Evaluating Reimbursement Pathway of Digital Health **Technologies across Five European Countries**

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Background

- ► The digital health market is evolving rapidly, with digital health technologies (DHTs) poised to become a key driver of healthcare delivery.
- ▶ DHTs differ from general wellness apps and have a specific medical purpose, such as aiding diagnosis, and helping with prevention, management, or treatment of a medical disorder or disease.^{1, 2}
- ► These technologies include digital tools aimed for use as a therapeutic product, or as an adjunct to other therapeutic products (drugs, biologics, and devices).
- ▶ DHTs show significant promise in improving patient outcomes.^{2, 3}
- Regulatory and health technology assessment (HTA) frameworks are lagging behind the fast-paced development of DHTs, notably seen in the delayed adoption of Artificial Intelligence (AI) based diagnostic tools for eye health.⁴

Results (continued)

Italy

- > Policy Framework: Italy's digital health strategy is part of broader healthcare reform plans to integrate digital technology in the traditional healthcare system, with significant funds for digital health through the National Recovery and Resilience Plan (NRRP).⁵
- **Process and Reimbursement:** Telemedicine and e-health is generally supported by the Italian health authorities at the national level but reimbursement pathways for digital health applications are yet to be defined.⁶
- **Impact and Opportunities**: With a substantial NRRP investment, Italy is poised to increase the scale of its digital health capabilities exponentially. The key challenge is to create a unified regulatory environment, which can enable these investments to reach their full potential.

Spain

Policy Framework: There is no national framework for the assessment and reimbursement of DHTs in Spain. Regional communities are the ones responsible for the assessment and reimbursement, and they can adopt digital health solutions at their own discretion.¹⁷



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► Market access for DHTs is currently inconsistent and can benefit from harmonization across HTA frameworks to incorporate these technologies into the healthcare landscape.²⁻⁷

Objective

To understand the pricing and reimbursement (P&R) policies for DHTs across the United Kingdom (UK), Germany, France, Italy and Spain, with a focus on their reimbursement frameworks, processes, and consequences on digital health adoption.

Methods

Data Collection

► A targeted literature review was conducted by searching MEDLINE® and P&R policy documents from January 1, 2020, to May 24, 2024. A descriptive analysis was used to identify similarities and differences in the reimbursement policies.

Inclusion Criteria

Documents were included if they provided insights on digital health policies, specifically in the form of reimbursement pathways, regulatory criteria or evidence standards.

Analytical Framework

► A qualitative content analysis was conducted to identify trends and variations among national frameworks. Key parameters analyzed for each country included digital health reimbursement policies, focusing on regulatory structures, approval processes, evidence requirements, and stakeholder involvement.

- **Process and Reimbursement:** There is no national strategy for evaluating and funding digital health. Some regions, including Andalusia and Madrid, have established their own systems of assessment.^{4, 17}
- **Impact and Opportunities:** The decentralized approach allows for solutions developed at the regional level that can be tailored to local needs, but also presents vast differences in access to digital health technologies from one part of the country to another.

Table 1: Market Access Landscape for DHTs in Five European Countries

Aspect	Feature	ИК	Germany	France	Italy	Spain
Evaluation	System Type	Decentralised and Centralised	Centralised	Centralised	Decentralised	Decentralised
	Responsible Bodies	NICE, Regional	BfArM	ANS, CNEDIMTS	Various	Various
Reimbursement	System Type	Decentralised	Centralised	Centralised	Decentralised	Decentralised
	Decision Maker	Local ICS	BfArM	Ministry of Health and Social Security	Regional	Regional
Funding	System Type	Decentralised	Centralised	Centralised	Decentralised	Decentralised
	Funding Body	Local Economies	GKV-SV	CEPS	Regional	Regional
Frameworks for DHTs	Presence	Yes	Yes	Yes	No	No
	Details	Non-binding, Evidence Standards Framework Digital Health Technologies (Tier A, B, and C)	Non-binding, Digital Supply Act	Non-binding, Digital Medical Devices Including Telemedicine	N/A	N/A

ANS - Agence du Numérique en Santé; BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte; CEPS - Comité Économique des Produits de Santé; CNEDiMTS - Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé; GKV-SV - Gesetzliche Krankenversicherung-Spitzenverband; ICS – Integrated Care Systems; N/A – Not Applicable

Comparative Analysis



The included records highlighted that the UK, Germany and Italy were among the first countries to develop P&R policies for DHT in 2019. Germany, France, and Italy have structured processes for evaluating and integrating DHT into their healthcare systems, emphasizing clinical benefits and quality. The UK and France feature multiple layers of assessment and regional involvement in decision-making while Germany and Italy maintain some level of national

Results

Eleven papers and seven P&R policy documents were identified for the digital health reimbursement models in the UK, Germany, France, Italy and Spain. The documents identified the associated policies, procedures and issues related to market entry and reimbursement.



- Policy Framework: NICE (the National Institute for Health and Care Excellence) evaluates digital health technologies for their clinical effectiveness and costeffectiveness.⁸
- **Process and Reimbursement:** Although digital tools identified by NICE are eligible to be funded by the NHS, actual implementation is left up to local health authorities - meaning access depends on local healthcare policies which are somewhat disorganized and inconsistent.^{2,9}
- **Impact and Opportunities:** NICE is a national decision-making body in the UK and has a robust evaluation process, but the absence of a single national reimbursement pathway may limit the scale and equity of access for digital health technologies that are eventually approved.^{2, 5}

Germany

- **Policy Framework:** The pathway of digital health reimbursement is embedded in the Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG), which allows DHTs—known in Germany as DiGAs —to be fast-tracked through a centralised evaluation process carried out by the Federal Institute for Drugs and Medical Devices (BfArM).¹⁰
- **Process and Reimbursement:** If a DHT is shown to work, be safe, and to have a positive healthcare impact, it can be immediately reimbursed by statutory health insurance. This includes a novel provision under which the price is initially set by the manufacturer for the first year, during which effectiveness data are gathered to justify permanent inclusion and pricing discussions.¹¹⁻¹⁴

oversight in the approval and integration of DHT.



Germany leads the path through a defined fast-track process that leads to an expedited and broader market access. Spain lacks a specific reimbursement process and relies on regional discretion. France has a centralized committee for evaluation and price negotiation, while Italy's integration is influenced by regional tariffs and pilot projects. The UK's reliance on regional decision-making without a national reimbursement pathway contrast with other countries.



Germany, UK, and France do not define DHTs at the government level and treat them as general medical devices. Most regulatory bodies consider DHTs to be a sub-category of software as a medical device (SaMD) instead of a separate regulatory category.¹

Future Outlook

- ▶ In January 2022, the EU's Health Technology Assessment Regulation came into force and will apply from January 2025. Joint Clinical Assessments (JCA) will include selected medical devices depending on DHT type, their medical device risk class, and whether they meet JCA review criteria.³
- Changes in individual markets should be monitored closely as the HTA regulation is implemented across the EU. Tracking how JCA influence DHT adoption is crucial in evaluating uniformity across markets.
- > As DHTs continue to evolve, traditional safety concerns like adverse events or physical harm will be less apparent for DHTs or medical devices. Instead, the emphasis will be on improved data security and accessibility, which will be vital in maintaining patient trust and driving widespread adoption of DHTs in healthcare.
- Al supports evidence generation and clinical decisions in digital health but requires transparency and fairness to avoid biased outcomes. NICE emphasizes that Al is meant to complement, not substitute, human oversight.¹⁸

Conclusions

- The study highlights significant variability in the P&R policies for DHTs across the five European countries.
- Despite general interest in embracing new digital tools, differing frameworks and regulations create challenges for developers.
- These differences can impact healthcare systems by delaying access or causing inconsistent reimbursement requirements.
- Future research should consider the impact of variability in P&R policies on patient access delays. It should also assess the effects of these policies on reimbursement outcomes.

References

- 1. Wang et al. Npj Digital Medicine. 2023;6(1). doi:10.1038/s41746-023-00777-z
- 11. Schimdt et al. Npj Digital Medicine. 2024; 7. doi: 10.1038/s41746-024-01137-1

Impact and Opportunities: The design of the pathway encourages innovation and speeds up access for patients to new technologies that can make a difference. In this way, Germany is in a promising position in the digitisation of Europe's healthcare system.

France

- **Policy Framework:** There is currently no national framework for DHTs in France. However, France is progressing towards integration of digital solutions through existing healthcare technology assessment processes run by the Haute Autorité de Santé (HAS).¹⁵
- **Process and Reimbursement:** To be reimbursed by the national general health insurance schemes, a digital health product must demonstrate efficacy and safety. For specific digital therapies, reimbursement can be obtained through the national pilot programme for digital therapies, which was launched in 2020.^{2, 14}
- **Impact and Opportunities:** In addition to continued pilot programmes, HAS's role in reviewing digital health tools is a sign of more structured digital health integration going forward, suggesting that digital health technology adoption in France will continue to be prudent but progressive.¹⁶
- 2. MedTech Europe. 2021. <u>https://www.medtecheurope.org/wp-</u> content/uploads/2021/11/2111_v4.8_mte_dht_reimbursement16.11.2021-2.pdf. [Date Accessed: September 13, 2024]
- EFPIA. 2023. https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-ineurope.pdf. [Date Accessed: September 17, 2024]
- 4. Tan et al. *Lancet Glob Health*. 2023;11(9). doi: 10.1016/S2214-109X(23)00323-6
- 5. Walzer et al. 2022. https://www.ispor.org/docs/default-source/euro2022/isporeu22walzerpdf.pdf?sfvrsn=f3c8cd0e_0. [Date Accessed: October 7, 2024]
- 6. Kessel et al. JMIR Mhealth Uhealth. 2023;11. doi: 10.2196/49003
- 7. Mezei et al. Front Public Health. 2023;11. doi: 10.3389/fpubh.2023.1197949
- digital-health-technologies. [Date Accessed: October 2, 2024]
- 9. NHS Transformation Directorate. <u>https://transform.england.nhs.uk/key-tools-and-info/digital-technology-</u> assessment-criteria-dtac/. [Date Accessed: September 23, 2024]
- 10. BFARM Digital Health Applications (DIGA). BFARMWEB. https://www.bfarm.de/EN/Medicaldevices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/_node.html. [Date Accessed: October 14, 2024]

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Authors report employment with Evidinno Outcomes Research Inc.

- 12. Stern et al. THE LANCET. 2022;4(3). doi: 10.1016/S2589-7500(21)00292-2
- 13. Lantzsch et al. BMC Health Services Research. 2022;22(1). doi:10.1186/s12913-022-08500-6
- 14. Groene et al. Frontiers in Digital Health. 2023;5. doi:10.3389/fdgth.2023.1217479
- 15. Ministère des Solidarités et de la Santé / Haute Autorité de Santé. 2024. https://hassante.fr/upload/docs/application/pdf/2023-03/pecan_guide_de_depot_de_dossier.pdf. [Date Accessed: September 30, 2024]
- 16. Agence Du Numérique En Santé. https://esante.gouv.fr/espace-presse/lancement-de-la-prise-encharge-anticipee-des-dispositifs-medicaux-numeriques. [Date Accessed: September 25, 2024]
- 17. eHealth innovation in Spain. https://gnius.esante.gouv.fr/en/international-digital-health-systems/ehealthin-spain. [Date Accessed: October 4, 2024]
- 8. NICE. https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for- 18. NICE. https://www.nice.org.uk/about/what-we-do/our-research-work/use-of-ai-in-evidence-generation-nice-position-statement. [Date Accessed: October 23, 2024]

