organizations. For instance, Health Technology Wales (HTW) employs the ESF to aid in the selection of technology topics for appraisal. It serves as a guide for determining whether a technology has reached a sufficient level of maturity to undergo appraisal. Since 2021, HTW has conducted appraisals of more than 30 technologies.[39]

Another example is the way the Accelerated Access Collaborative within NHS England has incorporated the NICE ESF for digital health technologies into its Artificial Intelligence in Health and Care Award. This is an NHS AI Lab programme run by the Accelerated Access Collaborative (AAC) in partnership with the National Institute for Health Research (NIHR). This aims to make funding available to accelerate the testing and evaluation of the most promising AI technologies which meet the strategic aims set out in the NHS Long Term Plan.[40]

The UK MHRA has introduced the "Software and AI as a Medical Device Change Programme"[35], to establish clear regulatory requirements for software and AI technologies and ensure the protection of patients.

In 2022, NICE issued a recommendation endorsing the use of the Sleepio App as a practical alternative to sleeping pills. The Sleepio application utilizes an advanced AI algorithm to provide individuals with customized digital cognitive-behavioral therapy for insomnia (CBT-I). The app has demonstrated cost savings for the NHS as well as helping reduce reliance on potentially addictive medications such as zolpidem and zopiclone.[41]

DIGITAL TECHNOLOGY ASSESSMENT CRITERIA (DTAC)

Complementary to the EFS, the Digital Technology Assessment Criteria (DTAC) have been developed with the aim of providing confidence to NHS staff, patients, and citizens that all DHT employed within the NHS adhere to national standards. These criteria are established in regulations and industry best practices, covering five essential categories. DHTs may be judged to either meet or not meet the requirements in four categories, which encompass clinical safety, data protection, technical security, and interoperability. Additionally, they receive a numerical score in the fifth category, which assesses usability and accessibility.[9]

This pathway is designed to harmonize with the priorities and requirements of the NHS while accommodating the diverse characteristics of various digital technologies. The overarching goal is to establish robust and proportional assessment frameworks for DHTs that align with the NHS's key objectives and priorities.[42]

EARLY VALUE ASSESSMENT (EVA) FOR MEDTECH)

The UK's Early Value Assessment (EVA) process serves as a guiding framework for the NHS to assess the worth of diverse medical technologies, with a particular focus on digital health innovations. Its primary objective is to identify technologies that can deliver optimal benefits to patients.

Unlike the comprehensive evidence base required for full NICE endorsement, EVA provides recommendations for technology use while evidence continues to be gathered, allowing for more agile decision-making and implementation in healthcare settings.

Within the EVA process, various aspects are explored, including the potential of technologies, the identification of evidence gaps, and the selection of priority areas for health and social care. The process specifically evaluates technologies that address national healthcare needs that are currently unmet, aligning with the NHS Long Term Plan aimed at enhancing patient access to healthcare services.

For a technology to qualify under EVA, it must possess appropriate certification (such as DTAC approval), offer benefits to both patients and the healthcare system, and require further evidence collection. EVA aims to provide early signals regarding the value of these technologies, especially when multiple promising technologies with similar applications are under consideration.[43]

In conclusion, the future of digital health reimbursement pathways in Europe is promising, with countries such as Germany, Belgium, France and the UK leading the way in developing regulations and frameworks to support the adoption and reimbursement of DHS. The efforts being made reflect the growing recognition of the potential of digital health in improving healthcare outcomes and the commitment to ensuring that innovative and effective digital solutions reach patients in a timely manner.

European Taskforce for Harmonized Evaluation of Digital Medical Devices (DMDs)

Recognizing the importance of a unified approach to evaluation and reimbursement of DHS in the EU, a joint task force was formed in April 2022. Comprising representatives from various European public and academic institutions, the task force aims to establish a harmonized assessment framework that supports national appraisal and reimbursement of DMDs by statutory health insurance organizations.

Table 2: Comparison between DiGA and PECAN reimbursement pathways

PLATFORM	DIGA IN GERMANY	PECAN IN FRANCE
PRODUCTS	DTx	DTx and telemonitoring solutions
MEDICAL DEVICES CLASSES	I and II	I, IIa, IIb, III
TIME BEFORE SUBMISSION OF THE PERMANENT LISTING	12 – 24 months	6 – 9 months
STUDIES NEEDED TO BE COMPLETED	Pilot study indicating positive healthcare effect	Clinical study – completed or with intermediate results

Source: IQVIA materials, IQVIA France Market experts.

Chaired by the French ministerial eHealth delegation and co-chaired by the European Network for Health Technology Assessment (EUnetHTA), the task force is coordinated by the European Institute of Innovation and Technology (EIT Health). It was launched during the French Presidency of the Council of the European Union with the objective of maximizing the use of the European Health Data Space, optimizing resource utilization, enhancing the quality of health technology assessment (HTA) in the EU, and avoiding duplication of HTA efforts. The task force focuses on harmonizing clinical evaluation criteria and methodologies for DMDs in Europe.[44]

To achieve consensus on the definitions of digital medical devices and to provide scientific consensus and recommendations to other EU Member States, the task force initiated an open call for experts from the industrial and private sectors in July 2022. The aim is to gather perspectives from diverse stakeholders and real-world examples to better understand the practical implications of proposed regulations and to enhance the validity of the task force's recommendations.[23] This collaborative effort seeks to bridge the gap between suggested regulations and their applicability in real-life scenarios.

As an example of requirements harmonization, France made sure that its PECAN platform requirements overlap with those of DiGA. As DiGA served France as an inspiration, DiGA's acceptance implies fulfillment of all the steps necessary for PECAN too (Table 2).

Despite the fragmented and non-uniform reimbursement landscape for DHS across European nations, certain countries have made considerable strides in establishing dedicated reimbursement pathways. Looking ahead, the future of digital health reimbursement pathways in Europe appears promising.

Conclusion

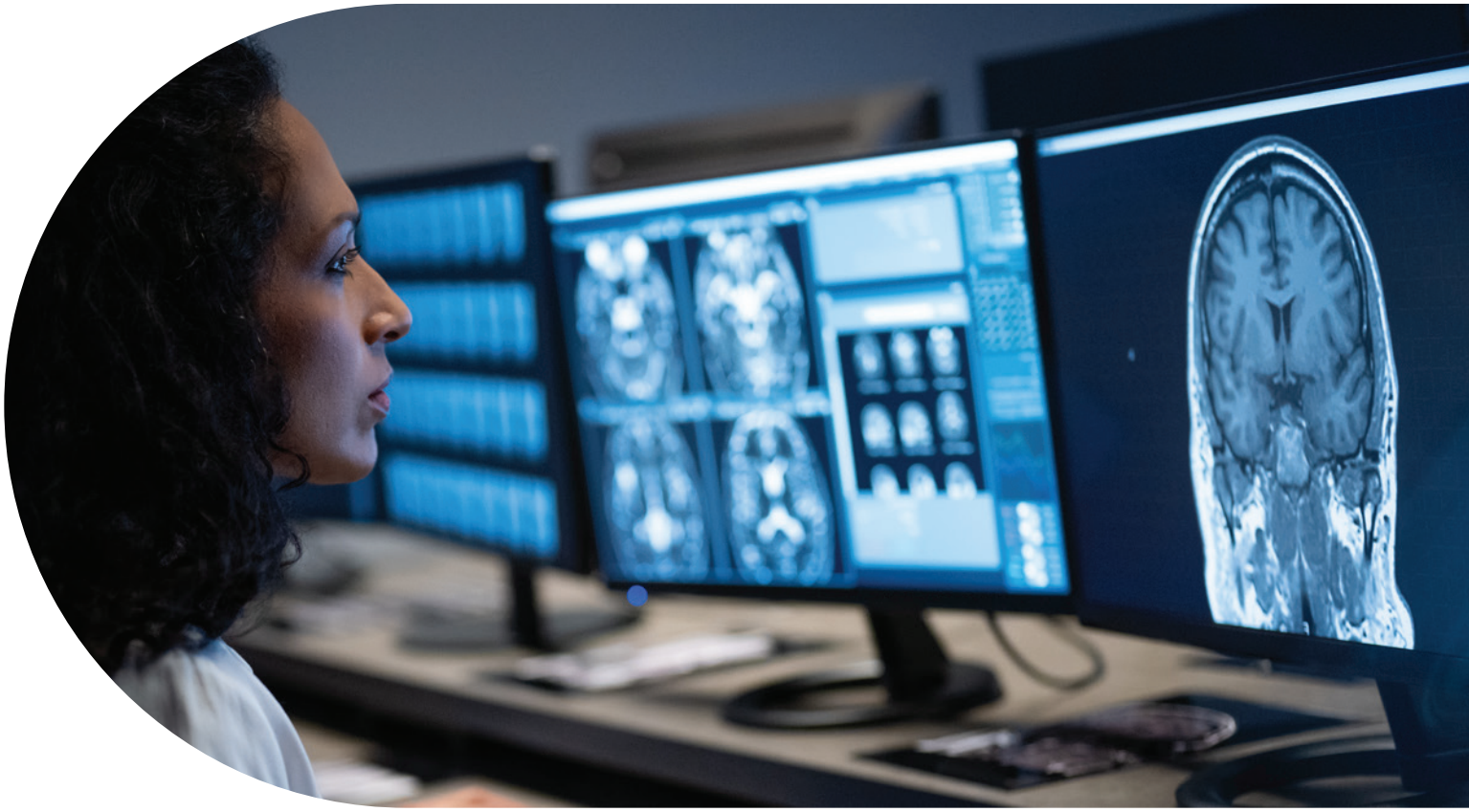
The adoption of DHS in Europe is witnessing remarkable growth, presenting exciting prospects for MedTech companies. However, the lack of adequate funding and reimbursement mechanisms poses a significant barrier to widespread adoption.

Despite the fragmented and non-uniform reimbursement landscape for DHS across European nations, certain countries have made considerable strides in establishing dedicated reimbursement pathways. Germany, with its pioneering Digital Healthcare Act Fast Track platform, DiGA, leads the way in reimbursement processes for SaMD. DiGA empowers digital health developers to charge national health insurers for prescriptions, providing a clear and efficient reimbursement pathway.

Looking ahead, the future of digital health reimbursement pathways in Europe appears promising. Inspired by Germany's DiGA Fast Track process, several countries have adopted frameworks for evaluating and reimbursing digital health apps. France, closely following DiGA, has recently announced its PECAN early access reimbursement program, and the UK, with centralized evaluations and local reimbursement decisions, has developed regulations and initiatives to foster the growth and adoption of digital solutions in healthcare.

For MedTech companies operating in the digital health sector, it is paramount to stay informed about the evolving reimbursement pathways in Europe. By comprehending the reimbursement landscape and actively engaging in regulatory processes, companies can navigate the market effectively and ensure the accessibility and affordability of their SaMD solutions.

Manufacturers should continue to monitor developments in reimbursement regulations, collaborate with relevant stakeholders, and adapt their strategies to seize the opportunities presented by the dynamic digital health landscape in Europe.



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Appendix A

List of digital apps reimbursed in Germany

Application Name	DIGA-ID	Date	Manufacturer	Trial/ Permanent	Switched to Permanent	Type of DiGA	Risk Class	Category
Kalmeda	350	9/25/2020	mynoise GmbH	Permanent	12/20/2021	App	I	Ears
velibra	316	10/1/2020	GAIA AG	Permanent		Web App	I	Psyche
zanadio	294	10/22/2020	aidhere GmbH	Permanent	08/15/2022	App	I	Hormones and metabolism
Vivira	387	10/22/2020	ViviraHealthLab GmbH	Permanent	2/17/2022	App	I	Muscles, bones, joints
Invirto	300	12/3/2020	Sympatient GmbH	Permanent	12/2/2022	App	I	Psyche
Selfapys Online-Kurs bei Depression	876	12/16/2020	Selfapy GmbH	Permanent	4/11/2022	Browser based web app	I	Psyche
Rehappy	691	12/29/2020	Rehappy GmbH	Revoked		App	I	Heart and circulation
somnio	508	10/22/2020	mementor DE GmbH	Permanent		Browser based web app	I	Psyche
elevida	419	12/15/2020	GAIA AG	Permanent		Browser based web app	I	Nervous system
deprexis	450	2/20/2021	GAIA AG	Permanent		Browser based web app	I	Psyche
Mindable	329	4/29/2021	Mindable Health UG	Permanent	04/28/2023	App	I	Psyche
CANKADO PRO-React Onco	961	5/3/2021	CANKADO Service GmbH	Revoked		App, Web App	I	Cancer
Selfapys Online-Kurs bei Panikstörung	1052	6/19/2021	Selfapy GmbH	Revoked		Browser based web app	I	Psyche
Selfapys Online-Kurs bei Generalisierter Angststörung	1049	6/19/2021	Selfapy GmbH	Permanent	11/18/2022	Browser based web app	I	Psyche
NichtraucherHel-den-App	1085	7/3/2021	Sanero Medical GmbH	Permanent	06/30/2023	App	I	Psyche
ESYSTA AppmitESYSTA Portal	939	7/4/2021	EmperraGmb-HE-Health Technologies	Revoked		App, Web App	I	Hormones and metabolism
Mawendo	993	8/9/2021	Mawendo GmbH	Trial		Browser based web app	I	Muscles, bones, joints
vorvida	868	8/7/2021	GAIA AG	Permanent		Browser based web app	I	Psyche
Oviva Direkt für Adipositas	872	3/10/2021	Ovivia AG	Permanent	06/30/2023	App	I	Hormones and metabolism

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Appendix A *continued*

List of digital apps reimbursed in Germany, continued...

Application Name	DIGA-ID	Date	Manufacturer	Trial/ Permanent	Switched to Permanent	Type of DiGA	Risk Class	Category
companion patella powered by medi - proved by Dt. Kniegesellschaft	998	10/4/2021	PrehApp GmbH	Trial		Browser based web app	I	Muscles, bones, joints
Novego: Depressionen bewältigen	1110	10/10/2021	IVPNetworks GmbH	Trial		Browser based web app	I	Psyche
Kranus Edera	1282	12/18/2021	Kranus Health GmbH	Permanent	03/27/2023	App	I	Genitals, kidneys and urinary tract
HelloBetter ratiopharm chronischer Schmerz	1304	12/18/2021	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent	07/17/2023	Browser based web app	I	Muscles, bones, joints
Cara Care für Reizdarm	1346	12/26/2021	HiDoc Technologies GmbH	Trial		App	I	Digestion
HelloBetter Stress und Burnout	965	10/18/2021	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent		Browser based web app	I	Other
HelloBetter Diabetes und Depression	1376	12/11/2021	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent		Browser based web app	I	Hormones and metabo-lism
neolexon Aphasie	1196	2/6/2022	Limedix GmbH	Trial		App, Web App	I	Other
Meine Tinnitus App - Das digitale Tinnitus Counseling	1496	3/6/2022	Sonormed GmbH	Trial		App	I	Ears
HelloBetter Vaginismus Plus	1497	2/4/2022	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent		Browser based web app	I	Psyche
Vitadio bei Diabetes Typ 2	746	4/15/2022	Vitadio s.r.o	Trial		App	I	Hormones and metabolism
PINK! Coach	1464	6/27/2022	PINK gegen Brustkrebs GmbH	Trial		App	I	Cancer
HelloBetter Panik	1513	4/3/2022	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent		Browser based web app	I	Psyche
Vitadio bei Diabetes Typ 2	746	4/15/2022	Vitadio s.r.o	Trial		App	I	Hormones and metabolism

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Appendix A *continued*

List of digital apps reimbursed in Germany, continued...

Application Name	DIGA-ID	Date	Manufacturer	Trial/ Permanent	Switched to Permanent	Type of DiGA	Risk Class	Category
PINK! Coach	1464	6/27/2022	PINK gegen Brustkrebs GmbH	Trial		App	I	Cancer
HelloBetter Panik	1513	4/3/2022	GET.ON Institut für Online Gesundheit-strainings GmbH	Permanent		Browser based web app	I	Psyche
edupression.com	1815	12/26/2022	SOFY GmbH	Trial		Browser based web app	I	Psyche
elona therapy Depression	1254	12/26/2022	Elona Health GmbH	Trial		App, Web App	I	Psyche
endo app	1734	09/10/2022	Endo Health GmbH	Trial		App	I	Genitals, kidneys and urinary tract
HelloBetter Schlafen	1772	12/18/2022	GET.ON Institute for Online Health Training GmbH	Trial		Browser based web app	I	Nervous system
Kaia COPD: Meine aktive COPD Therapie	1329	12/26/2022	kaia health software GmbH	Trial		App	IIa	Respiratory tract
Kaia Rücken-schmerzen - Rückentraining für Zuhause	1330	02/03/2023	Kaia Health Software GmbH	Permanent		App	IIa	Muscles, bones, joints
levidex	752	01/07/2023	GAIA AG	Trial		Browser based web app	I	Nervous system
mebix	2078	07/14/2023	Vision2B GmbH	Trial		App	I	hormones and metabolism
My7steps app	1786	02/17/2023	Ipso Healthcare GmbH	Trial		Browser based web app	I	Psyche
NeuroNation MED	1113	05/13/2023	Synaptikon GmbH	Trial		App	I	Psyche
Novego: Ängste überwinden	1820	03/24/2023	IVPNetworks GmbH	Trial		Browser based web app	I	Psyche
optimune	1613	07/14/2022	GAIA AG	Trial		Browser based web app	I	Cancer
priovi - digitale Unterstützung der Borderline-Behan-dlung	1853	03/05/2023	GAIA AG	Trial		Browser based web app	I	Psyche
ProHerz	1823	05/15/2023	ProCarement GmbH	Trial		App	I	Heart and circulation
re.flex	474	09/29/2022	Kineto Tech Rehab SRL	Trial		App	I	Muscles, bones, joints
Selfapys Online-Kurs bei Binge-Eating-Störung	1830	01/05/2023	Selfapy GmbH	Trial		Browser based web app, App, Combination App/web app	I	Psyche

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Appendix A *continued*

List of digital apps reimbursed in Germany, continued...

Application Name	DIGA-ID	Date	Manufacturer	Trial/ Permanent	Switched to Permanent	Type of DiGA	Risk Class	Category
Selfapys Online-Kurs bei Bulimia Nervosa	1834	01/05/2023	Selfapy GmbH	Trial		Browser based web app, App, Combination App/web app	I	Psyche
Selfapys Online-Kurs bei chronischen Schmerzen	1954	04/21/2023	Selfapy GmbH	Trial		Browser based web app, App, Combination App/web app	I	Muscles, bones, joints
sinCephalea - Migräneprophy-laxe	1775	10/10/2022	Perfood GmbH	Trial		App	I	Nervous system
Smoke Free - Rauchen aufhören	1909	01/29/2023	Smoke Free 23 GmbH	Trial		App	I	Psyche
M-sense Migräne	315	12/16/2020	Newsenselab GmbH	Revoked		App	I	Nervous system
Mika	875	03/25/2021	Fosanis GmbH	Revoked		App	I	Cancer

Appendix B

Medical Apps with M1, M2, and M3 Classification in Belgium

Product	Level	Developer	Indication	User	Type
AirviewTM	2	Resmed	Screening and management of patients suffering from Sleep disorderd breathing or respiratory failure.	HCPs	Web application
AWELL CALCULATED SCORE SUITE	1	Awell Health	Support in designing, implementing and executing care pathways.	HCPs	Web application
Bingli	1	Bingli	Patients use Bingli to be better prepared for their doctor/hospital visit.	HCPs/Patients	Mobile and web application
Brizzy	1	NOMICS	Enables simple and accurate Sleep Disordered Breathing testing using Jaw Activity (Jawac).	HCPs	Web application
CardiacSense	1	Arseus Hospital NV	Reliable and validated cardiac measurements (Beat by beat pulse rate, ECG, Atrial fibrillation detection, and, in the future additional heart arrhythmias), vital parameters and BP monitoring.	HCPs/Patients	Mobile and web application
CardioCare@Home	2	Byteflies	Cardiac information collection and transmission to a healthcare provider.	HCPs/Patients	Web application
Care Orchestrator	1	Philips Belgium Commercial	Remote monitoring and management of sleep and respiratory patients.	HCPs	Web application
CareLink System	1	Medtronic Belgium	Digital solution for remote monitoring of cardiac implanted patients.	HCPs/Patients	Mobile and web application
CloudCare by Diabeter	1	Medtronic Belgium	Increases outcomes and experiences of patients and drive clinic efficiencies by differentiating patients needing face to face visits and remote consultations.	HCPs/Patients	Mobile and web application
Comarch HomeHealth 2.0	1	Comarch AG - Belgian Branch	Provides remote medical care to connect patients who needs monitoring with healthcare providers.	HCPs/Patients	Mobile application
Comunicare	2	Comunicare Solutions	Digital care companion that enables a better communication between patients and caregivers.	Patients	Mobile application
EagleView	1	M-ighty NV	Ambulatory intelligent patient follow up system that measures several vital signs parameters through a set of medical devices, or through a medical grade wearable on the chest.	HCPs/Patients	Web application
epihunter	1	Epihunter NV	Signals, video-records and logs epileptic absence seizures and focal onset im-paired awareness seizures in real-time.	Patients, families	Mobile and web application
FibriCheck	2	Qompium	Registers heart rhythm disorders and associated symptoms.	Patients	Mobile and web application

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Medical Apps with M1, M2, and M3 Classification in Belgium, continued

Product	Level	Developer	Indication	User	Type
FreeStyle Libre Flash Glucose Monitoring System	2	Abbott SA/NV	Measures interstitial fluid glucose levels in people (aged 4 and older) with diabetes mellitus, including pregnant women.	Patients	Mobile and web application
Guardian Connect App	1	Medtronic Belgium	Records, displays, alerts blood glucose levels, supports in diabetes management.	Patients	Mobile and web application
Healthentia	2	INNOVATION SPRINT SPRL	The main purpose of the application is to support the capturing of data in clinical studies.	Researchers / Patients	Mobile and web application
HypnoVR	1	HypnoVR	Virtual reality (VR) hypnosis solution intended to improve management of patients' pain, stress and anxiety by providing an alternative or complementary solution to chemical treatments.	HCPs	Medical device
icompanion	1	icometrix	Gives patients with multiple sclerosis and their treating neurologists more insight into the patient's disease course.	HCPs/Patients	Mobile and web application
moveUP Coach	3-	moveUP	Provides a service to be able to offer the optimal treatment for hip and knee arthroplasty patients, both before and after surgery.	HCPs/Patients	Mobile and web application
myDiabby Healthcare	1	MyDiabby Healthcare (MDHC)	Telemonitoring platform specializing in the management of diabetes.	HCPs/Patients	Mobile and web application
MyMedicoach	1	Mymedicoach	The aim of the app is to increase compliance with treatments (non-medicinal: physical exercises, meditation, actions to be carried out regularly, etc.).	HCPs/Patients	Web application
mySugr	2	Roche Diagnostics Belgium NV	Support with diabetes therapy by always having data available and making it easily visible.	Patients	Mobile application
NeuroPath	1	NeuroPath SRL/BV	Digital Health Platform that collects and consolidates the multitude of symptoms of neurodegenerative diseases to provide therapy and remote patient monitoring.	HCPs/Patients	Mobile and web application
Neuroventis Platform	1	Neuroventis	Platform medical device software that provides digital tools for patients and healthcare professionals intended to manage neurological disorders.	HCPs/Patients	Mobile application
Noona	2	Varian Medical Systems Belgium	Cloud-based patient-reported outcomes (PRO) solution that helps the care team identify patients in need of urgent care based on symptom severity.	HCPs/Patients	Mobile and web application
Nucleus Smart App	2	Cochlear	Provides a convenient and easy way to tailor hearing to personal preferencesfor cochlear implant users.	Patients	Mobile application

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Appendix B *continued*

Medical Apps with M1, M2, and M3 Classification in Belgium, continued

Product	Level	Developer	Indication	User	Type
Nutrow	1	Dim3	Medical software that integrates and displays nutritionally relevant patient data coming from multiple sources for a complete nutrition management process of adult patients.	HCPs	Web application
ONCOLAXY	1	Resilience	Solution dedicated to remote monitoring and support for oncology patients.	HCPs/Patients	Mobile and web application
OneTouch Reveal	1	Lifescan	Intended for use by people with diabetes to view, track, trend and share data from the OneTouch blood glucose meters to support diabetes management.	Patients	Mobile and web application
PACSonWEB	1	Dobco Medical Systems	The purpose of the application is to visualize medical imaging examinations and to share them between healthcare providers and with the patient.	HCPs/Patients	Mobile and web application
Plateforme Maela	2	Medtronic Belgium	Maela is a digital solution for patient engagement and monitoring.	Patients	Mobile and web application
RemeCare	2	Remecare BV	Through the mobile application, patients can report their medication intake, vital signs, symptoms and side-effects on a daily basis.	HCPs/Patients	Mobile application
SkinVision	1	SkinVision BV	Provides an immediate risk indication for the most common types of skin cancer of a specific spot on the skin, based on a photo taken with a smartphone.	HCPs/Patients	Mobile and web application
Sunrise	1	Sunrise	Allows rapid and at home diagnosis of sleep apnea.	HCPs/Patients	Mobile and web application
SyncVR Fit	1	SyncVR Medical B.V.	Physical movement exercises and mental relaxation exercises to support patients in their physical activity and mental relaxation.	Patients	Mobile application
SyncVR Relax & Distract	1	SyncVR Medical B.V.	Solution to distract patients before, during and after medical or surgical procedures in order to decrease pain, anxiety and/or stress.	Patients	Mobile application
TelePHON.digital	1	Telephon.digital BV	Blended therapy support, screening & prevention.	HCPs/Patients	Web application
Well@Home	2	BeWell Innovations	Allows for patient follow-up using quality of life questionnaires, connected devices, and telemedicine.	HCPs/Patients	Mobile and web application

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Aleksandar leads the IQVIA Global MedTech Device Consulting Practice and has expertise in life sciences industry spanning strategy consulting, entrepreneurial market expansion, and digital innovation.

With a background in clinical neurology and engineering, he defined, developed, and commercialized novel medical devices and diagnostics. These include research and development to launch of a brain perfusion MR imaging solution as well as development of a disruptive go-to-market strategy for a $1B insulin pump business.

Aleksandar holds a doctorate from the University of Oxford, a US Department of State leadership award and has held research and innovation positions at Harvard University and Massachusetts General Hospital.

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