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Comprehensive policies for scaling systemic and equitable integration of digital health technologies

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Systemic integration and equitable adoption of Digital Health Technologies (DHTs) require timely, comprehensive, harmonised policies. This paper presents five complementary key enablers: defining DHTs in the scope of fit-for-purpose policy interventions, implementing AI-ready regulatory approaches, adopting dynamic assessment criteria, establishing dedicated reimbursement models, and promoting evidence generation, clinical guidelines, interoperability, and education. Cross-border and multistakeholder collaboration are also crucial to reducing fragmentation, addressing inequities, and driving scalable, systemic value.

Equitable and systemic integration of Digital Health Technologies: challenges and opportunities

Safe and effective Digital Health Technologies (DHTs), such as medical-grade connected sensors and digital health applications, are transforming healthcare on a global scale. However, fragmented policies and inequities in access and adoption hinder their full potential to empower providers, support patients and caregivers, and enhance care. In the EU, while countries like Germany, France, and Belgium have established dedicated frameworks for assessing and reimbursing DHTs, others are at different stages of progress — from early planning to consolidation — or still rely on ad hoc approaches or lack fit-for-purpose pathways altogether[1]. This uneven landscape contributes to disparities in access and hinders the systemic integration of DHTs across Member States. Beyond access, adoption requires targeted policy interventions, ecosystem efforts and technology management approaches[2]. As the EU further advances towards a Health Union and digital single market with emerging regulations as the Health Technology Assessment Regulation (HTAR)[3], the European Health Data Space (EHDS)[4], and the AI Act[5], there is urgency to both ensure safety and scale innovation through harmonised policies. This Comment proposes five complementary policy interventions to support equitable access, adoption, and systemic integration of DHTs across Europe and beyond.

Building on the concept of a policy "full-stack"[6], we extend our focus beyond regulatory clarity and access, to systemic integration and adoption. We further account for the rising role of Artificial Intelligence (AI) and offer actionable recommendations to bridge existing policy gaps. Our framework incorporates five key components: (1) defining DHTs in the scope of targeted policy interventions; (2) ensuring AI-ready regulatory frameworks and Accelerated Access Pathways; (3) establishing dynamic, fit-for-purpose Health Technology Assessments (HTAs); (4) implementing access and reimbursement best practices; and (5) supporting system and clinical integration. We also advocate for multistakeholder collaboration and cross-country harmonisation to reduce fragmentation and scale innovation. Together, these mutually reinforcing enablers provide actionable pathways for systemic integration of DHTs (Fig. 1).

Defining DHTs in scope of fit-for-purpose policies

Defining the subset of DHTs requiring (more) targeted policies is key to enabling fit-for-purpose interventions and cross-country harmonisation. While their terminology may differ, national frameworks in Germany, France, and Belgium consistently focus on software applications certified as medical devices under the EU Medical Device Regulation (MDR)[7]—formally referred to in the MDR as Medical Device Software (MDSW)—with a demonstrable health benefit. To date, these targeted policies have focused exclusively on safe and effective software devices intended for direct use by patients or jointly by patients and healthcare professionals (HCPs). By contrast, those intended solely for HCP use have not yet been included in their scope and remain subject to traditional medical device regulatory and reimbursement pathways.

Germany's 2019 Digital Healthcare Act[8] and Digital Health Applications Ordinance (DiGAV)[9] established the first legal basis and criteria for reimbursing Digital Health Applications ("Digitale Gesundheitsanwendungen", DiGA) via statutory health insurance. Initially limited to Class I and IIa patient-facing or jointly patient- and HCP-facing software certified under the MDR, eligibility expanded under the Digital Act (DigiG) to encompass class IIb devices, including remote monitoring devices, under somewhat more restrictive conditions[10,11]. France formally recognized Digital Medical Devices (Dispositifs Médicaux Numériques) for therapeutic and remote monitoring purposes as a distinct medical device subgroup in 2023[12]. Belgium's mHealth initiative, launched in 2018 and revised in 2024, introduced a multi-level validation and reimbursement framework for MDR-certified software applications that allow patients to share health-related information (with or without sensors) with healthcare professionals[13]. Examples of DHTs currently in scope of existing fit-for-purpose policy frameworks include safe and effective Digital Therapeutics[14] (DTx), remote patient monitoring devices[15] and digital care support programs[16] (Table 1).

At the EU level, research and harmonisation initiatives have begun using the term *Digital Medical Devices* (DMDs)[17–21] to refer to the subset of certified MDSW that is supported by evidence of a demonstrable health

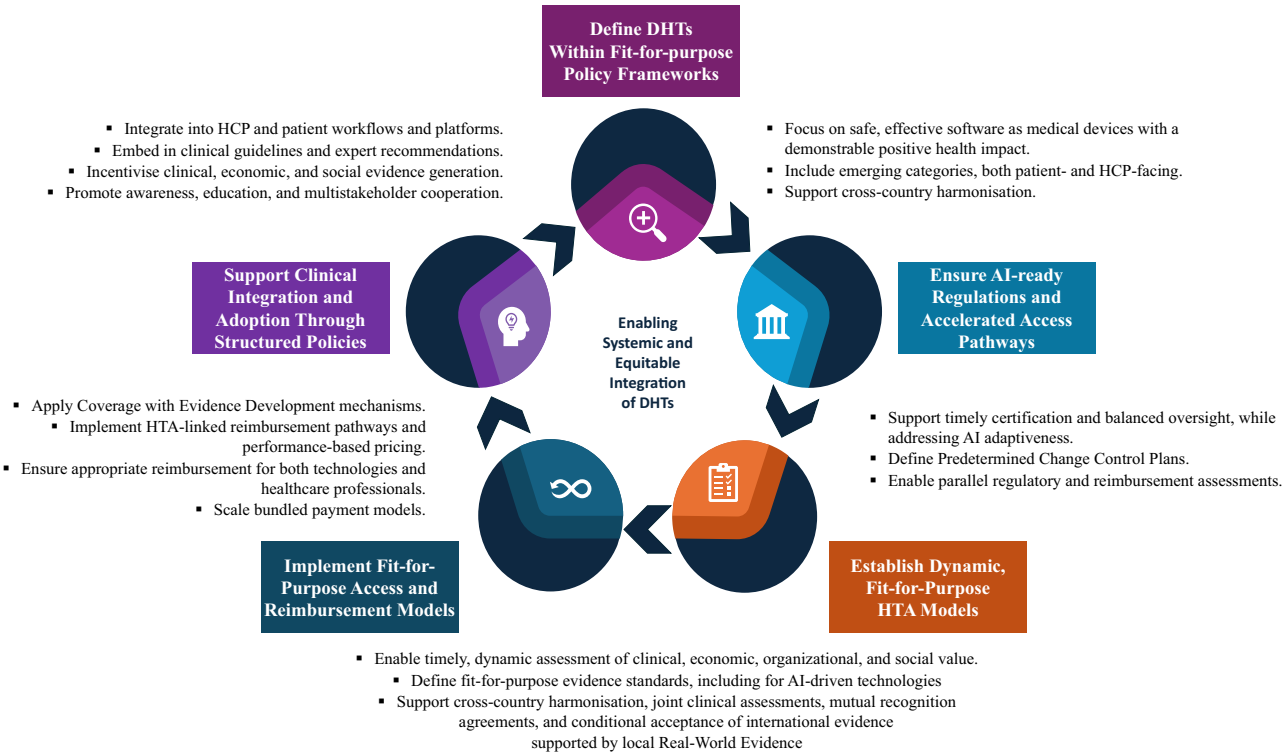

Fig. 1 | A virtuous policy cycle for systemic and equitable integration of Digital Health Technologies. The five mutually reinforcing policy enablers—(1) defining DHTs within fit-for-purpose policy frameworks, (2) ensuring AI-ready regulations and Accelerated Access Pathways, (3) establishing dynamic, fit-for-purpose Health Technology Assessment (HTA) models, (4) implementing fit-for-purpose access and reimbursement models, and (5) supporting clinical integration and adoption through structured policies—form a comprehensive and actionable policy framework to enable systemic and equitable integration of DHTs, scaling impact and promoting harmonisation within and across health systems.

benefit and is therefore within the scope of targeted policy interventions. While all DMDs are MDSW, not all MDSW qualify as DMDs, as some—particularly lower-risk class devices—may lack evidence to claim a demonstrable positive care impact (Fig. 2).

Beyond the scope of existing formal frameworks, we recommend three key evolutions. While current targeted policies are limited to patient-facing DMDs, we propose that DMDs intended exclusively for HCPs—such as software-based clinical decision support systems—should also be included. Many of the regulatory, clinical, and implementation challenges—further elaborated in the following sections—are equally relevant to these HCP-facing technologies.

In addition to the current focus on disease management, treatment or monitoring, we argue that targeted policies should encompass DMDs for primary prevention. Increasing access to DMDs that address modifiable risk factors—such as smoking, unhealthy diets, sedentary lifestyles, and hypertension—through widely accessible mobile technologies could support population-level behaviour change and reduce the burden of preventable non-communicable diseases (NCDs)[22]. This emerging field, at the crossroads between behavioural science and digital health, holds significant potential[23]. While primary prevention is often underfunded, this shift could be operationalised by integrating prevention-focused DMDs into national NCD strategies, linking their use to incentive mechanisms—as conditional cash transfers or reward systems—and aligning them with EU-level initiatives like the EU4Health Programme[24] or the Healthier Together NCD initiative[25].

Finally, as DMDs are increasingly co-developed and/or launched alongside pharmaceuticals and traditional medical devices, policy frameworks should evolve beyond the current narrow focus on "stand-alone" digital devices. The U.S. Food and Drug Administration (FDA)'s Prescription Drug Use-Related Software framework begins to address this by allowing software to be included in drug labels when added clinical benefits are demonstrated[26].

AI-Ready Regulatory Approaches & Accelerated Access Pathways

DMDs must meet jurisdiction-specific regulations, such as the MDR in the EU, to achieve certification for market placement. However, discrepancies between regulatory and reimbursement requirements often delay patient access. Currently, there are no guarantees that the clinical evidence required for certification will be sufficient for HTA and coverage decisions. To address these gaps and fragmentation, we recommend adopting Accelerated Access Pathways at the EU level, as already proposed for high-risk devices[27] and implemented in specific settings in the U.S.[28], which support simultaneous regulatory and reimbursement assessments—streamlining certification, reducing delays, and promoting cross-country harmonisation.

Furthermore, as AI—particularly generative AI—is increasingly integrated into DMDs, regulations must strike a balance between enabling innovation through algorithmic adaptiveness and autonomy, and ensuring continuous product safety and performance. Predetermined Change Control Plans, as developed jointly by the FDA, UK's MHRA, and Health

Table 1 | Non-exhaustive examples of Digital Health Technologies in scope of existing fit-for-purpose policy frameworks in Germany, France, and Belgium

Type of DHT	Definition	Example Product	In scope of existing fit-for-purpose policy frameworks in Germany, France and Belgium
Digital Therapeutics (DTx)	Health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health.	Cognitive-behavioural therapy delivered via a patient-facing mobile application to treat anxiety or depression, supported by evidence of a relevant clinical benefit.	Yes – provided the software is certified as a medical device and shown to have a demonstrable positive health impact, as defined by national fit-for-purpose health technology assessment frameworks (see section "Fit-for-Purpose and Dynamic Health Technology Assessments" and Tables 2 and 3).
Remote Patient Monitoring (RPM) Devices	Digital health technologies to collect and transmit patients' health data to healthcare providers for health monitoring and management.	Software applications that collect vital signs from connected wearables or electronic patient-reported outcomes (ePROs) through validated digital questionnaires, transmitting data securely to clinicians and, thereby, enabling relevant demonstrable health improvements.	Yes – provided the software is certified as a medical device and shown to have a demonstrable positive health impact, as defined by national fit-for-purpose health technology assessment frameworks (see section "Fit-for-Purpose and Dynamic Health Technology Assessments" and Tables 2 and 3).
Digital care support programs	Digital solutions intended to help patients better manage their care of a specific disease or medical condition.	A patient-facing software application providing structured education and self-management support for chronic diseases, such as medication reminders, nutritional guidance, and lifestyle tracking, contributing to measurable care benefits.	Yes – provided the software is certified as a medical device and shown to have a demonstrable positive health impact, as defined by national fit-for-purpose health technology assessment frameworks (see section "Fit-for-Purpose and Dynamic Health Technology Assessments" and Tables 2 and 3).

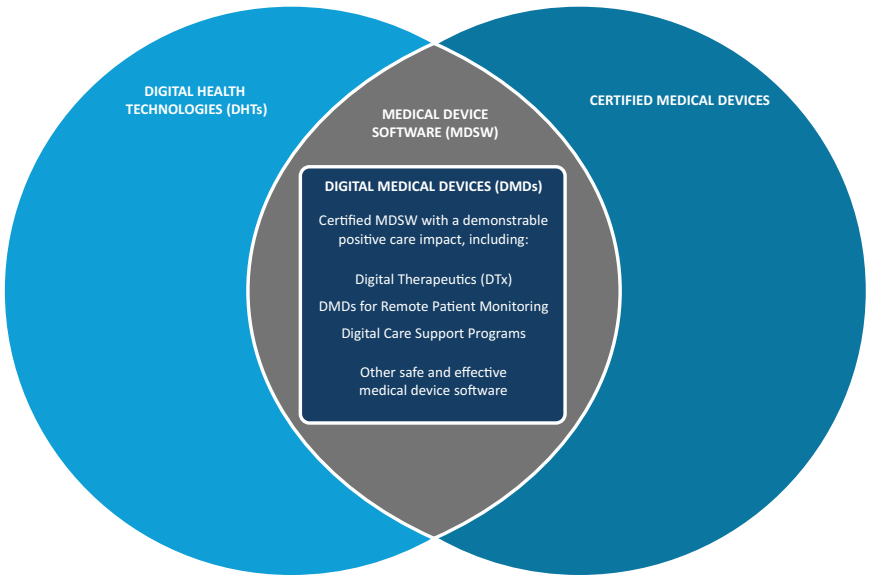

Fig. 2 | The emerging terminology of Digital Medical Devices in scope of fit-for-purpose policies. Digital Health Technologies (DHTs) that fall within existing formal fit-for-purpose policy frameworks in the EU share key characteristics: (i) they are certified as medical device software (MDSW) under the EU's Medical Device Regulation (MDR); (ii) they demonstrate a positive health impact; (iii) they are intended for direct use by patients or jointly by patients and healthcare professionals; (iv) they are not intended for primary prevention; (v) they are typically "stand-alone", not provided with a medicinal product. This subset of both safe and effective MDSW is increasingly referred to in Europe as *Digital Medical Devices* (DMDs). We recommend expanding the scope of fit-for-purpose policies also to include HCP-facing DMDs, those used alongside pharmaceuticals, and those intended for primary prevention. Note: the sizes of the areas in the Venn diagram are not representative of actual market sizes.

Canada, offer a pathway for safe and efficient iteration of AI-based features without requiring repeated regulatory approval[29,30]. We propose defining and adopting similar mechanisms across the EU.

Finally, in the EU, aligning the MDR with the AI Act is essential to avoid delayed certification, which could hinder timely availability of AI-driven DMDs across EU markets. We recommend ensuring that notified bodies can effectively perform simultaneous assessments under both regulations for all AI-driven DMDs that require conformity assessment under the MDR and are therefore classified as "high-risk" under the AI Act, as specified in Recital 50.

Fit-for-Purpose and Dynamic Health Technology Assessments

Establishing market access pathways for DMDs requires fit-for-purpose HTA criteria, appropriate for the dynamic software development process and for its unique characteristics[31]. Germany's DiGAV outlines

requirements for DiGA assessments overseen by the Federal Institute for Drugs and Medical Devices (BfArM). France's PECAN (Prise en charge anticipée numérique) pathway uses parallel assessments: CNEDiMTS ("Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé") evaluates clinical benefits and organizational improvements, and the Digital Health Agency ("Agence du Numérique en Santé") ensures interoperability and security compliance. Belgium's multi-level framework includes technical, clinical, and economic criteria. England has dedicated evidence standards for DHTs, the Digital Technology Assessment Criteria as a baseline for NHS integration[32] and NICE's Early Value Assessment[33] for accelerated evaluations.

HTA criteria for DMDs are formally converging across countries. Table 2 and Table 3 apply the HTA Core Model®—a framework developed by the European Network for Health Technology Assessment[34]—to highlight converging standards and scalable best practices for cross-country harmonisation. However, fragmentation persists due to diverse local dossier structures, supplementary standards and regulations, and limited evidence transferability.

Policymakers should harmonise technical, legal and safety standards. Joint clinical assessments, mutual recognition agreements, and conditional international evidence recognition based on local Real-World Evidence (RWE) generation are timely measures. Shared metrics to capture health economic, organizational and social outcomes will also be key to valuing DMD's broader impact. Efforts to harmonise assessments and voluntary cooperation under the HTAR[35], will be fundamental. Globally, initiatives to clarify regulatory process across jurisdictions[36] represent a valuable resource in the current patchworked policy environment.

Further, current policy frameworks do not systematically adopt "dynamic HTAs", which are designed to accommodate software updates and would be particularly suitable for assessing DMDs[37]. Unlike drugs, which are marketed in their approved form indefinitely, DMDs require updates to improve software compatibility, functionality, and security. They also efficiently record Real-World-Data (RWD), enabling RWE generation to dynamically assess care impact, adoption and inform performance-based pricing models[38,39]. As DMDs increasingly integrate adaptive and generative AI, dynamic HTAs will become even more critical. England has begun updating its evidence standards with expert-based consensus recommendations for AI-driven technologies[40], recognizing that traditional methods used to assess the clinical and economic benefit of drugs or conventional medical devices do not sufficiently capture the specificities of these technologies. Among other requirements, the recommendations specify that vendors should provide a clear definition of the level of autonomy with which the AI-system is expected to operate, a post-deployment oversight process, and a post-deployment change management plan prior to deployment. We propose evolving towards dynamic, fit-for-purpose HTAs for DMDs to better address these emerging complexities.

Access, pricing and reimbursement mechanisms

Reimbursement is key to bridging regulatory approval, HTA, and equitable access. England illustrates this challenge: despite clear regulatory and HTA standards, NICE recommendations are not directly linked to reimbursement by local boards, limiting systemic adoption[41]. While DMD reimbursement models vary across countries—also reflecting differences in health system structure, financing, and governance—common enablers that could be adapted and scaled internationally include: early access pathways through Coverage with Evidence Development (CED) mechanisms, HTA-linked reimbursement, and fit-for-purpose pricing models.

Germany's DiGA "Fast-Track" grants temporary reimbursement, while additional evidence is generated, for up to 12 months (with possible extensions) for DMDs below risk class IIb; France's PECAN pathway enables early coverage for therapeutic and telemonitoring DMDs, and Belgium's "M3-light" stage allows provisional reimbursement. All models require DMDs to meet technical and safety standards as prerequisites, with healthcare benefits assessed following temporary coverage. CED pathways suit DMDs given their short lifecycle, frequent updates, lower risk, and capability to generate RWE via early use.

Linking HTA to centralized national reimbursement decisions, as in Germany and France, ensures more timely, equitable and systemic access to DMDs. Decentralized systems would also benefit from stronger HTA-reimbursement alignment. Italy's new National HTA Program is advancing in this direction[42].

In Germany, manufacturers set an initial DiGA price for a product's first 12 months (which should typically align with provisional access), followed by evidence-based negotiations with the National Association of Statutory Health Insurance Funds. France's PECAN pathway sets predefined prices for telemonitoring DMDs (up to €50/patient/month for telemonitoring DMDs with organizational impact, and up to €73.33, €82.50, and €91.67/patient/month for those with clinical impact on quality of life, morbidity, and mortality, respectively; in addition to up to €28/patient/month for HCP remuneration)[43] and therapeutic DMDs (€435 for the first three months, then €38.30/month, capped at €780.00 annually)[44]; manufacturers can then apply for a 5-year listing and negotiate prices under common law. Belgium's first bundled payment model integrates telemonitoring DMD reimbursement into predefined care pathways, starting with congestive heart failure[45]. This fixed model includes a one-time €200/patient startup fee (covering prescription, device provision, patient training, and first-month oversight) and monthly fees of €90/patient for months 2–6, then €45/patient/month from month 7 onward. Patients face no cost-sharing, and a €24.92/patient annual fee supports general practitioners' coordination. The U.S. also reimburses provider services for telemonitoring of both chronic and acute conditions, including separate billing codes for device set-up, data interpretation, and remote treatment management[46,47].

With respect to pricing and payment models, we advocate expanding HCP reimbursement across countries and DMD types, acknowledging their pivotal role in enabling appropriate adoption and clinical integration, including for patient-facing technologies. As we recommend including HCP-facing DMDs within the scope of dedicated policies, we also note that while regulatory and HTA pathways may align with those for patient-facing DMDs, reimbursement models themselves often differ. Instead of individual access-based mechanisms—such as prescription or patient activation—HCP-facing DMDs are typically funded through institutional procurement or bundled payments, including Diagnosis-Related Groups, requiring adapted reimbursement approaches.

More broadly, bundled payment models can and should be advanced to facilitate aligned adoption and use incentives, appropriately embedding all types of DMDs into care pathways as care-improving or cost-saving innovations. Pricing and reimbursement models should also incentivize long-term adherence, as DMD usage tends to decrease after the initial months[48,49]: linking dynamic HTAs to performance-based pricing should support this, as set forth by Germany's DigiG.

Systemic adoption and clinical integration

Regulatory frameworks, HTA criteria, and reimbursement pathways are essential but insufficient to achieve systemic adoption. Germany's DiGA program exemplifies this gap: only 12% of outpatient doctors and psychotherapists prescribed a DiGA, two-thirds of whom prescribed just one or two, while approximately 20% early adopters account for 60% of DiGA

Table 2 | Overview of HTA Requirements Across Established European Frameworks and Convergence Outlook for HTA Core Model® Domains Within the Scope of Rapid Relative Effectiveness Assessment (REA)

HTA Core Model® Domains Within the Scope of REA	Established HTA Requirements for Digital Medical Devices (DMDs) in the EU and Convergence Outlook	Current Cross-Country Convergence	Opportunity for Future Convergence
Health Problem and Current Use of Technology	■ **Consistent requirement** for a structured **description of the health problem addressed by DMDs**, including disease burden, target population, current standards of care, and unmet needs. **Innovative features** intended to improve clinical or organisational outcomes must also be clearly identified. ■ **Strong convergence** in the domains of information required, but **national differences** in epidemiology, care pathways, and clinical practices necessitate country-specific integrations. Through strengthened **cross-country cooperation, core domains could be standardised** while allowing for **country-specific elements**. E.g. although DMDs are not yet covered by Joint Clinical Assessments (JCAs) under the Health Technology Assessment Regulation (HTAR), the structured approach being developed—standardising key domains while allowing for the integration of national variations—could serve as a model to support greater convergence in future DMD assessments.	**Medium**	**High**
Description and Technical Characteristics	■ **Consistent requirement** for a structured description of the **technical characteristics** of DMDs, including intended functionality, interoperability features, cybersecurity safeguards, usability and accessibility aspects, and data protection measures. **Certification under the EU MDR** provides a common regulatory baseline across Member States. **International interoperability standards** (such as HL7 FHIR, ISO/IEEE 11073, and SNOMED CT) are widely referenced. **Usability and stakeholder engagement** practices are increasingly appreciated, although not consistently mandated through harmonised evaluation metrics. ■ **Strong baseline convergence** through the MDR and the widespread adoption of international interoperability standards, with **general alignment** on the domains of technical information required. However, **supplementary national requirements** for technical documentation, interoperability, and cybersecurity standards introduce fragmentation. **Broader reliance on international standards** and **shared centred design principles**, combined with agreement to limit supplementary national requirements, could enhance harmonisation.	**Medium**	**High**
Safety	■ **Consistent requirement** for **compliance** with the EU MDR, ISO safety standards, the General Data Protection Regulation (GDPR), and other key EU regulations. **Technical stability** and **cybersecurity resilience** are commonly required, although not always mandated through harmonised evaluation standards. ■ **Strong baseline regulatory convergence**, but supplementary and diverse **national standards and dossier structures** introduce fragmentation. Continued **cross-country** commitment to **harmonisation** —and alignment with broader EU legislation such as the Cyber Resilience Act, the EU Cybersecurity Act, the revised eIDAS Regulation, the NIS2 Directive, and the European Health Data Space (EHDS)—could support greater consistency in system-level safety, cybersecurity, and data governance for digital health technologies.	**Medium**	**High**
Clinical Effectiveness	■ Clinical effectiveness is **consistently required**, with **flexible methods** accepted—particularly for lower-risk DMDs. **Comparative approaches** and **relevant endpoints** are generally expected; **Randomized Controlled Trials** (RCTs) remain the *de facto* gold standard. **Evidence transferability** is formally permitted, though supplementary local data is often needed. E.g. In Germany, broad legal criteria apply, but all reimbursed DiGAs to date include at least one RCT. DMDs certified under the MDR as Class I or IIa may demonstrate patient-relevant structural/procedural benefits instead of medical benefits, though common assessment metrics remain limited. ■ **Convergence** on the need for **robust effectiveness data**, though **variation remains** in accepted designs, endpoints, comparators, and use of RWE. **Strengthened voluntary cooperation** among HTA bodies, **mutual recognition** agreements, **conditional acceptance** of evidence supported by **RWE generation**, and **shared outcome metrics** for broad patient-relevant and procedural improvements should be encouraged and could progressively enhance harmonisation.	**Medium**	**High**

Convergence Level Key: Low: Limited convergence across Member States with major differences in requirements, standards, or methodologies. **Medium:** General convergence on key domains or principles, but assessments remain nationally driven, and fragmentation persists. **High:** Strong convergence on domains, processes, and/or standards across Member States, with mechanisms in place to progressively integrate national variations where needed.

Rapid Relative Effectiveness Assessment (REA) is a streamlined subset of health technology assessment (HTA) that focuses on evaluating the clinical effectiveness and safety of a health technology compared to existing alternatives. It is typically used to harmonize clinical evaluations across EU Member States, while allowing national authorities to retain responsibility for context-specific assessments. Under the EU HTA Regulation (HTAR), REA forms the core scope of Joint Clinical Assessments (JCAs) conducted at the EU level.

Table 3 | Overview of HTA Requirements Across Established European Frameworks and Convergence Outlook for HTA Core Model® Domains Beyond Rapid Relative Effectiveness Assessment (REA)

HTA Core Model® Domains Beyond the Scope of REA	Established HTA Requirements for Digital Medical Devices (DMDs) in the EU and Convergence Outlook	Current Cross-Country Convergence	Opportunity for Future Convergence
Costs and Economic Evaluation	■ **Economic evaluation requirements** for DMDs **vary**. Belgium and England require cost-effectiveness analysis. England's NICE has also proposed a strategic transformation of its HealthTech program, removing the cost-saving requirement for medical technologies and allowing broader cost-effectiveness assessments that weigh patient and system benefits, to expand NHS adoption of medical devices, digital and AI-based innovations. Germany and France do not require economic analysis, though it is often considered in pricing and reimbursement decisions. ■ While **convergence remains limited**, alignment on **fit-for-purpose frameworks and principles** for economic analysis of DMDs, which reflect their broader value dimensions could progressively support greater alignment while **preserving flexibility** for local cost structures, resource valuations, and healthcare priorities.	**Low**	**Medium**
Ethical Analysis	■ Ethical, fairness, equity, and environmental considerations are **increasingly acknowledged** in DMD assessments, but systematic evaluation remains **inconsistent**. ■ While recognition of their importance is growing, **shared principles, metrics, and data collection frameworks** are still lacking. Defining **common approaches at the EU level**—while **allowing flexibility** to reflect local societal values (e.g. by applying different weights to ethical and equity considerations)—could progressively support alignment.	**Medium**	**High**
Organisational Aspects	■ **Organisational impacts** of DMDs are **increasingly acknowledged**, but structured evaluation remains **inconsistent** across Member States. Germany's DiGA pathway accepts evidence of positive patient-relevant structural and procedural improvements for DMDs certified under the MDR as Class I or IIa; France's HAS guidance also recommends reporting on organisational outcomes. Shared evaluation standards are lacking. ■ While convergence is limited, **alignment on key domains**—such as workflow integration, resource use, workforce readiness, and access to care—could enhance the assessment of DMDs' systemic value across countries, while **preserving flexibility** for national delivery models.	**Medium**	**Medium**
Social Aspects	■ Social aspects—such as patient empowerment, digital equity, and health literacy—are **increasingly acknowledged** in DMD evaluations, though they are not mandated and standardised assessments remain limited. ■ While recognition of social impact is growing, the development of **shared metrics** for empowerment, equity, and patient-reported experience outcomes could support greater alignment across the EU Member States, while **preserving flexibility** to reflect national contexts (e.g. by weighting these dimensions differently).	**Medium**	**High**

Convergence Level Key: Low: Limited convergence across Member States with major differences in requirements, standards, or methodologies. **Medium:** General convergence on key domains or principles, but assessments remain nationally driven, and fragmentation persists. **High:** Strong convergence on domains, processes, and/or standards across Member States, with mechanisms in place to progressively integrate national variations where needed.

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prescriptions[50]. Such dynamics are typical of emergent technologies but simultaneously highlight the need for comprehensive strategies.

While manufacturers should define appropriate go-to-market strategies, policies must ensure adequate infrastructure, interoperable health information systems, and widespread connectivity. Seamless integration with HCP's and patients' Electronic Health Records is needed for adoption and RWD value generation—aligning with the EU Digital Decade[51] goals and the EHDS.

Embedding DMDs in clinical guidelines, or expert consensus where evidence is still evolving[52], is crucial for appropriate clinical integration. Policies should incentivize evidence generation and the integration of DMDs into care protocols. Expedited assessment and reimbursement should be considered for DMDs that operationalise or digitalise established clinical guidelines, enabling their structured and timely implementation in practice. Engaging digital health experts within medical societies, patient associations and policy forums can drive these processes, positioning DMDs as integral to a *digitally-enhanced* standard of care.

Despite their potential to improve care, robust economic and social impact data on DMDs remains limited[53]. Research on organizational optimization, patient and HCP empowerment, equity, cost-effectiveness, and sustainability should be incentivized.

Policies should also embed digital competencies in continuing and undergraduate education for all stakeholders and broad multistakeholder engagement—including physicians, nurses, pharmacists, patient associations, ethical committees, administrators, researchers, manufacturers,

policymakers and digital health experts—is vital. Public-private partnerships can further drive scalability and sustainability.

Concluding considerations

The five policy enablers outlined in this article—clarifying DHTs in scope of dedicated policies, establishing AI-ready regulatory frameworks and Accelerated Access Pathways, adopting fit-for-purpose dynamic HTAs, implementing dedicated reimbursement models, and fostering system readiness—are not only essential but also highly complementary and mutually reinforcing. Dedicated reimbursement models for DMDs can incentivise higher-quality evidence generation, which in turn supports dynamic HTAs addressing the iterative nature of software updates and the complexities of AI. Dynamic HTAs can bridge post-market evidence with regulatory oversight, enabling the evolution of AI-ready frameworks that ensure safe, timely, and adaptive approval of emerging innovations. Simultaneously, system readiness initiatives, promoting interoperability, education, and clinical integration, would enable adoption, real-world application, and RWE, generating the data needed to refine policies and generate systemic data-driven value.

However, translating these policy enablers into practice can present challenges. It will require visionary policies, sustained commitment, deliberate and concerted ecosystem efforts, strong cross-country cooperation, multistakeholder engagement, and time and resources. Differences in national priorities, regulatory capacities, healthcare infrastructure, and resource availability may slow coordinated progress. Digital skills development, integration of DMDs within care pathways, and continuous evidence generation are evolving enablers that demand long-term investment and structured incentives. Real-world validation remains ongoing, and unforeseen barriers to systemic and equitable adoption may emerge. Ensuring sustainability for both healthcare systems and manufacturers will also be critical for long-term value generation and scalability. Additionally, further application and evidence generation will be crucial to validate and refine these policy approaches over time.

Finally, harmonizing EU-level regulations—and fully realizing the vision of a European Health Union and a digital single market—has been both a mission and a challenge for years. Nevertheless, the need and opportunity to build on pioneering efforts and lessons learned is timely. Successfully innovating complex healthcare systems demands comprehensive policies that drive aligned and effective multistakeholder action across all levels of the health and innovation ecosystems. By rooting these enablers within a comprehensive policy framework and fostering cross-country harmonization, stakeholders can create a virtuous cycle of innovation, access, and equity—scaling the systemic integration of DHTs while ensuring their broad and equitable benefits across healthcare systems.

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Author contributions

A.M.C.S. conceptualized the study and drafted the manuscript. R.T. and A.D.S. contributed to revisions, refinement of arguments and final integration. All authors reviewed and approved the final version of the manuscript.

Competing interests

A.D.S. reports serving on the Scientific Advisory Board of the German Society for Digital Medicine and the Advisory Board of the Peterson Health Technology Institute. The remaining authors declare no competing interests.

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